CMS Collection Powers (2-2)

- Recover from **any** entity "required" or responsible to repay
- Recover from **any** entity receiving the other insurance proceeds

Act § 1862(b)(2)(B)(ii) – (iv)

MSP Collection Process (1-4)

MSP Timeline

- Beneficiary, or representative, provides notice to Medicare within 60 days of receiving a settlement. 42 C.F.R. § 411.24(h)
- CMS Information Gathering (MSPRC)

MSP Collection Process (2-4)

- CMS sends collection letter
- Amount is determined by a Coordination of Benefits Contractor based on claims for Medicare services

MSP Collection Process (3-4)

- Required Letter Contents
  - Repayment process
  - Waiver of repayment procedures, and
  - Applicable appeals process

MSP Collection Process (4-4)

- Beneficiary/Representative responds by:
  - Paying amount claimed
  - Seeking a reduction
  - Seeking a waiver

MSP Recovery Amount

- CMS may recover an amount equal to the Medicare payment for injuries covered by the liability insurance, up to the full amount payable under the insurance.

42 C.F.R. § 411.24(c)

MSP Recovery Limitations (1-2)

No MSP recovery for services covered by Medicare after the date of settlement

- Unless settlement includes future medical services.

MSP Recovery Limitations (2-2)

Medicare must reduce its MSP recovery for **Procurement Costs**

- Proportionate share of attorneys' fees/costs

42 C.F.R. § 411.37(a)(1) and (d)

Appeals Issues

Reduction of MSP Claim Sought

- Unrelated charges included in MSP Claim. MSPM, ch. 7, § 50.4.4.
- Compromise of Small Settlement; CMS Regional Offices ONLY!!
  - Act § 1862(b)(2)(B)(v)
  - 42 C.F.R. § 411.28(b)

Wrongful Death Settlements (1-6)

Elimination of MSP Claim

- The actual damages available for the stated claim determine if Medicare has a valid MSP claim.

Wrongful Death Settlements (2-6)

Elimination of MSP Claim

- Medical expenses must be available for MSP recovery.

Wrongful Death Settlements (3-6)

Alabama: **Only** punitive damages are available for recovery.

- Alabama Wrongful Death Statute, Alabama Code § 6-5-410
- Merrell v. Alabama Power Co., 382 So. 2d 494, 496 (Ala. 1980)
- *Wood v. Wayman*, 2010 Ala. LEXIS 80, at 9 (Ala. May 7, 2010)

Wrongful Death Settlements (4-6)

Florida: *Bradley et al. v. Sebelius*, 621 F. 3d 1330 (11th Cir. 2010)

- "MSP Manuals are not binding and are not entitled to substantial deference." *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)

Wrongful Death Settlements (5-6)

Zinman v. Shalala, 67 F.3d 841, 845 (9th Cir. 1995)

- Medicare was "entitled to full reimbursement of conditional Medicare payments when a beneficiary receives a discounted settlement from a third party." *Id. at 846.*

Wrongful Death Settlements (6-6)

Hadden v. United States, 661 F.3d 298 (6th Cir. 2011)

- A beneficiary cannot tell a third party that it is responsible for all of his medical expenses, on the one hand, and later tell Medicare that the same party was responsible for only 10% of them, on the other.

Workers' Compensation Awards (1-2)

Workers' Compensation plan is the primary payer for recipients.

- Act § 1862(b)(2)(A)
- 42 C.F.R. §§ 411.40 – 411.47

Workers' Compensation Awards (2-2)

When determined, the settlement:

- Represents a compromise of disputed claims, and
- The specified apportionment is fair to Medicare.

CMS Regional Offices handle approval of Apportionments

See *MSPM, supra,* ch. 7, §§ 40.3.4-40.3.5.1

SMART Act (1-4)

Strengthening Medicare and Repaying Taxpayers Act of 2012 (the SMART Act)

SMART Act (2-4)

APPLICABLE PLAN APPEALS

- Liability insurance (including self-insurance),
- No-fault insurance, or
- Workers' Compensation law or plan

SMART Act (3-4)

Establishment of appeal rights for Applicable Plans

- CMS-6055-F
- Establishes a formal appeals process for applicable plans
- Effective April 28, 2015

SMART Act (4-4)

Identified Debtor

- CMS' decision regarding who or what entity to pursue for recovery is not an "initial determination"
- This decision is not subject to appeal, regardless of the identified debtor

SMART Act – Regulations (1-4)

- If Medicare pursues MSP recovery directly from a beneficiary, the beneficiary has formal appeal rights under 42 C.F.R. Part 405, subpart I.

SMART Act – Regulations (2-4)

- However, previously, if Medicare pursued MSP recovery directly from an applicable plan, the plan had no formal appeal rights under 42 C.F.R. Part 405, subpart I.
- Although the CMS recovery contractor addressed any disputes raised by the applicable plan.

SMART Act – Regulations (3-4)

Identified Debtor

The applicable plan may appeal only issues involving:

- The existence of the debt, and/or
- The amount of the debt

42 C.F.R. § 405.924(b)(16)

SMART Act – Regulations (4-4)

- The existing regulations were amended to establish a right of appeal and formal appeals process for applicable plans

42 C.F.R. § 405.947

SMART Act -Initial Determination (1-3)

When is a Demand Letter an Initial Determination?

- Generally a demand letter is not an "initial determination" 42 C.F.R. § 405.926(k)

KEY – Who is the Identified Debtor

SMART Act - Initial Determination (2-3)

When is a Demand Letter an Initial Determination?

If an Applicable Plan:

- A demand letter issued prior to April 28, 2015 is not an "initial determination."
- A recovery demand letter issued on or after April 28, 2015 is an "initial determination."

SMART Act - Initial Determination (3-3)

When the applicable plan is not the identified debtor, receipt of a courtesy copy (cc) does not give an applicable plan party status or the ability to appeal.

SMART Act – Party Status?

When recovery is pursued directly from an applicable plan:

- Only the applicable plan is a party
- The Plan must provide notice to the beneficiary
- The beneficiary is not a party and does not participate in the appeal

SMART Act - Proof of Representation

42 C.F.R. § 405.910

- Non-beneficiary parties do not need to provide a HICN
- There is no one-year duration limitation for an appointment of representation. The appointment is valid for the duration of any subsequent appeal, unless specifically revoked.

SMART Act - "Causation"

- Section 1862(b)(2)(B)(ii) of the Act
- Judgment, a payment conditioned upon the recipient's compromise, waiver, or release (*whether or not there is a determination or admission of liability*) of payment is sufficient.
- CMS is not required to establish "causation."

SMART Act - Interest

Determinations regarding waiver of interest are not "initial determinations" and are not subject to appeal.

SMART Act - Procurement Costs

- Conversely, there is no pro rata reduction for attorney fees and other costs where the applicable plan is the identified debtor.
- Pro rata reduction for attorney fees and procurement costs is ONLY applicable where the beneficiary is the identified debtor.

SMART Act - Confidentiality

- Claims of confidentiality by either the beneficiary or the applicable plan are not valid
- A confidentiality agreement in connection with the settlement does not override the consent for release of information.

42 C.F.R. § 411.24(a)

Case File Review (1-2)

Identify:

- Who is the demand made against (beneficiary or Applicable Plan)
- What is the date of the accident/incident
- What is the date of the settlement

Case File Review (2-2)

Identify:

- What injuries were suffered
- What type of recovery is available
- What are the procurement costs (if applicable)
- Attorney fees
- Other costs

Module Review (1-2)

Now that you have completed this module, you should be able to:

- Understand how the Medicare Secondary Payer program works,
- Identify the ways MSP claims can be reduced;

Module Review (2-2)

- Determine settlement recoveries in wrongful death and Workers' Compensation awards; and
- Identify the procedural differences under the SMART Act.

U.S. Department of Health & Human Services
Office of Medicare Hearings and Appeals

Procedural Rules and Policies

Amanda Axeen
Director, PEPD
Amanda.Axeen@hhs.gov

Agenda

1. OTR Decisions
2. Timely Filing
3. Amount in Controversy
4. Content/Copy Requirements
5. Representatives
6. CMS and CMS Contractor Roles
7. Administrative Record
8. New Evidence
9. Dismissals
10. Remands and Requests for Information

OTR Decisions (42 C.F.R. § 405.1038)

- A hearing is not required when:
  - The appeal is a request for review of a dismissal.
  - Final rule change: The decision is fully favorable to the appellant(s) on every issue, *and no other party to the appeal is liable for the claims at issue.*
  - Final rule change: All parties *who would be sent a notice of hearing* waive the oral hearing.
    - Revised form: OMHA-104 replaces HHS-723, OMHA-114 replaces HHS-731.
  - Final rule change: The appellant lives outside the United States, and does not state that he or she wishes to appear, and no other parties *who would be sent a notice of hearing* want to appear.

OTR Decisions (42 C.F.R. § 405.1038)

- A hearing is not required when (*cont'd*):
  - Final rule change: CMS or a contractor submits a written statement indicating an item or service should be covered or payment should be made.
    - In this case, a stipulated decision may be issued finding in favor of the appellant or other liable parties on this basis alone.
    - No findings of fact, conclusions of law, or further explanation of the reasons for the decision are required.
    - If the amount of payment is an issue before the OMHA adjudicator, the statement from CMS or a contractor must also agree to the amount of payment the parties believe should be made.

Timely Filing (42 C.F.R. § 405.1014)

- Requests must be timely filed within 60 calendar days of *receipt* of the reconsideration.
  - Final Rule Change: Amended §§ 422.602 and 423.1972 for conformity.
- 5 calendar day presumption for receipt of reconsideration.
  - Evidence showing later receipt ≠ good cause determination.
- Requests filed in the wrong place, but on time, are timely.
  - Final Rule Change: § 405.1014(c)(2) now states explicitly.

Timely Filing (42 C.F.R. § 405.1014)

- Requests for extension of time must be in writing.
  - Revised Form: OMHA-103 replaces HHS-727.
- § 405.942(b)(2) and (b)(3) guidance on good cause for untimely filing.
- Final rule change: For appeals of statistical samples, appellants must file the request for hearing within 60 calendar days of the date the appellant receives the *last* reconsideration for the sample claims.

Timely Filing (42 C.F.R. § 405.1014)

Requests for hearing

- If timely, or if evidence supports appellant had good cause for untimely filing, proceed.
- If untimely and you do not find good cause, stop. Case must be reassigned to an ALJ.

Requests for review of a dismissal

- If timely, or if evidence supports appellant had good cause for untimely filing, proceed.
- If untimely and no good cause, you may issue a dismissal.

Amount in Controversy (42 C.F.R. § 405.1006)

- Amount in controversy
  - $160 for CY 2018.
  - $200 for QIO appeals under part 478.
- Amount charged individual for items/services
  - *Less* any payments made/awarded.
  - Final rule change: *Less* any deductible/coinsurance *that may be collected.*
- § 405.1006(d)(2) exception: If payment made or beneficiary liability is limited under § 1879 of the Social Security Act, calculate as amount beneficiary would have been charged.

Amount in Controversy (42 C.F.R. § 405.1006)

- Final rule change: Four new exceptions:
  - **(d)(3) (Item or service terminations):** Use the amount the beneficiary would have been charged if the beneficiary had received the items or services the beneficiary asserts should be covered.
  - **(d)(4) (Overpayments):** Use the amount on demand letter.
  - **(d)(5) (Coinsurance and deductible challenges):** Use the difference between contractor-determined amount and amount beneficiary argues should have been charged.
  - **(d)(6) (Fee schedule or contractor price challenges):** Use the difference between contractor-determined allowable amount and amount appellant argues should have been allowed.

Amount in Controversy (42 C.F.R. § 405.1006)

- Aggregation to meet the AIC
  - All claims must have been reconsidered.
  - If *single* appellant, claims must involve delivery of same or related items or services.
  - If *multiple* appellants, must involve common issues of law and fact.
  - Request must state why appellant(s) believe the claims involve common issues or delivery of same or related items or services.
  - Final rule change: Aggregation request must be filed with the request(s) for hearing.

Amount in Controversy (42 C.F.R. § 405.1006)

- If timely AIC met, proceed.
- If AIC not met, stop. Case must be reassigned to an ALJ.
- If an aggregation request was made:
  - And you determine that the requirements for aggregation were met, proceed.
  - And you determine that the requirements for aggregation were not met, stop. Case must be reassigned to an ALJ.

Content and Copy Requirements (42 C.F.R. § 405.1014)

- Final rule change: § 405.1014(a) provides required elements for a complete request for hearing *or review*.
  - See § 423.2014 for Part D requirements, which differ.
  - There are no content requirements for Part C or appeals of SSA reconsiderations.
  - Revised form: OMHA-100 replaces CMS-20034A/B.
- Final rule change: If a request is not complete, appellant must be provided an opportunity to complete (and adjudication time frame does not begin until completed).
- Final rule change: Supporting materials submitted with the request that clearly provide required information must be considered.

Content and Copy Requirements (42 C.F.R. § 405.1014)

- § 405.1014 required elements
  - Beneficiary name, address, and HICN (or MBI)*
  - Final rule change: Name, address, *and telephone number* of appellant and representative (if any).
  - QIC case number.
  - Final rule change: Dates of service, *if applicable.*
  - Appellant's reasons for disagreement with QIC decision.
  - Statement of any additional evidence to be submitted, and when it will be submitted.
  - Final rule change: For appeals of statistical samples, the reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted.

**Pursuant to CJB 18-001, OMHA adjudicators must accept either a HICN or MBI in satisfaction of any regulatory or sub-regulatory requirements pertaining to a HICN.*

Content and Copy Requirements (42 C.F.R. § 405.1014)

- Final rule change: Appellants must send a copy of request for hearing *or review* to all parties *who were sent QIC reconsideration or dismissal*.
- Final rule change: Acceptable evidence that a copy was sent includes:
  - Certification on form OMHA-100.
  - Indication on request that copies were sent (e.g., "cc" line) (must include name/address of recipient(s)).
  - Affidavit or certificate of service that identifies name/address of recipient(s), and what was sent.
  - Mailing or shipping receipt that identifies name/address of recipient(s), and what was sent.

Content and Copy Requirements (42 C.F.R. § 405.1014)

- Final rule change: Documentation that is necessary to complete request must also be sent. Evidence submitted with the request may either be provided with the copy of the request, or briefly described and furnished upon request.
- Final rule change: Appellants must be given opportunity to cure.
  - Extends adjudication time frame.
  - Failure to cure after notice = dismissal.
  - Does not apply to unrepresented beneficiaries. OMHA sends copies on behalf of an unrepresented beneficiary. (*See* OCPM II-3-6 E.1.e.ii).
    - New template: OMHA-310T

Representatives (42 C.F.R. § 405.910)

- Two types of representatives—authorized and appointed.
  - Representative may be *authorized* under state or other applicable law (e.g., court-appointed guardian or healthcare proxy/POA), and have all the rights and responsibilities of the represented party.
  - Representatives may also be *appointed* using form CMS-1696 or a conforming written instrument.
- If appointment instrument is defective, appellant must be given an opportunity to cure.
  - Final rule change: Tolls adjudication time frame.

Representatives (42 C.F.R. § 405.910)

Valid appointments must:

- Be in writing and signed/dated by party *and* rep.
- Provide a statement appointing rep to act on behalf of party and (for beneficiaries) authorizing adjudicator to release PII/PHI to rep.
- Include a written explanation of purpose and scope of representation.
- Contain party's and rep's name, address, and phone number.
- If beneficiary is represented party, include HICN (or MBI).*
- Final rule change: If provider/supplier is represented party, include NPI.

*Pursuant to CJB 18-001, OMHA adjudicators must accept either a HICN or MBI in satisfaction of any regulatory or sub-regulatory requirements pertaining to a HICN.

CMS and CMS Contractor Roles

- Final rule change: CMS or CMS contractors may file elections to be *non-party* participant within 30 calendar days of receipt of a notice of hearing.
  - Requests may be sent to Central Ops mail stop (for unassigned cases) or to the assigned adjudicator.
  - Must copy parties who were sent a copy of the notice of reconsideration.
  - No party status unless assigned to an ALJ and a hearing is scheduled.
  - Attorney adjudicators may not request participation (only an ALJ may do this).

CMS and CMS Contractor Roles

- Limits on the number of entities that may attend oral hearing do not apply to on-the-record reviews.
- Position papers and written testimony may be submitted within 14 calendar days of the election to participate.
- If election is invalid (untimely, or parties not copied), must send written notice to CMS or contractor *and* parties who were entitled to receive notice of election no later than date decision, dismissal, or remand is mailed.

Administrative Record (42 C.F.R. § 405.1042)

- The administrative record is a complete record of the evidence and administrative proceedings.
- Must be exhibited—even OTRs. *See* OCPM II-4 for exhibiting standards.
- Final rule change: Must include any evidence excluded or not considered (but does not need to be exhibited).
  - OCPM New Evidence Cover Sheet
- Final rule change: Must include duplicative evidence (but does not need to be exhibited).
  - OCPM Duplicates Cover Sheet

Administrative Record (42 C.F.R. § 405.1042)

- While an appeal is pending with OMHA, parties may request and must be provided with a copy of the administrative record (including recordings).
  - Must be furnished in a manner that protects PII.
  - OMHA does not currently charge for copies of the record.
  - If party requests opportunity to comment on record, time frame is tolled.
- After a decision, dismissal, or remand is issued, requests for copies of the record must be sent to the records custodian (AdQIC for appeals of Part A/B QIC reconsiderations), Council, or QIC, as appropriate.
  - Does not apply to requests for copies of decisions only. If the decision is uploaded in MAS, which is an official system of record, copies should be provided by OMHA staff.

New Evidence (§§405.1018, 405.1028)

- Good cause is required for the introduction of new evidence for the first time at the OMHA level by a provider, supplier, or a beneficiary represented by a provider or supplier.
  - This requirement stems from § 1869(b)(3) of the Social Security Act, and is not applicable to Part D appeals (where only the enrollee is a party), Part C appeals, or QIO appeals under part 478. (*See* §§ 422.562(d), 478.40(c), 422.608).
  - Final rule clarification: Also 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.

New Evidence (42 C.F.R. §§ 405.1018, 405.1028)

- Final rule change: § 405.1018(c)(2) now states: "If a statement explaining why the evidence was not previously submitted to the QIC or a prior decision-maker is not included with the evidence, the evidence will not be considered."
- Final rule change: § 405.1046(a)(2)(ii) now requires that, for any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to § 405.1028, the (notice of) decision must include a discussion of the new evidence and the good cause determination that was made.

New Evidence (42 C.F.R. §§ 405.1018, 405.1028)

- Good cause (where required) may be found when the new evidence is material to an issue addressed in, but not identified as material prior to, the QIC's reconsideration.
- Final rule change: § 405.1028(a)(2) 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.

Dismissals (42 C.F.R. § 405.1052)

- Attorney adjudicators may dismiss *requests for review of a dismissal* for any reason, including, but not limited to:
  - Withdrawal
  - Incomplete request
  - Failure to copy
  - Untimely filing
  - Invalid representation
- Attorney adjudicators may only dismiss *requests for hearing* that have been withdrawn.

Dismissals (42 C.F.R. § 405.1052)

- Attorney adjudicators may develop procedural deficiencies (for example, may send an interim cure letter for untimely filing, invalid AOR, etc.).
  - If the appellant cures the defect, or provides a response that the attorney adjudicator determines establishes good cause, the attorney adjudicator may proceed.
  - If the appellant fails to respond, or responds but does not cure the defect or establish good cause, stop. The case must be reassigned to an ALJ.
- Final rule change: Attorney adjudicators (and ALJs) may now vacate their own prior dismissals of requests for hearing or review within 6 months of the date of the notice of dismissal.

Remands and Requests for Information 42 C.F.R. §§ 405.1034, 405.1056, 405.1058

- Final rule change: § 405.1034 now deals exclusively with requests for information; remands are now covered under §§ 405.1056 and 405.1058.
- May request information if:
  - Missing information is essential to resolving issues on appeal; and
  - Information can be provided only by CMS or its contractors.
    - Does *not* include information that is publically available on the internet or in a printed location, or that is in the possession of one of the parties to the appeal.
    - *Does* include official copies of redetermination and reconsideration decisions.
      - BUT (final rule change): If an electronic copy of the missing redetermination or reconsideration was uploaded in MAS, must accept the electronic copy as an official copy, and should not issue a request for information.

Remands and Requests for Information 42 C.F.R. §§ 405.1034, 405.1056, 405.1058

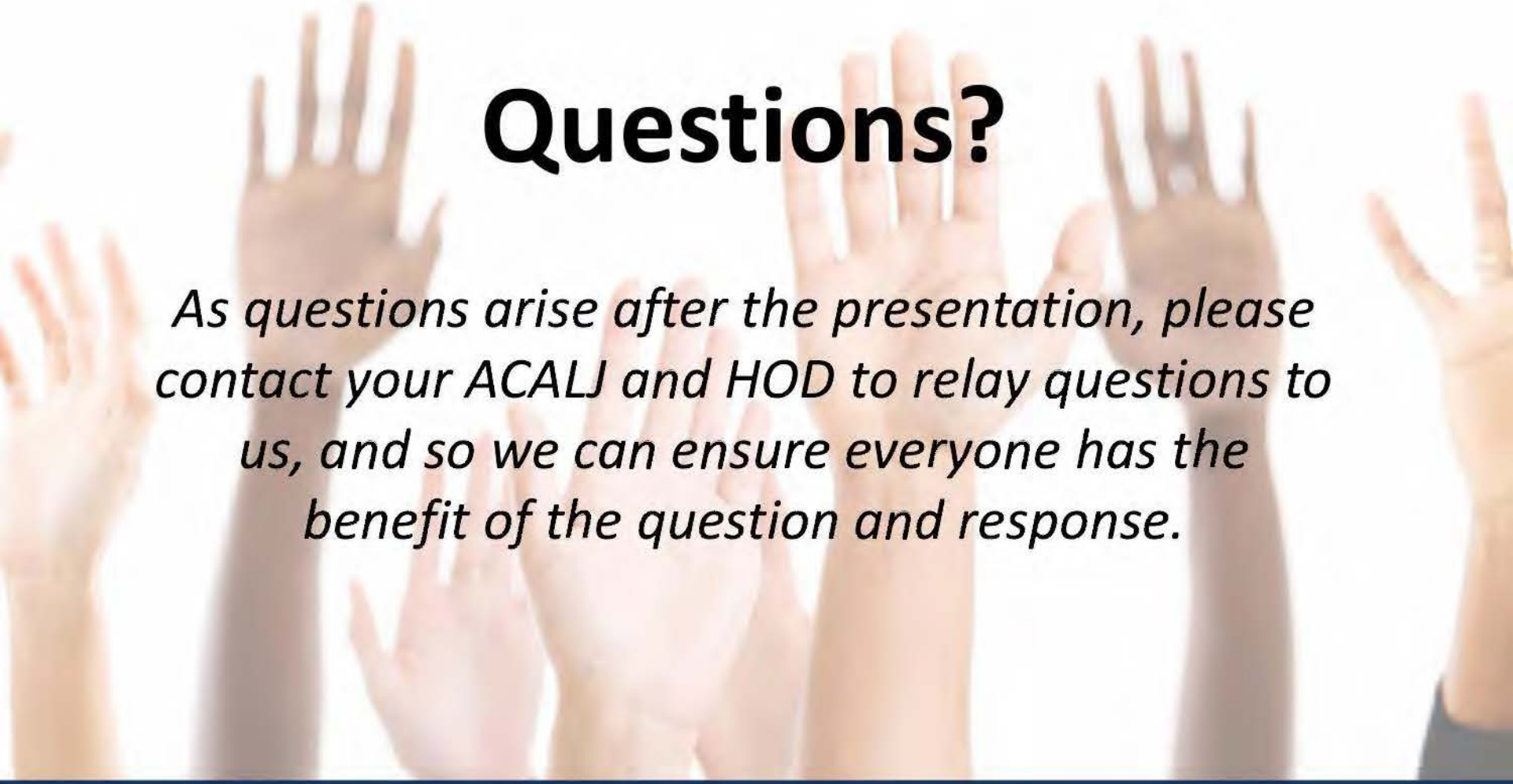
- If missing information is requested, QIC has 15 calendar days after receipt of request to furnish information or otherwise respond to request.
  - Adjudication time period (if any) is extended by lesser of time between request and response, or 20 calendar days.
- If an official copy of a redetermination or reconsideration is requested, but not received, or if the QIC does not furnish the case file for an appeal, remand is authorized under § 405.1056(a).
  - If QIC is able to reconstruct record, the case is returned to OMHA and is no longer remanded.
  - Tolls adjudication time frame.

Remands and Requests for Information
42 C.F.R. §§ 405.1034, 405.1056, 405.1058

- Final rule change: § 405.1056(b) permits remand if QIC issued a reconsideration on the merits, but no redetermination was conducted, or the redetermination request was dismissed.
- Final rule change: § 405.1056(c) permits remand when:
  - The appellant and CMS or a CMS contractor jointly request a remand to the QIC;
  - The request includes the reasons why the case should be remanded; and
  - The OMHA adjudicator determines that a remand will likely resolve the matter in dispute (for example, CMS requests a remand in order to reopen the case and pay the claim at issue).

Remands and Requests for Information 42 C.F.R. §§ 405.1034, 405.1056, 405.1058

- § 405.1056(d) permits remand if the OMHA adjudicator determines the QIC's dismissal of a reconsideration request was in error.
- § 405.1056(e) permits remand if the appellant is entitled to relief because the LCD or NCD that was applied was invalidated by the Departmental Appeals Board or a higher tribunal.
- Final rule change: § 405.1056(g) permits a party or CMS or a contractor to request review of a remand it believes was not authorized under § 405.1056.



Questions?

As questions arise after the presentation, please contact your ACALJ and HOD to relay questions to us, and so we can ensure everyone has the benefit of the question and response.

Module 1:
Department of Health and Human Services (HHS) - Office of Medicare Hearings and Appeals (OMHA) Organizational Overview

After this session, you will be able to:

1. Discuss the organizational structure of HHS.
2. Discuss important historical highlights relative to the formation of OMHA.
3. Discuss the Mission and Vision of OMHA.
4. Discuss the organizational structure of OMHA.
5. Define commonly used acronyms that are relevant to the organizational structure and operations of HHS and OMHA.

Required Reading/Reference:

- ✓ Refer to the HHS website for an organization overview of HHS https://www.hhs.gov/about/agencies/orgchart/index.html and OMHA https://www.hhs.gov/about/agencies/omha/about/organizational-chart/index.html

Introduction – Background and Rationale

"IT WAS ONCE SAID THAT THE MORAL TEST OF GOVERNMENT IS HOW THAT GOVERNMENT TREATS THOSE WHO ARE IN THE DAWN OF LIFE, THE CHILDREN; THOSE WHO ARE IN THE TWILIGHT OF LIFE, THE ELDERLY; AND THOSE WHO ARE IN THE SHADOWS OF LIFE, THE SICK, THE NEEDY AND THE HANDICAPPED."

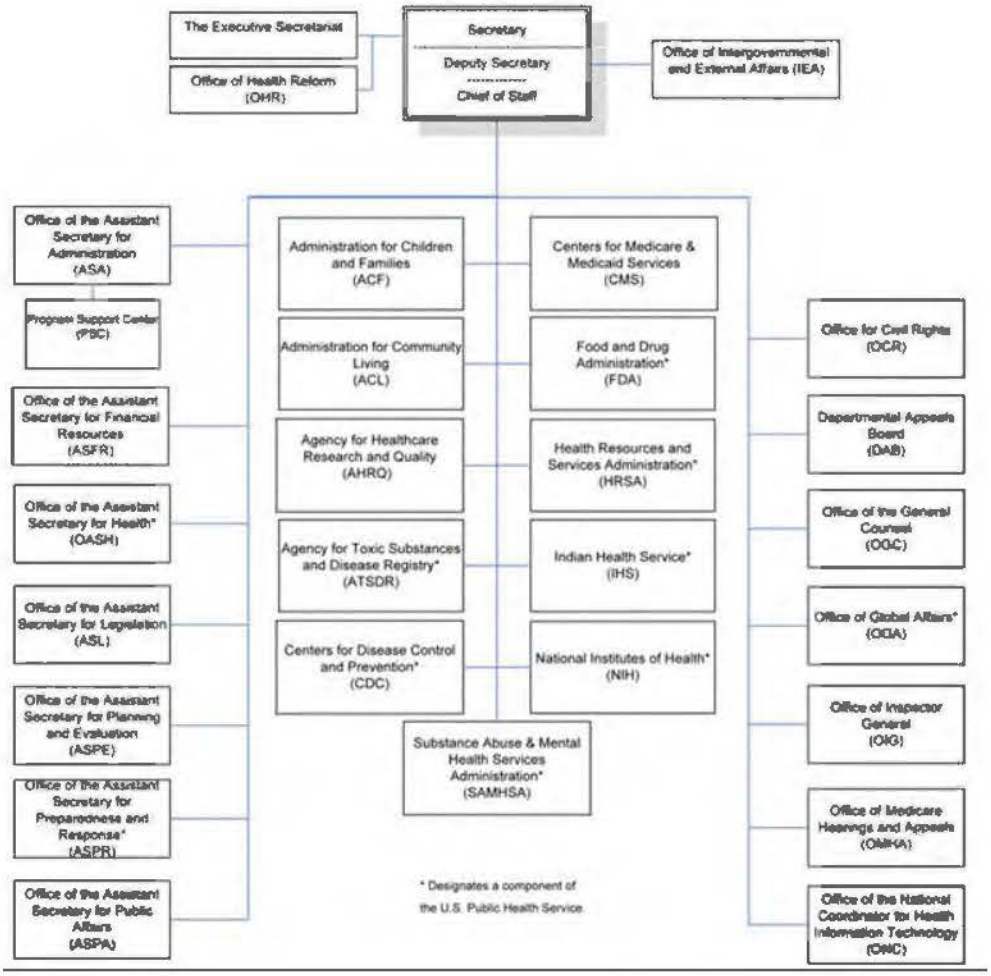
123 Cong. Rec. 37287 (1977) (remarks at the dedication of the Hubert H. Humphrey Building, November 1, 1977).

HHS protects the health of all Americans by providing essential human services, especially for those who are least able to help themselves. HHS administers almost a quarter of all federal outlays, which includes more grant dollars than all other federal agencies combined.

HHS directs more than 100 programs that cover a wide spectrum of activities. In managing its many programs, HHS works closely with state and local governments. In particular, HHS's Medicare program serves as the nation's largest health insurer and handles more than 1 billion claims per year. Together, Medicare and Medicaid provide healthcare insurance for one in four Americans. *See* https://www.cms.gov/Newsroom/PressToolkit.html.

Objective 1: Discuss the organizational structure of HHS

https://www.hhs.gov/about/budget/fy2017/performance/performance-plan-overview/index.html



HHS is divided into two branches: the Office of the Secretary (OS) which is comprised of fourteen Staff Divisions, one of which is OMHA; and a second branch that is comprised of HHS's eleven Operating Divisions, one of which is the Centers for Medicare & Medicaid Services (CMS).

This is a noteworthy distinction when analyzing the independent roles of OMHA and CMS.

The OS and HHS's Operating Divisions, as well as the HHS Regional Offices, administer HHS programs, many of which are provided at the local level by state or county agencies, or through private sector grantees. *See* interactive organizational chart at http://www.hhs.gov/about/agencies/orgchart/index.html.

Office of the Secretary (OS)

The OS serves as HHS's chief policy officer and general manager. OS administers and oversees the organization of HHS as well as its programs and activities. The fourteen OS Staff Divisions provide direct support for the Secretary's initiatives including:

- Office of the Assistant Secretary for Administration (ASA)
    - *Program Support Center*
- Office of the Assistant Secretary for Financial Resources (ASFR)
- Office of the Assistant Secretary for Health (OASH)
    - *Surgeon General*
- Office of the Assistant Secretary for Legislation (ASL)
- Office of the Assistant Secretary for Planning and Evaluation (ASPE)
- Office of the Assistant Secretary for Preparedness and Response (ASPR)
- Office for Civil Rights (OCR)
- Departmental Appeals Board (DAB)
- Office of the General Counsel (OGC)
- Office of Global Affairs (OGA)
- Office of Inspector General (OIG)
- **Office of Medicare Hearings and Appeals (OMHA)**
- Office of the National Coordinator for Health Information Technology (ONC)

Operating Divisions

Among the eleven Operating Divisions of HHS, eight agencies comprise the U.S. Public Health Service and three agencies comprise the human service agencies. These divisions administer a wide variety of health and human services and conduct life-saving research for the nation, protecting and serving all Americans HHS' Operating Divisions are:

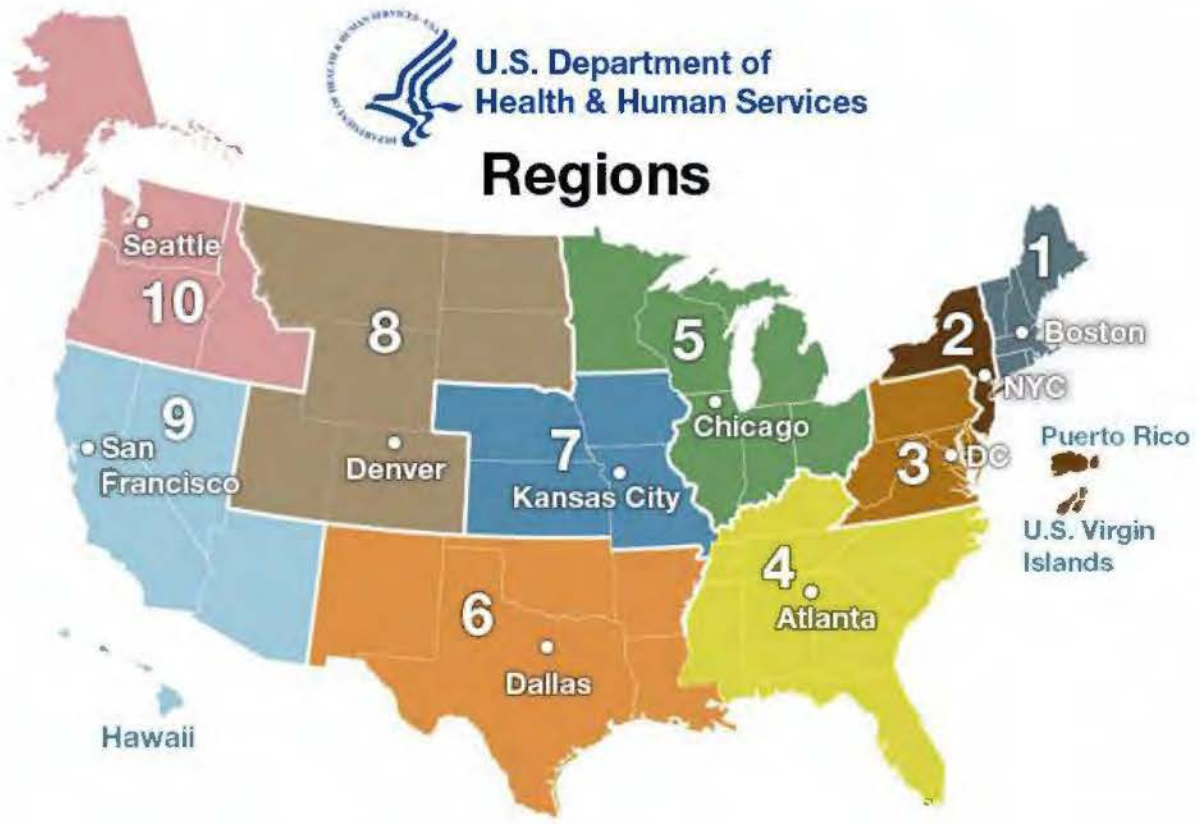
- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

HHS Regional Offices

Within HHS, the Office of Intergovernmental and External Affairs, which serves as the liaison to state, local and tribal governments and non-governmental organizations, has established ten Regional Offices, each led by a President-appointed Regional Director.

The Regional Directors ensure HHS maintains close contact with state, local, and tribal partners and address the needs of communities and individuals serviced through HHS programs and policies. .

Not all HHS agencies are structured around the Regional Offices. OMHA's field offices report directly to the Office of the Chief Judge (OCJ or Headquarters) and are not aligned within the Regional Office structure.



Objective 2: Discuss important historical highlights relative to the formation of OMHA

Historical Highlights

The roots of HHS go back as far as the early days of our nation.

1798

Passage of an act for the relief of sick and disabled seamen, which established a federal network of hospitals for the care of merchant seamen, the forerunner of today's U.S. Public Health Service).

1871

The first Supervising Surgeon, later called the Surgeon General, for the Marine Hospital Service is appointed.

1902

Conversion of the Marine Hospital Service into the Public Health and Marine Hospital Service in recognition of its expanding activities in the field of Public Health.

1912

The Public Health and Marine Hospital Service is shortened to the Public Health Service.

1935

The Social Security Act (Act) was passed on August 14, 1935. The Act established the Social Security Board as an independent agency.

1939

The Social Security Board lost its independent status when it was subsumed by the newly created Federal Security Agency (FSA).

1946

The Social Security Board was renamed the Social Security Administration (SSA) under the President's Reorganization Plan of 1946. Arthur Altmeyer, previously the chairman of the Social Security Board, became SSA's first Commissioner.

1953

President Eisenhower abolished FSA and created the Cabinet-level Department of Health, Education, and Welfare (HEW), which officially came into existence on April 11, 1953. SSA became part of HEW at that time, and Oveta Culp Hobby became the first Secretary of HEW.

1965

Medicare and Medicaid programs were created, making comprehensive health care available to millions of Americans.

1977

The Health Care Financing Administration (HCFA) was created to manage Medicare and Medicaid separately from SSA.

1979

The Department of Education Organization Act was signed into law, providing for a separate Department of Education.

1980

HEW became HHS on May 4, 1980, and Patricia Roberts Harris was appointed as the first Secretary of HHS.

1994

President Clinton signed the Social Security Independence and Program Improvements Act to return SSA to being an independent agency.

1995

SSA became an independent agency on March 31, 1995.

1996

The Health Insurance Portability and Accountability Act (HIPAA) was enacted.

1997

The Balanced Budget Act of 1997 established a new Part C of the Medicare program, known then as Medicare+Choice, effective January 1999.

1999

The Ticket to Work and Work Incentives Improvement Act of 1999 was signed, making it possible for millions of Americans with disabilities to join the workforce without fear of losing their Medicaid and Medicare coverage. It also modernized the employment services system for people with disabilities.

2000

The Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Benefits Improvement and Protection Act of 2000 (BIPA) amended section 1869 of the Act by creating new appeal rights including a 90-day deadline to adjudicate Part A and Part B

2001

CMS was created, replacing HCFA.

HHS responds to the nation's first bioterrorism attack—delivery of anthrax through the mail.

2003

The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) was enacted; the most significant expansion of Medicare since its enactment, including a

prescription drug benefit (Part D). The MMA renamed the Medicare+Choice program (Part C) to the Medicare Advantage program. The MMA created OMHA and returned the responsibility for adjudicating the third level of Medicare claims appeals to HHS.

2005

OMHA opened its doors for business on July 1, 2005 with four Field Offices in Irvine, California; Miami, Florida; Cleveland, Ohio; and Arlington, Virginia.

2010

The Tax Relief and Health Care Act of 2006 required a permanent and national Recovery Audit Contractor program to be in place by January 1, 2010.

The Affordable Care Act was signed into law, putting in place comprehensive U.S. health insurance reforms.

2014

OMHA opens its fifth Field Office in Kansas City, Missouri.

2016

OMHA opens its sixth Field Office in Seattle, Washington.

2017

The Medicare appeals final rule became effective.

2018

OMHA opens its seventh through tenth Field Offices in Phoenix, Arizona; Atlanta, Georgia; New Orleans, Louisiana, and Albuquerque, New Mexico.

Creation of the Office of Medicare Hearings and Appeals

SSA within HHS

SSA was originally a part of HHS. Historically, Administrative Law Judges (ALJs) in SSA's Office of Hearings and Appeals (OHA) [now Office of Disability Adjudication and Review] conducted hearings on behalf of the Secretary of HHS on some but not all types of Medicare appeals, and the SSA Appeals Council provided the final level of review.

In the 1980s and early 1990s, the Secretary transferred some types of Medicare cases from OHA to ALJs at the Departmental Appeals Board (DAB) and provided that the DAB would issue the final decision on behalf of the Secretary in those cases. Specifically, the cases included:

- Program exclusions and civil money penalty cases brought by the HHS Office of the Inspector General or by CMS under various fraud and abuse authorities; and

- CMS provider and supplier certification and enforcement actions.

SSA Becomes an Independent Agency

In 1994, the Social Security Independence and Program Improvements Act (Independence Act) established SSA as an independent agency. The Independence Act stipulated a shared responsibility for the Medicare appeals process in which SSA would continue to perform the hearings function for Medicare appeals administered by SSA in 1994.

SSA continued to hear the following Medicare appeals on behalf of HHS:

- Determinations made by SSA under section 1869(b) of the Act concerning whether an individual is entitled to benefits under Part A or Part B of title XVIII (Medicare) of the Act. *See* 42 C.F.R. § 405.701(a)(1), and Parts 406 and 407;

- Determinations under section 1869(b) of the Act by Medicare intermediaries or carriers concerning claims for benefits under Part A or Part B of title XVIII. *See* 42 C.F.R. Part 405, Subparts G and H;

- Determinations under section 1852(g) of the Act by Medicare+Choice organizations under Part C of title XVIII with respect to specified payment or coverage issues. *See* 42 C.F.R. Part 422, Subpart M;

- Determinations made by Quality Improvement Organizations (QIOs), under section 1154 of the Act and the procedures in section 1155 of the Act, that services furnished or proposed to be furnished are not reasonable, necessary, or delivered in the most appropriate setting. *See* 42 C.F.R. Part 478, Subpart B.

To facilitate the continued performance of the Medicare hearings function by SSA after it became an independent agency, SSA and HCFA (now CMS) entered into a Memorandum of Understanding (the Umbrella MOU), effective March 31, 1995. The Umbrella MOU was designed to ensure both parties continued working cooperatively to maximize program efficiency, effectiveness and service to the public. In addition, Article V, Section 9, of the Umbrella MOU detailed the parties' commitment to further discussions regarding the potential transfer of the Medicare hearings function and related resources to HHS. The parties also agreed that the ultimate transfer of the ALJ hearings function was in the best interest of the public insomuch as HHS had administrative responsibility for the Medicare program.

On October 20, 1995, HHS and SSA signed an agreement (Supplemental Agreement), which transferred to HHS the appellate review functions performed by the SSA Appeals Council. This body, now called the Medicare Appeals Council (the Council), is housed within the DAB and reviews ALJ decisions in the types of cases detailed above. The Supplemental Agreement covers the appellate review of all pending and future cases, including hearings, where appropriate, in disputes involving:

1. Medicare entitlement/entitlement-related issues; and

2. Medicare coverage, claims reimbursement, and denial of service issues.

Why Create OMHA as a New Agency?

Despite its removal from HHS when it became an independent agency, SSA's OHA continued to adjudicate Medicare appeals. Although still a participant in this process, OHA's primary mission was to resolve disability appeals—the overwhelming majority of its workload. OHA's Medicare workload was relatively small, only representing about 11 percent of the appeals heard in Fiscal Year 2003. As a consequence, most of OHA's ALJs had greater expertise in Social Security matters than in Medicare. Because of their separate and distinct missions, and for the sake of administrative simplicity, HHS and SSA contemplated transferring OHA's Medicare appeals workload from SSA to HHS for many years, but an agreement between the two agencies on specific details of the transfer was never reached.

The Medicare appeals process had been the subject of widespread concern for quite some time. The Government Accountability Office (GAO) reported poor coordination between SSA and HHS, which affected their abilities to effectively manage the appeals process. GAO also found that having the process managed by separate federal entities (HHS and SSA) created the challenge that neither HHS nor SSA was managing and overseeing the entire process; this structure had complicated the appeals bodies' attempts to streamline the process. Both HHS and SSA were criticized for the length of time it took to render decisions, particularly SSA's OHA and HHS's Council.

Enacted on December 21, 2000, BIPA amended section 1869 of the Act by creating new appeal rights and requiring major revisions to the Medicare appeals process:

- Increased Medicare payments to providers and managed health care organizations;
- Reduced certain Medicare beneficiary copayments;
- Improved Medicare's coverage of preventive services;

- Created a new Medicaid prospective payment system (PPS) for federally qualified health centers and rural health clinics;
- Amended section 1869 of the Act creating new appeal rights and requiring major revisions to the Medicare appeals process; and
- Added a 90-day timeframe for Part A and Part B ALJ decisions.

In anticipation of BIPA, HHS and SSA then began negotiations; and it was tentatively agreed that, pending budget approval, responsibility for Medicare hearings would be transferred beginning October 1, 2003.

Meanwhile, Congress was considering Medicare reform legislation that would significantly impact the processing of Medicare appeals. Specifically, the legislation would delay the transfer of the appeals function to not earlier than July 1, 2005 and not later than October 1, 2005, and it would require that the ALJs hearing Medicare appeals were to be organizationally and functionally separate from CMS.

In the MMA, Congress mandated that SSA transfer its responsibility for adjudicating Medicare appeals to HHS, with the result that all levels of the process would reside within a single federal agency. MMA specified that the transfer be completed not earlier than July 1, 2005, and not later than October 1, 2005. MMA also directed SSA and HHS to develop a transfer plan addressing 13 specific elements related to the transfer:

1. Transition timetable
2. Workload
3. Cost projections and financing
4. Regulations
5. Feasibility of precedential authority
6. Geographic distribution
7. Access to ALJs
8. Shared resources
9. Case tracking
10. Hiring
11. Training
12. Independence of ALJs
13. Performance standards

OMHA opened for business July 1, 2005.

Objective 3: Discuss the OMHA Mission and OMHA Vision

OMHA Mission

The Office of Medicare Hearings and Appeals (OMHA) is a responsive forum for fair, credible, and timely decision-making through an accomplished, innovative and resilient workforce. Each employee makes a difference by contributing to shaping American healthcare.

OMHA Vision

World class adjudication for the public good.

Objective 4: Discuss the organizational structure of OMHA

OMHA's Organizational Structure

OMHA was created by the MMA to simplify the Medicare administrative appeals process and make it more efficient. Unless an appeal is dismissed or remanded, an OMHA ALJ or attorney adjudicator conducts a *de novo* review of an appellant's case and issues a decision based on the facts and the law.

OMHA is organizationally and functionally separate from CMS. OMHA, under direct delegation from the Secretary of HHS, administers the nationwide hearings and appeals program for Medicare entitlement and claims appeals.

The Chief Administrative Law Judge leads the entire agency, which consists of six field offices and a headquarters office. Each field office consists of many Supervisory Administrative Law Judges (SALJs) who are overseen by an Associate Chief Administrative Law Judge.

Office of the Chief Judge

The Office of the Chief Judge, also referred to as OMHA Headquarters, consists of the Chief Administrative Law Judge, the Deputy Chief Administrative Law Judge, the Office of Operations, the Office of Programs, as well as a Special Assistant and Chief Attorney Advisor who provide direct support to the Chief Administrative Law Judge.

Office of Operations

The Office of Operations is comprised of two divisions led by directors who report to an executive director who is a member of the Senior Executive Service (SES). The two divisions within the Office of Operations are:

1. Field Operations Division
2. Central Operations Division

Office of Programs

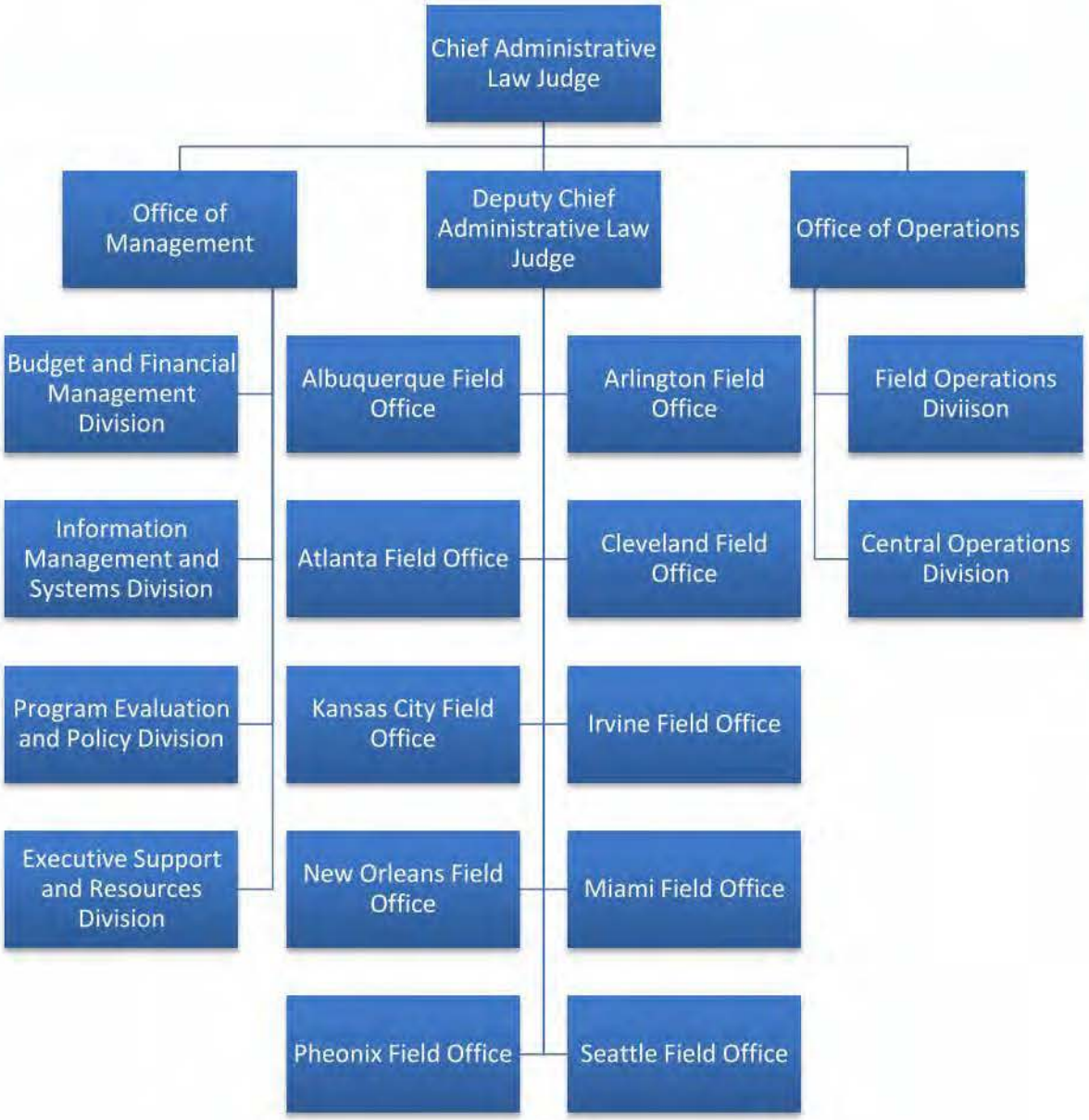
The Office of Programs is comprised of four divisions led by directors who report to a SES-level executive director. The Office of Programs is responsible for leading OMHA's efforts to develop policies, evaluate operational efficiencies, streamline processes, and manage information technology. The four divisions within the Office of Programs are:

1. Budget and Financial Management Division
2. Information Management and Systems Division
3. Program Evaluation and Policy Division
4. Executive Support and Resources Division

OMHA Field Offices

OMHA is staffed with SALJs who conduct impartial *de novo* hearings and make decisions in Medicare entitlement and claim appeals. OMHA's ten Field Offices are:

- Arlington Field Office (Arlington, VA)
- Albuquerque Field Office (Albuquerque, NM)
- Atlanta Field Office (Atlanta, GA)
- Cleveland Field Office (Cleveland, OH)
- Irvine Field Office (Irvine, CA)
- Kansas City Field Office (Kansas City, MO)
- Miami Field Office (Miami, FL)
- New Orleans Field Office (New Orleans, LA)
- Phoenix Field Office (Phoenix, AZ)
- Seattle Field Office (Seattle, WA)


Chief Administrative Law Judge
Office of Management
Deputy Chief Administrative Law Judge
Office of Operations
Budget and Financial Management Division
Albuquerque Field Office
Arlington Field Office
Field Operations Diviison
Information Management and Systems Division
Atlanta Field Office
Cleveland Field Office
Central Operations Division
Program Evaluation and Policy Division
Kansas City Field Office
Irvine Field Office
Executive Support and Resources Division
New Orleans Field Office
Miami Field Office
Pheonix Field Office
Seattle Field Office

Objective 5: Define commonly used acronyms and terms that are relevant to the organizational structure and personnel of HHS, OMHA and other organizations

Frequently Used Acronyms

AAJ - Administrative Appeals Judge
ACALJ - Associate Chief Administrative Law Judge
AdQIC - Administrative Qualified Independent Contractor
ALJ - Administrative Law Judge
BIPA - Benefits Improvement and Protection Act of 2000
CALJ - Chief Administrative Law Judge
CMS - Centers for Medicare & Medicaid Services
DAB - Departmental Appeals Board
DCALJ - Deputy Chief Administrative Law Judge
HOD - Hearing Office Director
HQ - Headquarters (Office of the Chief Judge; Arlington, VA)
LMS - Learning Management System
MAC - Medicare Appeals Council (the Council)
MMA - Medicare Prescription Drug, Improvement, and Modernization Act of 2003
OCJ - Office of the Chief Judge (also called HQ)
QIC - Qualified Independent Contractor
QIO - Quality Improvement Organization
RAC - Recovery Audit Contractor
SALJ - Supervisory Administrative Law Judge
SSA - Social Security Administration
VTC - Video-teleconferencing

Module 3:
Medicare – Know the Basics

After this session you will:

1. Gain a basic understanding of Medicare statutory history
2. Identify the statutes, regulations, and policy that govern the Medicare program
3. Define key terms related to the Medicare program
4. Describe the basic benefit for Medicare Parts A, B, C, and D

Suggested Reading/Reference:

- ✓ Title XVIII of the Social Security Act
- ✓ 42 C.F.R. Part 400: Introduction and Definitions
- ✓ 42 C.F.R. Part 411: Exclusions from Medicare and Limitations on Medicare Payment
- ✓ 42 C.F.R. Part 417: Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans
- ✓ 42 C.F.R. Part 422: Medicare Advantage Program (Medicare Part C)
- ✓ 42 C.F.R. Part 423: Voluntary Medicare Prescription Drug Benefit (Part D)
- ✓ 42 C.F.R. Part 424: Conditions for Medicare Payment
- ✓ Medicare General Information, Eligibility and Entitlement Manual (MGIEEM)
- ✓ Medicare Benefit Policy Manual (MBPM)
- ✓ Medicare Claims Processing Manual (MCPM)
- ✓ Medicare Program Integrity Manual (MPIM)
- ✓ Quality Improvement Organizations Manual
- ✓ Medicare Managed Care Manual (MMCM)
- ✓ Medicare Prescription Drug Manual (MPDM)

Introduction – Background and Rationale

Within the "Know the Basics" lesson, you will gain a basic understanding of Medicare statutory history. You will also be introduced to specific statutes, regulations, and policy that govern the Medicare program. Finally, you will learn to distinguish between Medicare Parts A, B, C, and D.

Objective 1: Gain a basic understanding of Medicare statutory history

On July 30, 1965, President Lyndon Johnson signed Title XVIII of the Social Security Act (the Act) into law, which established Medicare. Medicare is a health insurance program that provides basic coverage of institutional and supplemental medical care for the aged and disabled. Coverage of care from institutional providers (e.g., hospitals, skilled nursing facilities, inpatient rehabilitation facilities, hospice facilities, and home health care) is referred to as **Medicare Part A (Hospital Insurance)**. Coverage of supplemental medical care (e.g., physician services, diagnostic tests, ambulance transportation, durable medical equipment, certain drugs and biologicals, outpatient rehabilitation, prosthetics and orthotics, etc.) is referred to as **Medicare Part B (Supplementary Medical Insurance)**.

The Act has been amended multiple times since 1965 to include new features and limitations to the Medicare program. The **Balanced Budget Act of 1997 (BBA)** amended the Act to include a prospective payment system for various services (e.g., inpatient rehabilitation, home health, and skilled nursing facility services).

The BBA also created Medicare Part C (initially called the Part C Medicare + Choice program). Medicare Part C offers an alternative for beneficiaries regarding how their Medicare benefits are administered. Instead of receiving Hospital and Supplementary Medical Insurance benefits through the traditional Medicare Parts A and B entities, Part C enrollees receive them through coordinated care plans, e.g., a Health Maintenance Organization (HMO) or Preferred Provider Organization (PPO).

The **Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)** amended the Act to revise the Medicare appeals process. This included adding the 90-calendar day deadline for processing Administrative Law Judge (ALJ) appeals.

The most recent changes to Medicare relevant to Medicare claims appeals came with the **Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)**. The MMA substantially overhauled the Medicare appeals process. The MMA transferred the responsibility for Medicare ALJ appeals from the Social Security Administration (SSA) to the U.S. Department of Health and Human Services (HHS). The MMA created the Office of Medicare Hearings and Appeals (OMHA). The MMA also renamed the "Part C Medicare + Choice" plans to "Medicare Advantage" plans (with the MMA, these plans could now offer prescription drug coverage). Further, the MMA established the Medicare Part D Prescription Drug Program. Medicare Part D provides an optional outpatient prescription drug benefit to beneficiaries.

Objective 2: Identify the statutes, regulations, and policy, which govern the Medicare program

Binding Authorities:

Title XVIII of the Act established the Medicare program. The Act authorized the Secretary of HHS to develop standards and policies for the administration of the Medicare program.

The Code of Federal Regulations (C.F.R.) contains the implementing regulations for Title XVIII of the Act. Title 42 of the C.F.R. contains most of the regulations relevant to the Medicare program and the appeals adjudicated by OMHA. However, Title 20 of the C.F.R. contains regulations pertinent to "Medicare entitlement" benefits as well as Income-Related Monthly Adjustment Amount (IRMAA) determinations. Any proposed and final regulations are published in the Federal Register, which often contains important information as to how HHS interprets and applies specific regulations.

The Act and all regulations pertaining to the Medicare program are binding on ALJs and attorney adjudicators.[1]

National Coverage Determinations (NCDs) are decisions issued by the Centers for Medicare & Medicaid Services (CMS) that establish whether a particular item or service is covered nationally under the Act.[2] NCDs are published in the Medicare National Coverage Determinations Manual (MNCDM) and are binding on ALJs and attorney adjudicators.[3] OMHA adjudicators may not review the appropriateness of NCDs.[4] However, an ALJ or attorney adjudicator "may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim."[5]

CMS Rulings are decisions issued by the Administrator of CMS that serve as precedent, final decisions, orders, and statements regarding nationwide Medicare policy and interpretation.[6]Prior to the creation of CMS, Medicare administrative rulings were issued by CMS' predecessor-in-interest, the Health Care Financing Administration (HCFA). CMS Rulings and HCFA Rulings are binding on all HHS adjudicators.[7]

Precedential Decisions of the Medicare Appeals Council are decisions that the Chair of the HHS Departmental Appeals Board (DAB) has designated as having precedential effect. The Council's legal analysis and interpretation of a Medicare authority or provision in a precedential decision is binding on adjudicators at all levels of administrative review, and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect. Factual findings must also be applied in appeals involving the same parties if the relevant facts are the same and the underlying factual circumstances have not changed.[8]

Persuasive Authorities:

In administering the Medicare program, CMS and its contractors also issue program guidance (such as manual instructions and program memoranda) and Local Coverage Determinations.

Medicare policy manuals contain CMS program issuances, day-to-day operating instructions, policies, and procedures for the administration of the Medicare program. **Medicare transmittals** are periodic notices regarding changes to Medicare manuals.

Local Coverage Determinations[9] (LCDs) are regional determinations by a Medicare Administrative Contractor (MAC) regarding coverage for particular items or services under

1 42 C.F.R. § 405.1063(a).
[2] 42 C.F.R. § 405.1060(a).
[3] *Id.* § 405.1060(b).
[4] *Id.*
[5] *Id.*
[6] 42 C.F.R. § 405.1063(b); CMS Ruling 01-01.
[7] *Id.*
[8] 42 C.F.R. § 401.109.
[9] Formerly referred to as Local Medical Review Policies (LMRPs).

Medicare Part A or Medicare Part B, as applicable, for claims arising in that MAC's jurisdiction.[10] Additionally, the MACs update the content of their LCDs on a continual basis, so for any given Medicare claim, the applicable LCD is the one that was in effect on the date of service at issue. For example, in determining the medical necessity of hospice services rendered in Maryland, an attorney advisor should consult the LCD published by the MAC with jurisdiction in that region and corresponding with the date of service at issue.

ALJs and attorney adjudicators are not bound by LCDs or CMS program guidance (such as manual instructions and program memoranda); however, they must give substantial deference when such policies apply in a particular case.[11] While an ALJ or attorney adjudicator may decline to follow such policy in a particular case, the ALJ or attorney adjudicator must explain the reason(s) for disregarding the policy.[12]

Objective 3: Define key terms related to the Medicare program.

Medicare payment and reimbursement principles primarily encompass five components, including: (1) eligibility; (2) coverage; (3) certification; (4) payment; and (5) assignment. The following table lists some key Medicare terms applicable to OMHA's adjudication process.

Term	Description
Assignment	In Original Medicare, this means a healthcare practitioner (e.g., physician, physical therapist) agrees to accept the Medicare-approved amount as full payment. If the beneficiary is an enrollee of Original Medicare, it can save the beneficiary money if his/her doctor accepts assignment. The beneficiary still must pay his/her share of the cost of the doctor's visit (e.g., deductible, coinsurance, etc.).
Benefit Period	The way Medicare measures the beneficiary's use of hospital and skilled nursing facility (SNF) services. A benefit period begins the day the beneficiary is admitted to a hospital or SNF. The benefit period ends when the beneficiary has not received any hospital care (or skilled care in a SNF) for 60 consecutive days. If the beneficiary is enrolled in traditional Medicare and is admitted to the hospital or a skilled nursing facility after one benefit period has ended, a new benefit period begins. The beneficiary must pay the inpatient hospital deductible for each benefit period. There is no limit to the number of benefit periods available to the beneficiary.

[10] 42 C.F.R. § 400.202.
[11] 42 C.F.R. § 405.1062.
[12] *Id.*

Term	Description
Coinsurance	The percentage of the Medicare payment rate or a hospital's billed charge the beneficiary has to pay after his or her annual deductible for Medicare Part B items or services is met.
Deductible	The amount the beneficiary must pay for health care before Medicare begins to pay, either for each benefit period for Part A, or each year for Part B. These amounts can change every year.
Entitlement	A right to benefits as defined by the Act or the Railroad Retirement Benefits. Medicare Part A is an entitlement program.
Medically Reasonable and Necessary	A term of art used to describe when items or services are furnished consistent with applicable Medicare coverage criteria.
Prospective Payment System (PPS)	A method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount. The payment amount for a particular service is derived based on the classification system of that service (for example, Diagnosis-related groups (DRGs) for inpatient hospital services).
Provider	Generally, an entity that furnishes medical services, e.g. hospitals, SNFs, home health agencies (HHAs), hospices, rural health clinics (RHCs), rehabilitation agencies, physicians, chiropractors, etc.
Supplier	Generally, any company, person, or agency that sells or rents durable medical equipment, medical items or supplies (e.g., wheelchairs, portable oxygen supplies, diabetic supplies, etc.).

Objective 4: Describe the basic benefit for Medicare Parts A, B, C, and D

Medicare Part A Coverage[13]

In general, Medicare Part A helps cover the expensive and intensive inpatient care furnished in institutions such as hospitals, SNFs, inpatient rehabilitation facilities (IRFs), and long-term acute care hospitals (LTACs). Additionally, Part A provides coverage for qualifying hospice care, home health services, and inpatient care in a Religious Nonmedical Health Care Institution (RNHCI).

Medicare Part A Eligibility[14]

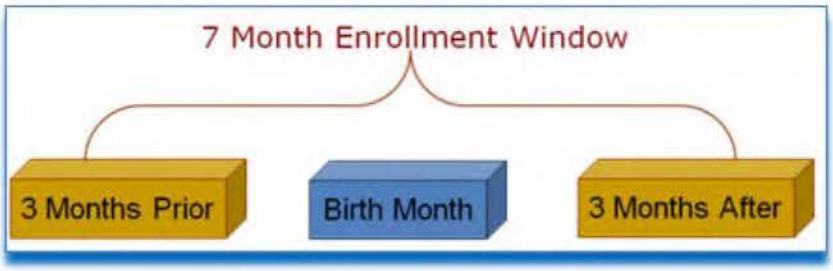
Generally, Medicare Part A eligibility can be broken down into the following groups:

[13] See *CMS, Medicare General Information, Eligibility and Entitlement Manual (MGIEEM) (Internet-Only Manual Publ'n 100–1)* ch. 2, § 10 (Sept. 2002).
[14] 42 C.F.R. Part 406, Subparts A and B.

- Individuals who are entitled or eligible to receive Social Security or Railroad Retirement benefits at age 65 or earlier are automatically enrolled in Medicare Part A at age 65 and pay no monthly Part A premium.[15]
- Individuals who are not eligible to receive Social Security or Railroad Retirement benefits, but who are otherwise eligible for premium-free Medicare Part A and who file an application.[16]
- Disabled individuals of any age, who have been entitled to disability benefits for at least 25 consecutive months under Social Security or Railroad Retirement programs, are automatically entitled to premium-free Part A benefits. [17]
- Individuals of any age with amyotrophic lateral sclerosis (ALS) and receiving Social Security or Railroad Retirement benefits, are eligible for premium-free Part A benefits with no waiting period, in accordance with section 226(h) of the Social Security Act.
- Individuals with end-stage renal disease (ESRD) are eligible for premium-free Part A benefits, upon application, and generally after a three-month waiting period. Medicare defines ESRD as that stage of kidney impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.[18]
- Individuals who do not qualify for premium-free Part A, but who are otherwise eligible for Premium Hospital Insurance, may apply to Part A, but subject to monthly premiums.[19]

Medicare Part A Enrollment[20]

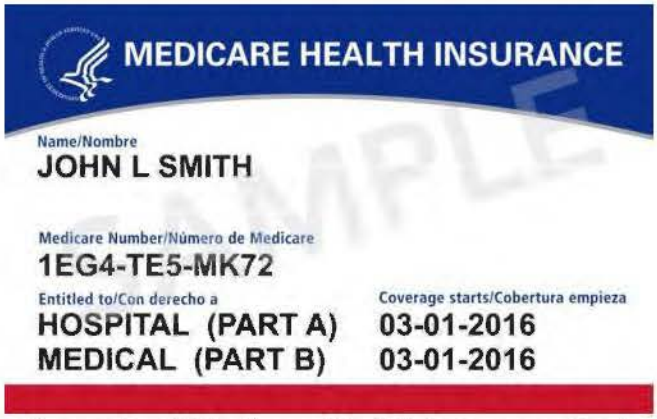
Benefits normally begin on the first day of the month the beneficiary's 65th birthday for those individuals choosing to receive Medicare when they reach 65, unless their birthday is the 1st day of the month, and then their benefit begins the month before their birthday. Thus, an individual whose 65th birthday is June 1, 2011, will begin receiving Medicare Part A benefits on May 1, 2011. Also, an individual whose 65th birthday is June 30, 2011 will begin receiving Medicare Part A benefits on June 1, 2011.



Part A Enrollment Based on 65th Birthday

[15] 42 C.F.R. §§ 406.6(b) and 406.10.
[16] 42 C.F.R. §§ 406.6(c) and 406.11.
[17] 42 C.F.R. § 406.12.
[18] 42 C.F.R. § 406.13.
[19] 42 C.F.R. § 406, Subpart C.
[20] 42 C.F.R. Part 406, Subparts A and C.

CMS or the Railroad Retirement Board, as applicable, issues each Medicare beneficiary a "Medicare Health Insurance Card" to be used as evidence of entitlement to Medicare benefits. The card displays the beneficiary's name, Medicare Beneficiary Identifier (which replaced the health insurance claim number (HICN) beginning on April 1, 2018, gender, extent of entitlement, and the effective date of the entitlement.



Example of Medicare Health Insurance Card

Medicare Part A Monthly Premium[21]

Most people do not pay a Medicare Part A premium because they paid Medicare taxes while working.

Medicare Part A Late Enrollment Penalty[22]

If a Beneficiary is eligible for premium-free Part A and does not enroll when first eligible, their monthly premium may go up 10%. The higher premium will have to be paid for twice the number of years they could have had Part A but did not sign up.

Medicare Part A Deductibles and Cost Sharing

Beneficiaries are responsible for an annual deductible when admitted to the hospital. The deductible covers beneficiaries' share of costs for the first 60 days of Medicare-covered inpatient hospital care in a benefit period. Beneficiaries are also responsible for a daily coinsurance amount for the 61st through 90th day of hospitalization.

The deductible and cost sharing amounts change annually. Information is published in the Federal Register.[23]

Medicare Part B Coverage[24]

Part B helps cover medically reasonable and necessary physician and non-physician practitioner services provided in inpatient and outpatient settings, hospital outpatient care, preventive

[21] 42 C.F.R. § 406.32.
[22] 42 C.F.R. § 406.32(d).
[23] See CMS-8059-N, CMS-8060-N, and CMS-8061-N.
[24] See *42* C.F.R. Part 407.

services (including an annual physical exam), ambulance transportation, durable medical equipment, and diagnostic tests.[25]

Medicare Part B Eligibility[26]

A Medicare beneficiary is eligible to enroll in Medicare Part B if he or she is entitled to Medicare Part A benefits:

- As an individual age 65 or older who is entitled to Social Security retirement benefits or Railroad Retirement benefits, or who is eligible for Social Security retirement benefits;
- As an individual age 65 or older who is not eligible for Social Security retirement benefits or Railroad Retirement benefits, or eligible for such benefits on the basis of government employment
  - ✓ who has sufficient quarters of coverage,
  - ✓ is a resident of the United States, and,
  - ✓ either a citizen of the United States or an alien lawfully admitted for permanent residence who has resided continuously in the United States during the five years immediately prior to enrollment;
- As an individual under age 65 who for 25 months has been entitled to Social Security disability benefits or Railroad Retirement disability benefits; as an individual with ESRD; or, as a Medicare-qualified government employment.

Medicare Part B Enrollment[27]

Any U.S. resident (except residents of Puerto Rico) who is entitled to premium-free Part A benefits is automatically enrolled in Part B unless he/she declines coverage.[28] People living in Puerto Rico who are eligible for automatic enrollment are only enrolled in premium-free Part A; they must actively enroll in Part B to get this coverage.[29]

Individuals who are not entitled to premium-free Part A, and who want to enroll in Part B, must do so at specifically designated times. The following identifies the various Part B enrollment periods available to beneficiaries:

- The Initial Enrollment Period (IEP) is the seven-month period beginning 3 months prior to the beneficiary's 65th birthday month and ending 3 months after their 65th birthday. For example, if the beneficiary's birthday is July 4, the initial enrollment period begins on April 1 and ends on October 31.[30]
- General Enrollment Period, January 1 through March 31 annually, is available for individuals that did not enroll during their initial enrollment period.[31]

---

[25] See *MGIEEM, supra*, ch. 2, § 40.
[26] 42 C.F.R. §§ 406.10–406.15, 407.10.
[27] 42 C.F.R. Part 407, Subpart B.
[28] 42 C.F.R. § 407.17(a).
[29] 42 C.F.R. § 407.17(a)(1).
[30] 42 C.F.R. § 407.14.
[31] 42 C.F.R. § 407.15.

- Special Enrollment Period is an 8-month period for beneficiaries to enroll after their group health plan coverage expires. Example: Corporation X furloughs a beneficiary and cancels their access to their group health plan. The beneficiary may apply for Part B during the special enrollment period.[32]
- An individual who has received disability benefits for 25 months may enroll for Medicare Part B benefits even if under the age of 65.[33]
- Also, persons with end-stage renal disease may enroll after a three-month waiting period.[34]

Medicare Part B Monthly Premium[35]

There is a monthly Part B premium. Most people will pay the standard premium amount; however, some must pay more than the standard premium based on their income as reported to the Internal Revenue Service (IRS).

Each year, Social Security will notify a beneficiary if he/she must pay more than the standard premium. The annual premiums are determined by the IRMAA. The modified adjusted gross income is the beneficiary's adjusted gross income plus their tax-exempt interest income. The standard premium or a higher premium can change each year depending on the beneficiary's income.

Medicare Part B Late Enrollment Penalty[36]

If the beneficiary does not sign up for Part B when first eligible, the beneficiary may have to pay a late enrollment penalty for as long as they are enrolled in Medicare. Subject to limited exceptions, an individual's monthly Part B premium amount will be increased 10% for each full 12-month period the enrollee could have been in enrolled in Part B, but was not.

Medicare Part B Deductibles and Cost Sharing

The Part B deductible changes annually. The amount is published in the Federal Register, usually in August, prior to the beginning of the Fiscal Year on October 1. The beneficiary may also be required to pay coinsurance or a copayment for outpatient hospital services.[37]

Medicare Part C – Medicare Advantage (MA)[38]

CMS is authorized to contract with public or private organizations to offer Medicare covered services through coordinated care plans. These plans are often referred to as Part C MA plans. The MA plan structures include HMOs (with or without Point-of-Service options (POS)); Provider Sponsored Organizations (PSOs); and PPOs.

---

[32] 42 C.F.R. § 407.20.
[33] 42 C.F.R. §§ 406.10-406.15 and 407.10.
[34] 42 C.F.R. § 407.18.
[35] Act § 1839; 42 C.F.R. Part 408, Subpart B.
[36] Act § 1839; 42 C.F.R. § 407.22.
[37] See CMS-8061-N.
[38] See CMS, *Medicare Managed Care Manual (MMCM) (Internet-Only Manual Publ'n 100–16)* (Jan. 2011).

Beneficiaries may choose from additional plan options, including regional PPO (RPPO) plans and special needs plans (SNPs). MA plans may also offer prescription drug coverage. Regulations governing the MA program are found at 42 C.F.R. Parts 422 and 423.

Medicare Part C Coverage[39]

MA Plan enrollees receive coverage for all the services and items that would be covered under Original Medicare (i.e., had they been enrolled under Medicare Parts A and B).[40] In addition to the same benefits available under Original Medicare, the MA Plan may offer supplemental benefits not offered under Parts A or B (e.g., vision, hearing, dental and/or health and wellness benefits).[41] Coverage for these supplemental benefits is typically dictated by the terms of the MA Plan's annual Evidence of Coverage (EOC).

In many instances, the MA Plan will require enrollees to obtain medical care from network providers, i.e., providers who have a contractual relationship with the MA Plan.[42] In these cases, care that otherwise satisfies applicable criteria may be denied coverage for being obtained out-of-network. However, MA Plans that include network restrictions must still cover out-of-network services under specified circumstances.[43]

Medicare Part C Eligibility/Enrollment[44]

MA Plans are available to most people who are entitled to Medicare. To be eligible to join an MA plan, one must:

- Be entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or Competitive Medical Plan (CMP) with a risk contract under Part 417 on December 31, 1998 may continue to be enrolled in the MA organization as an MA plan enrollee);
- Live in the plan's geographic service area or continuation area;
- Continue to pay the monthly Medicare Part B premium (However, some plans may offer an additional benefit by reducing the amount members pay for their Medicare Part B premium);
- Pay an additional monthly premium to the plan (if the plan has one).

An individual with ESRD usually cannot join an MA Plan. However, there are some exceptions, such as when a person is already in a plan and then develops ESRD.

Outside of the annual election period and the disenrollment period, beneficiaries cannot make changes to an MA plan unless they qualify for a special election period.

Medicare Part C Premium[45]

Medicare Part C monthly premiums vary by plan.

---

[39] Act §§ 1851–1852.
[40] 42 C.F.R. § 422.101(a).
[41] 42 C.F.R. § 422.102.
[42] 42 C.F.R. § 422.112.
[43] 42 C.F.R. § 422.112(a)(3), (a)(9).
[44] 42 C.F.R. Part 422, Subpart B.
[45] Act § 1854.

Medicare Part C Deductibles and Cost Sharing[46]

The amount a beneficiary pays for Part C deductibles, copayments, and/or coinsurance varies by plan.

Medicare Part D Coverage[47]

Part D drugs are defined in Part D of Title XVIII of the Act and in the regulations.[48] Part D sponsors are responsible for making appropriate coverage determinations and ensuring that covered Part D drugs satisfy all Part D statutory and regulatory requirements.

Medicare Part D – Prescription Drug Benefit[49]

Medicare Part D provides an optional outpatient prescription drug benefit to beneficiaries.

Medicare Part D Eligibility and Enrollment[50]

In general, an individual is eligible to enroll in a Medicare prescription drug plan (PDP) if:

- The individual is entitled to Medicare Part A and/or enrolled in Part B, provided that he/she will be entitled to receive services under Medicare Part A and/or Part B as of the effective date of coverage under the plan; and
- The individual permanently resides in the service area of a PDP.

Medicare Part D Late Enrollment Penalty[51]

If the beneficiary does not sign up for Part D when first eligible, the beneficiary may have to pay a late enrollment penalty for as long as they are enrolled in Medicare. The monthly premium for Part D may go up 1% of the average Part D premium for each month enrollment was delayed.[52]

Decisions regarding Part D late enrollment penalties may be appealed for reconsideration by CMS or an independent review entity.[53] However, decisions made through this process are not subject to appeal to OMHA, but may be reviewed and revised at the discretion of CMS.[54]

Medicare Part D Monthly Premium[55]

Most Medicare Prescription Drug Plans charge a monthly fee that varies by plan. This fee is charged in addition to the Medicare Part B premium. If a beneficiary belongs to an MA Plan (Part C) that includes Medicare prescription drug coverage, the monthly premium paid to the plan may include an amount for drug coverage.

---

[46] *Id.*
[47] 42 C.F.R. Part 423; *See* CMS, *Medicare Prescription Drug Benefit Manual (MPDBM) (Internet-Only Manual Publ'n* 100–18) (Sept. 2008).
[48] Act § 1860D-2(e); 42 C.F.R. § 423.100.
[49] Act § 1860D-1; 42 C.F.R. § 423.100.
[50] 42 C.F.R. Part 423, Subpart B.
[51] 42 C.F.R. § 423.46.
[52] Act § 1860D-13.
[53] 42 C.F.R. § 423.46(c).
[54] *Id.*
[55] 42 C.F.R. § 423.46(c); 42 C.F.R. Part 423, Subpart F.

If the beneficiary's modified adjusted gross income as reported on their IRS tax return from 2 years prior is above a certain limit, the beneficiary may pay a Part D-IRMAA in addition to their monthly plan premium. This extra amount is paid directly to Medicare, not to the Part D plan.

Medicare Part D Deductibles and Cost Sharing[56]

There is a yearly deductible for Medicare Part D Prescription Drug plans. This is the amount the beneficiary must pay each year for their prescription before the plan begins to pay its share of the covered drugs. Deductibles vary between Medicare drug plans and some plans do not have a deductible at all.

After the deductible is paid (if the plan has one), the beneficiary may also have to pay a copayment or coinsurance amount. Some plans have different levels or tiers of copayments or coinsurance, with different costs for different types of drugs. With a copayment, the beneficiary pays a set amount for all drugs on a tier. Coinsurance means the beneficiary pays a percentage of the cost of the drug.

Medicare Part D Not Eligible to Enroll[57]

An individual who is living abroad or is incarcerated is not eligible for Part D as he or she cannot meet the requirement of permanently residing in the service area of a Part D plan. Note: A PDP sponsor may not impose any additional eligibility requirements as a condition of enrollment other than those permitted by CMS.

[56] *Id.*
[57] 42 C.F.R. §§ 423.44(5)(iii) and 423.30(a)(1).

Module 4:
Medicare – Introduction to the Law

After this session you will:

1. Recognize the types of Centers for Medicare and Medicaid Services (CMS) contractors;
2. Describe the Medicare Parts A and B appeals process;
3. Describe the Medicare Part C Appeals process;
4. Describe the Medicare Part D Appeals process; and
5. Identify web-based resource links to OMHA-applicable statutes, regulations, and policies.

Suggested Reading/Reference:

- ✓ **Title XVIII of the Social Security Act**: Enacted in 1965, Title XVIII of the Social Security Act (the Act) established regulations for the Medicare program, which guarantees access to health insurance for all Americans aged 65 and older, younger people with specific disabilities, and individuals with end-stage renal disease.
- ✓ **42 C.F.R. Part 405**: Federal Health Insurance for the Aged and Disabled
  - ➢ **42 C.F.R. Part 405, Subpart I, §§ 405.900–1140**: Determinations, Redeterminations, Reconsiderations, and Appeals
- ✓ **42 C.F.R. § 411**: Exclusions from Medicare and Limitations on Medicare Payment
- ✓ **42 C.F.R. § 417**: Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans
- ✓ **42 C.F.R. § 422**: Medicare Advantage Program (Medicare Part C)
- ✓ **42 C.F.R. § 423**: Voluntary Medicare Prescription Drug Benefit
- ✓ **42 C.F.R. § 424**: Conditions for Medicare Payment
- ✓ **42 C.F.R. §§ 482–494**: Standards and Certifications
- ✓ ***Medicare Benefit Policy Manual, (Internet-Only Manual Publ'n 100–02)***
- ✓ ***Medicare Claims Processing Manual (Internet-Only Manual Publ'n 100–04)***
- ✓ ***Medicare Program Integrity Manual (Internet-Only Manual Publ'n Pub. 100–08)***
- ✓ ***Medicare Quality Improvement Organizations (Internet-Only Manual Publ'n 100–10)***
- ✓ ***Medicare Managed Care Manual (Internet-Only Manual Publ'n 100–16)***
- ✓ ***Medicare Prescription Drug Manual (Internet-Only Manual Publ'n 100–18)***

Introduction – Background and Rationale

Within the "Introduction to the Law" lesson, you will learn about the different CMS contractors. You will also gain an understanding the Medicare appeals program. Finally, you will learn of the web-based resources available to OMHA attorneys and adjudicators.

Objective 1: Recognize the types of CMS contractors

Medicare Administrative Contractors (MACs)

As required by section 911 of the Medicare Modernization Act (MMA), CMS has designated contractors to process Medicare claims. These contract entities are called Medicare Administrative Contractors (MACs).

Generally, MACs are assigned to regional jurisdictions (identified by state) in which they receive, review, and effectuate Medicare Part A and B claims. While most of the Part A and B claims are processed by these MACs, certain types of services are processed exclusively by dedicated entities. For instance, DME claims are processed by four DME MACs, each of which is responsible for a large region consisting of multiple states. Similarly, home health and hospice claims are processed by dedicated MACs assigned to large jurisdictions.

CMS regularly re-competes its MAC contracts, which results in ongoing changes to the entity assigned to a particular MAC jurisdiction. The chart appearing on the next page lists the current MAC contracts as of October 2017.[1]

[1] CMS: Medicare Administrative Contractors (MACs), https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/MACs-by-State-October-2017.pdf.

Medicare Administrative Contractors (MACs)
As of October 2017

MAC Jurisdiction	Processes Part A & Part B Claims for the following states:	MAC
DME A	Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont	Noridian Healthcare Solutions, LLC
DME B	Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin	CGS Administrators, LLC
DME C	Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, Puerto Rico, U.S. Virgin Islands	CGS Administrators, LLC
DME D	Alaska, Arizona, California, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
5	Iowa, Kansas, Missouri, Nebraska	Wisconsin Physicians Service Insurance Corporation
6	Illinois, Minnesota, Wisconsin **HH + H for the following states: Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Michigan, Minnesota, Nevada, New Jersey, New York, Northern Mariana Islands, Oregon, Puerto Rico, US Virgin Islands, Wisconsin and Washington	National Government Services, Inc.
8	Indiana, Michigan	Wisconsin Physicians Service Insurance Corporation
15	Kentucky, Ohio **HH + H for the following states: Delaware, District of Columbia, Colorado, Iowa, Kansas, Maryland, Missouri, Montana, Nebraska, North Dakota, Pennsylvania, South Dakota, Utah, Virginia, West Virginia, and Wyoming	CGS Administrators, LLC
E	California, Hawaii, Nevada, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
F	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming	Noridian Healthcare Solutions, LLC
H	Arkansas, Colorado, New Mexico, Oklahoma, Texas, Louisiana, Mississippi	Novitas Solutions, Inc.
J	Alabama, Georgia, Tennessee	Palmetto GBA, LLC
K	Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont **HH + H for the following states: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	National Government Services, Inc.
L	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania (includes Part B for counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia)	Novitas Solutions, Inc.
M	North Carolina, South Carolina, Virginia, West Virginia (excludes Part B for the counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia) **HH + H for the following states: Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, and Texas	Palmetto GBA, LLC
N	Florida, Puerto Rico, U.S. Virgin Islands	First Coast Service Options, Inc.

**Also Processes Home Health and Hospice claims

Recovery Audit Contractors (RAC)[2]

Section 306 of the MMA required CMS to implement a three year RAC demonstration (2005–2008). The Tax Relief and Healthcare Act of 2006, section 302, required a permanent and nationwide RAC program be expanded to all 50 states no later than 2010. Both of these statutes gave CMS the authority to pay the RACs on a contingency fee basis. CMS designed the RAC Program to:

1. Detect and correct past improper payments in the Medicare Fee-for-Service (FFS) program; and
2. Provide information to CMS and Medicare contractors that could help protect the Medicare Trust Funds by preventing future improper payments thereby lowering the Medicare FFS claims payment error rate.

Each RAC is responsible for identifying overpayment and underpayment in approximately ¼ of the country (See map below). The RACs detect and correct past improper overpayments and underpayments so that CMS can implement actions that will prevent future improper payments.

RACs review claims on a post-payment basis. They use the same Medicare policies as MACs and conduct two types of review: automated (no medical record needed) and complex (medical record required).

If a RAC has examined a provider, physician, or other supplier's claim(s) and determined that payment was not acceptable, the RAC will inform the provider/physician/other supplier and the MAC of the overpayment. A "Denial Letter" or "Overpayment Determination" is then issued to the provider/supplier informing them that their claim(s) was paid in error and that the provider/supplier must refund the amount in controversy to the Medicare trust fund.

The provider/physician/other supplier has appeal rights regarding this overpayment determination.

[2]CMS, Medicare Fee for Service Recovery Audit Program,, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/index.html.

On October 31, 2016, CMS awarded new fee-for-service (FFS) RAC contracts in four distinct geographical regions (Regions 1–4) and one nationwide DME/home health & hospice contract (Region 5). The RACs and their assigned regions are as follows:[3]

Zone Program Integrity Contractors (ZPICs) (Formerly Program Safeguard Contractors (PSCs))[4]

The Health Insurance Portability and Accountability Act (HIPAA) authorized CMS to contract with entities to promote the integrity of Medicare. The Medicare Integrity Program (MIP) was established to strengthen the ability to reduce fraud and abuse in the Medicare program. CMS began transferring the responsibility for detecting and deterring fraud and abuse in Medicare Parts A and B from MACs fraud units to Program Safeguard Contractors (PSCs). As part of their duties, PSCs conducted investigations to determine the facts and magnitude of alleged fraud and abuse. Beginning in 2008, the Zone Program Integrity Contractors (ZPICs) were created to

[3] Medicare Fee for Service Recovery Audit Program, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/

[4] CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n* 100-8, ch. 4; CMS, MLN Matters Number SE 1204 (Revised), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1204.pdf.

allow contractors to look across multiple payment types (e.g., Part A/B claims, home health/Hospice, and DME claims).

Data analysis is a tool for identifying actual or potential claim payment errors. Often ZPICs will conduct a post-payment review of claims and utilize statistical sampling of a provider/physician/other supplier's Medicare claims to determine fraud, abuse, or high payment error.

Similar to RACs, if a ZPIC finds that an overpayment occurred, it will notify the provider/supplier and the MAC. A "Denial Letter" or "Overpayment Determination" will then be issued to the provider/supplier informing them that their claim(s) were paid in error and that the provider/supplier must refund the amount in controversy to the Medicare trust fund. The provider/supplier has appeal rights regarding this determination. There are seven ZPIC zones. The names and jurisdiction for each ZPIC are listed below.[5]

ZPIC	Zone	States in Zone
Safeguard Services (SGS)	1	California, Hawaii, Nevada, American Samoa, Guam, and the Mariana Islands
AdvanceMed	2	Washington, Oregon, Idaho, Utah, Arizona, Wyoming, Montana, North Dakota, South Dakota, Nebraska, Kansas, Iowa, Missouri, Alaska
Cahaba	3	Minnesota, Wisconsin, Illinois, Indiana, Michigan, Ohio, Kentucky
Health Integrity	4	Colorado, New Mexico, Texas, and Oklahoma
AdvanceMed	5	Arkansas, Louisiana, Mississippi, Tennessee, Alabama, Georgia, North Carolina, South Carolina, Virginia, West Virginia
Under Protest	6	Pennsylvania, New York, Delaware, Maryland, D.C., New Jersey, Massachusetts, New Hampshire, Vermont, Maine, Rhode Island, Connecticut
SGS	7	Florida, Puerto Rico, Virgin Islands

Qualified Independent Contractors (QICs)

QICs issue Level II reconsideration decisions for Medicare Part A and Part B appeals (including DME appeals).[6] Additionally, the Administrative QIC (AdQIC) provides administrative support and is the custodian of record for case files for CMS, OMHA, and the other QICs.[7] The QICs and their covered states are as follows:[8]

Task Order ID	QIC Contractor	Covered States

[5] CMS, MLN Matters Number SE 1204 (Revised), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1204.pdf.
[6] 42 C.F.R. § 405.1004.
[7] CMS, *Medicare Claims Processing Manual (MCPM) (Internet-Only Manual Publ'n 100-4)*, ch. 29, § 330.3.
[8] CMS, Second Level of Appeal: Reconsideration by a Qualified Independent Contractor, http://www.cms.gov/medicare/appeals-and-grievances/orgmedffsappeals/reconsiderationbyaqualifiedindependentcontractor.html.

Task Order ID	QIC Contractor	Covered States
Part A EAST QIC	C2C Innovative Solutions, Inc.[9]	Colorado, New Mexico, Texas, Oklahoma, Arkansas, Louisiana, Mississippi, Alabama, Georgia, Florida, Tennessee, South Carolina, North Carolina, Virginia, West Virginia, Puerto Rico, Virgin Islands, Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, Connecticut, New Jersey, New York, Delaware, Maryland, Pennsylvania, Washington DC
Part A West QIC	Maximus, Inc.	Washington, Idaho, Montana, North Dakota, South Dakota, Iowa, Missouri, Kansas, Nebraska, Wyoming, Utah, Arizona, Nevada, California, Alaska, Hawaii, Oregon, Kentucky, Ohio, Indiana, Illinois, Minnesota, Michigan, Wisconsin, Guam, Northern Mariana Islands, American Samoa
Part B North QIC	C2C Innovative Solutions, Inc.	AK, WA, OR, CA, NV, AZ, UT, ID, MET, WY, ND, SD, NE, KS, MO, IZ, MN, WI, IL, IN, KY, MI, OH, PA, MD, DE, NJ, DC, CT, MA, NH, VT, ME, NY, Guam, Northern Mariana Islands, American Samoa
Part B South QIC	C2C Innovative Solutions, Inc.	CO, NM, TX, OK, AR, LA, MS, AL, TN, GA, FL, Puerto Rico, U.S. Virgin Islands, SC, NC, VA, WV
DME QIC	C2C Innovative Solutions, Inc.	All States and US territories
AdQIC	Q^2Administrators, LLC	Not applicable

Quality Improvement Organizations (QIOs) (Formerly Peer Review Organizations or PROs)[10]

QIOs are private, mostly not-for-profit organizations, which are staffed by professionals, mostly doctors and other health care professionals, who are trained to review medical care and help beneficiaries with complaints about the quality of care and to implement improvements in the quality of care available throughout the spectrum of care.

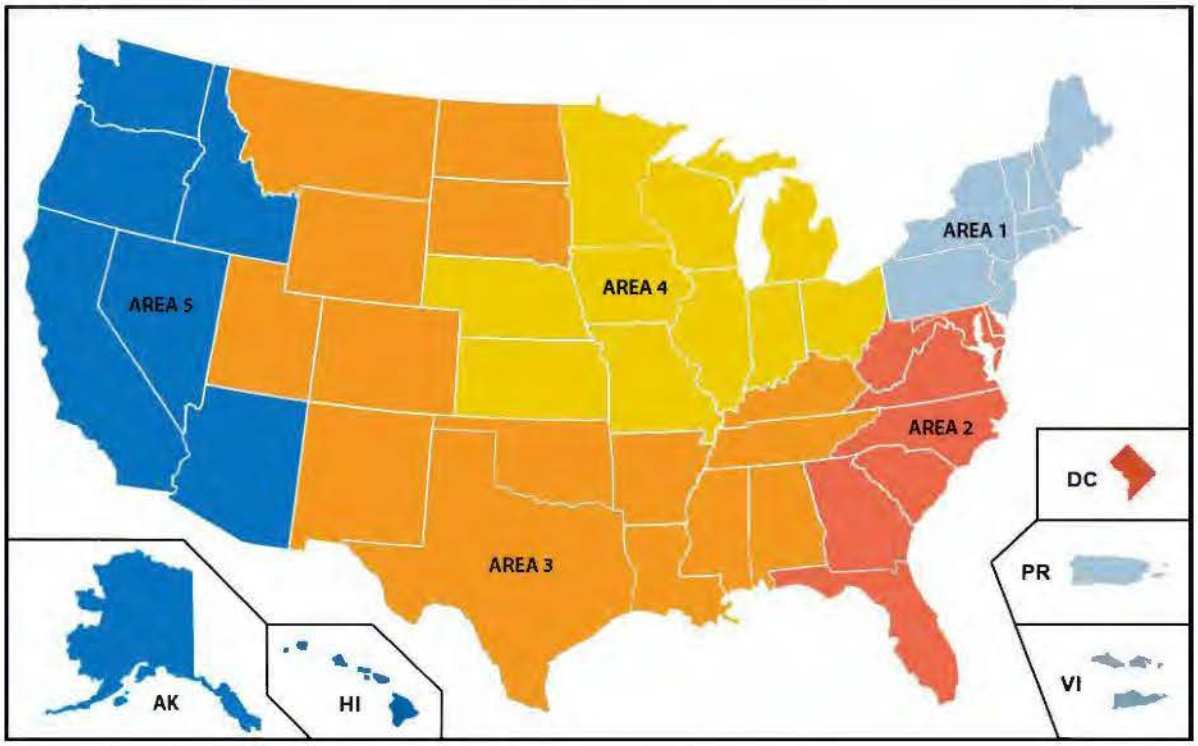
In the context of the Medicare administrative appeals process, CMS contracts with QIOs to facilitate appeals of certain provider determinations, e.g. termination of inpatient

[9] Effective February 14, 2017, the QIC Part A East contract transitioned from Maximus Federal Services, Inc. to C2C Innovative Solutions, Inc. (C2C).

[10] CMS, Quality Improvement Organizations, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/.

hospital or skilled nursing facility services. These contracts are organized in such a way that one organization in each state, as well as the District of Columbia, Puerto Rico, and the U.S. Virgin Islands serve as that state/jurisdiction's QIO contractor. In practice, CMS may contract with the same company to serve as the QIO for multiple states; nonetheless, for the Medicare administrative appeals purposes, there is only one QIO per state/jurisdiction.

Please see the following diagram for the current QIO contract assignments:[11]



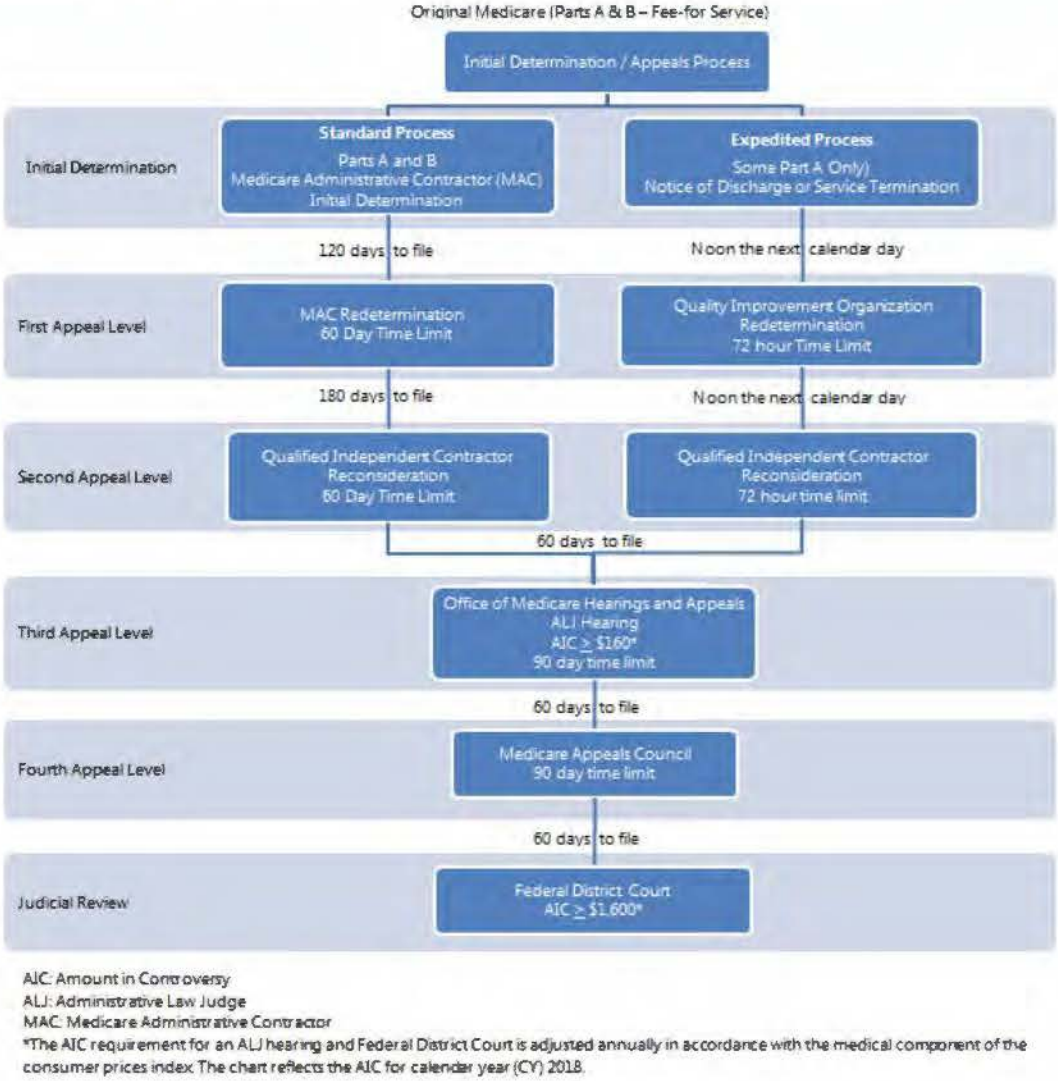
Area 1 - Livanta (866-815-5440) **Area 2 - KEPRO (844-455-8708)** **Area 3 - KEPRO (844-430-9504)**

Area 4 - KEPRO (855-408-8557) **Area 5 - Livanta (877-588-1123)**

Please note, OMHA reviews QIO appeals only related to Medicare claim coverage and termination issues. QIO actions concerning quality of care complaints are not within OMHA's jurisdiction.

[11] CMS, Report to Congress on the Administration, Cost and Impact of the Quality Improvement Organization (QIO) Program for Medicare Beneficiaries for Fiscal Year (FY) 2016, fig. 1, *available at* https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/Downloads/Annual-Report-to-Congress-QIO-Program-Fiscal-Year-2016.pdf

Objective 2: Describe the Medicare Parts A and B appeals process



Brief Overview of the Part A and Part B Appeals Process[12]

The MAC makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A party with appeal rights (e.g., provider, supplier, beneficiary, Medicaid state agency, etc.) who is dissatisfied with the initial determination may request the MAC perform a redetermination of the claim, if the requirements for obtaining a redetermination are met.

Following the MAC's redetermination, the party may request reconsideration from the QIC. The QIC will issue a reconsideration decision of the claim, if the requirements for obtaining reconsideration are met.

[12] See 42 C.F.R. § 405.904.

Next, the party may request an ALJ hearing. In most appeals, if the ALJ has jurisdiction over the appeal, the ALJ will conduct a hearing and then issue a decision. For cases where a hearing is not required, such as requests for on-the-record (OTR) review, an ALJ or an attorney adjudicator will review the casefile and issue a decision.

If the party is dissatisfied with the decision of the ALJ or attorney adjudicator, the party may submit a request for the Departmental Appeals Board's (DAB) Medicare Appeals Council (Council) to review the case. If the Council reviews the case and issues a decision, and the party is dissatisfied with the decision, the party may file suit in Federal district court, if the amount remaining in controversy and the other requirements for judicial review are met.

CMS contracts with and oversees the following entities:

1. MACs – initial coverage determinations; redeterminations; and final claim effectuation
2. QICs – reconsiderations
3. AdQICs – review of ALJ and attorney adjudicator decisions (to identify discrepancies in case identifiers or disposition language); coordinate effectuation with MACs; file CMS own motion referrals to the Medicare Appeals Council
4. QIOs – (for hospital and skilled nursing facility (SNF) termination cases only) - initial determination; redetermination

Below are some important terms associated with the Medicare appeals process:[13]

Term	Description
Appellant	Beneficiary, assignee or other person or entity that has filed and pursued an appeal concerning a particular initial determination. Designation as an appellant does not in itself convey standing to appeal the determination in question.
Appointed Representative	An individual appointed by a party to represent the party in a Medicare claim or claim appeal.
Assignee	A supplier furnishing items or services to a beneficiary and has accepted a valid assignment of a claim OR A provider or supplier furnishing items or services to a beneficiary, who is not already a party, and has accepted a valid assignment of the right to appeal a claim executed by the beneficiary.
Assignment of a Claim	The transfer by a beneficiary of his/her claim for payment to the supplier in return for the latter's promise not to charge more for his/her services than what the carrier finds to be the Medicare approved amount.
Assignment of Appeal Rights	The transfer by a beneficiary of his/her right to appeal to a provider or supplier who is not already a party, as provided in § 1869(b)(1)(C) of the Act.
Authorized	An individual authorized under State or other applicable law to act on

[13] 42 C.F.R. §§ 405.902 and 405.904.

Term	Description
Representative	behalf of a beneficiary or other party involved in the appeal. The authorized representative will have all of the rights and responsibilities of a beneficiary or party, as applicable, throughout the appeals process.
Initial Determination	The first adjudication made by a MAC, carrier or fiscal intermediary (FI) following a request for Medicare payment or the first determination made by a QIO either in a prepayment or post payment context.
Medicare Appeals Council or "Council"	Fourth level of appeal – The Council, made up of Administrative Appeals Judges, is a component of the DAB of the U.S. Department of Health and Human Services (HHS). The DAB is a staff division under the Office of the Secretary.
Party	An individual or entity listed in 42 C.F.R. § 405.906 with standing to appeal an initial determination and/or a subsequent administrative appeal determination.
Reconsideration	Second level of appeal – A party to the redetermination may request the reconsideration if dissatisfied with the redetermination decision. A QIC will conduct the reconsideration.
Redetermination	First level of appeal - An examination of a claim by the FI, carrier, or MAC personnel who are different from the personnel who made the initial claim determination. The appellant (the individual filing the appeal) has 120 days from the date of receipt of the initial claim determination to file an appeal. A redetermination must be requested in writing. A minimum monetary threshold is not required to request a redetermination.
Remand	To vacate a lower level appeal decision, or a portion of the decision, and return the case, or a portion of the case, to that level for a new decision.

First Level of Appeal: Redetermination by a Medicare Contractor

A redetermination is an examination of a claim by the MAC, but by personnel who are different from those who made the initial claim determination.

The appellant (the individual filing the appeal) has 120 calendar days from the date of receipt of the initial claim determination to file an appeal.[14]

- A redetermination must be requested in writing.[15]
- A minimum monetary threshold is not required to request a redetermination.[16]

Second Level of Appeal: Reconsideration

A party to the redetermination may request a reconsideration if dissatisfied with the redetermination decision.

- Any request for reconsideration must be filed within 180 calendar days from the date the party receives the notice of the redetermination.[17]

[14] 42 C.F.R. § 405.942(a).
[15] 42 C.F.R. § 405.944(b).
[16] 42 C.F.R. § 405.940.
[17] 42 C.F.R. § 405.962(a).

- The date of receipt of the redetermination will be presumed to be 5 calendar days after the date of the notice of redetermination, unless there is evidence to the contrary.[18]
- The request for reconsideration must be in writing and should be made on a standard CMS form.[19]
- A minimum monetary threshold is not required to request reconsideration.[20]
- When filing a request for reconsideration, a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination, including the redetermination.[21]
- Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier.[22]

Third Level of Appeal: OMHA

A party to the reconsideration may request an ALJ hearing within 60 calendar days of receipt of the reconsideration decision.[23]

- Receipt of the QIC decision is presumed to be 5 calendar days after the date of reconsideration, unless there is evidence to the contrary.[24]
- For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the entity specified in the reconsideration.[25]
- Generally, the amount remaining in controversy (AIC) is computed as the actual amount charged the individual for the items and services in the disputed claim, reduced by—any Medicare payments already made; and any deductible and/or coinsurance amounts that may be collected for the items or services.[26]
  - In certain circumstances, two or more claims may be aggregated to meet the AIC.[27]
- CMS or its contractors may elect to or be requested by the ALJ to participate in an ALJ hearing.[28]
- When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, the ALJ or attorney adjudicator must issue a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC's notice of reconsideration, unless the 90 calendar day period has been extended.[29]
- The issues before the ALJ or attorney adjudicator include all the issues for claims or appealed matter specified in the request for hearing that were brought out in the initial

[18] 42 C.F.R. § 405.962(a)(1).
[19] 42 C.F.R. § 405.964(b).
[20] 42 C.F.R. § 405.960.
[21] 42 C.F.R. § 405.966(a).
[22] 42 C.F.R. § 405.966(a)(2).
[23] 42 C.F.R. § 405.1002(a)(1).
[24] 42 C.F.R. § 405.1002(a)(3).
[25] 42 C.F.R. § 405.1002(a)(4).
[26] 42 C.F.R. § 405.1006(d)(1)(i)-(ii).
[27] 42 C.F.R. § 405.1006(e).
[28] 42 C.F.R. §§ 405.1010 and 405.1012.
[29] 42 C.F.R. § 405.1016(a).

determination, redetermination, or reconsideration that were not decided entirely in a party's favor.[30]

- An ALJ or attorney adjudicator may decide an appeal without conducting an ALJ hearing only when the following conditions are met:[31]
  - The evidence in the hearing record supports a finding fully in favor of the appellant(s) on every issue, no other party to the appeal is liable for claims at issue, and CMS or a contractor has not elected to be a party to the hearing;
  - All of the parties who would be sent a notice of hearing indicate in writing that they do not wish to appear before an ALJ at hearing; or
  - The appellant lives outside the U.S., does not inform OMHA that he or she wants to appear at a hearing before an ALJ, and there are no other parties who would be sent a notice of hearing and who wish to appear.
- A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.[32]

Fourth Level of Appeal: Review by the Medicare Appeals Council (Council)

If a party to an ALJ's or attorney adjudicator's decision or dismissal is dissatisfied with the decision, the party may request a review by the Council.[33] The Council can also review ALJ or attorney adjudicator decisions on its own motion pursuant to a CMS referral.[34]

- On review, the Council may adopt, modify, reverse or remand an ALJ or attorney adjudicator decision, or dismiss the request for hearing for any reason that the ALJ or attorney adjudicator could have dismissed it.[35]
- The Council's decision is final and binding on all parties unless a Federal district court issues a decision modifying the Council's decision.[36]

Fifth Level of Appeal: Judicial Review in Federal District Court

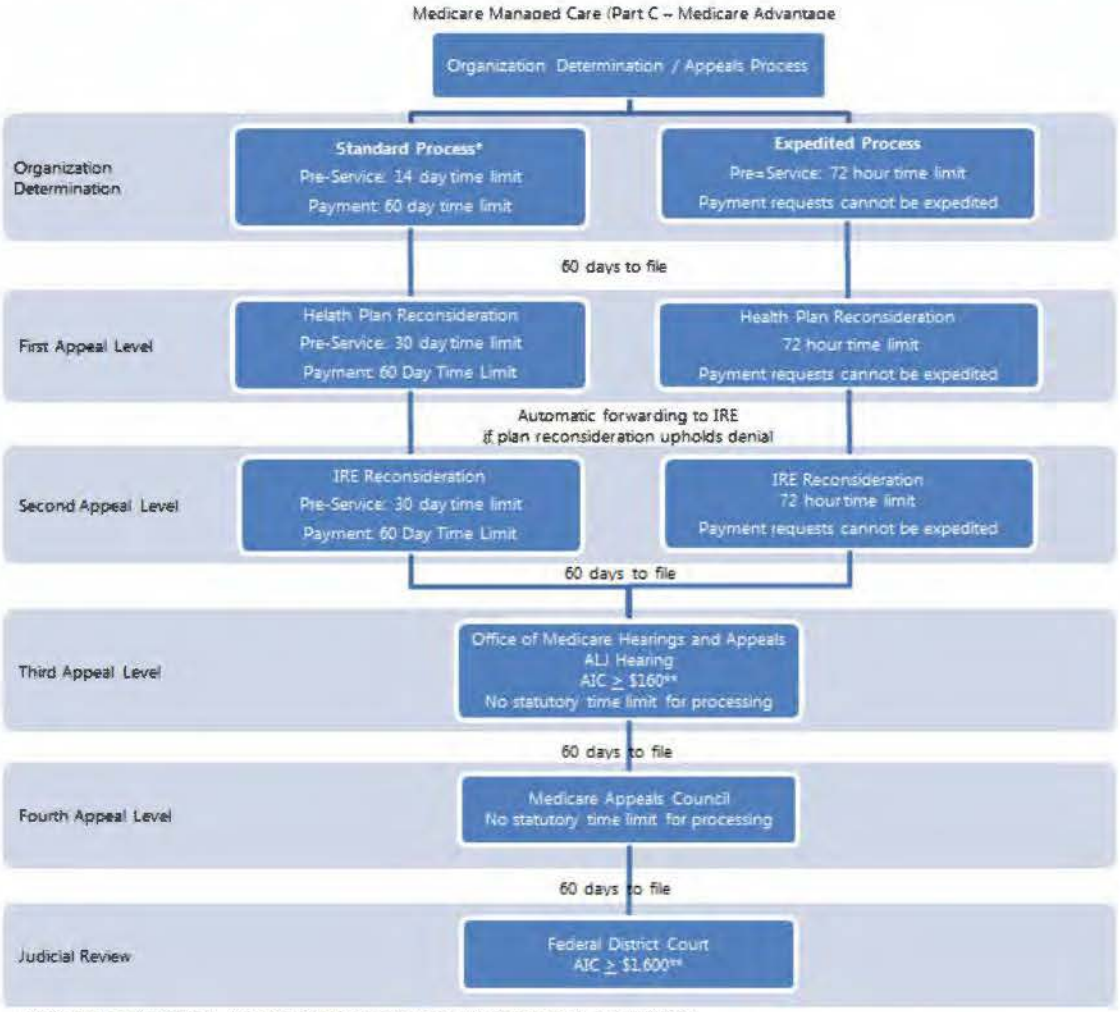
Parties dissatisfied with the Council's decision, or who request escalation to federal district court when the Council has not completed its review with the adjudication timeframe, may appeal by filing a civil action against the Secretary of HHS in federal district court.[37]

- Unless the Federal District Court order specifies otherwise, remanded cases return to the Council, who may make a decision or it may remand the case to an ALJ or attorney adjudicator for further action.[38]
- A copy of the administrative record organized and exhibited at the OMHA level—including a transcript of the hearing, if one occurred—is filed with the federal court.

---

[30] 42 C.F.R. § 405.1032(a).
[31] 42 C.F.R. § 405.1038(a)–(b).
[32] 42 C.F.R. § 405.1044.
[33] 42 C.F.R. § 405.1100.
[34] 42 C.F.R. § 405.1110.
[35] 42 C.F.R. §§ 405.1108(c), 405.1126(a), and 405.1128.
[36] 42 C.F.R. § 405.1130.
[37] 42 C.F.R. § 405.1136(a).
[38] 42 C.F.R. § 405.1138.

Objective 3: Describe the Medicare Part C Appeals Process



AIC: Amount in Controversy / ALJ: Administrative Law Judge / IRE: Independent Review Entity
* Plans must process 95% of all clean claims from out of network providers within 30 days. All other claims must be processed within 60 days.
** The AIC requirement for an ALJ hearing and Federal District Court is adjusted annually in accordance with the medical component of the consumer prices index. The chart reflects the AIC for calendar year (CY) 2018.

Medicare Advantage (MA) Organization Determinations[39]

An MA organization determination is any decision made by a Medicare health plan regarding:

- Receipt of, or payment for, a managed care item or service;
- The amount the health plan requires an enrollee to pay for an item or service; or
- A limit on the quantity of items or services.

An enrollee, an enrollee's representative, or any provider/supplier that furnishes, or intends to furnish, services to an enrollee, may request a standard organization determination by filing a request with the health plan.[40]

[39] 42 C.F.R. § 422.566.
[40] *Id.*

Reconsideration by the Medicare Advantage (Part C) Health Plan

If a Medicare health plan denies an enrollee's request for an item or service in whole or in part (issues an adverse organization determination), the enrollee may appeal the decision to the plan by requesting that the determination be reconsidered. An enrollee or an enrollee's representative may request a standard or expedited reconsideration.[41]

- Standard Timeframe:
  - Services: MA organization must issue reconsidered determination as expeditiously as enrollee's health requires, but no later than 30 calendar days from the date it receives the standard organization determination.[42]
  - Payment: 60 calendar days after receiving request.[43]
  - Expedited Timeframe – 72 hours after receiving request.[44]
- Expedited reconsiderations of an MA organization's reconsidered determination may be requested by an enrollee, an enrollee's representative, or any physician, regardless of whether the physician is affiliated with the health plan.[45]

Review by Part C Independent Review Entity (IRE)

If a health plan upholds its adverse organization determination, the plan must submit the case file and its decision for automatic review by the Part C Independent Review Entity (IRE).[46] Currently, MAXIMUS Federal Services is the Medicare Advantage (Part C) IRE.[47]

Request for an ALJ Hearing

If the Part C IRE upholds a Medicare health plan's adverse decision, the enrollee or enrollee's representative may appeal the IRE's decision by requesting an ALJ hearing.[48] The appeal request must be filed within 60 calendar days of the receipt of the notice of the IRE's reconsideration decision.[49] All requests must be made in writing.[50] Depending on the circumstances of the appeal, it may be adjudicated by an ALJ or an attorney adjudicator.[51] The claim must satisfy an amount in controversy requirement.[52]

Review by the Medicare Appeals Council

Any party dissatisfied with the ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the decision or dismissal.[53] Both the enrollee and the MA plan may seek Council review of an ALJ's or attorney adjudicator's action.

---

[41] 42 C.F.R. § 422.578.
[42] 42 C.F.R. § 422.590(a)(2).
[43] 42 C.F.R. § 422.590(b)(2).
[44] 42 C.F.R. § 422.590(d)(1).
[45] 42 C.F.R. § 422.590(d).
[46] 42 C.F.R. § 422.592(a).
[47] CMS: Review by Part C Independent Review Entity (IRE), https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/IRE.html.
[48] 42 C.F.R. § 422.600(a).
[49] 42 C.F.R. § 422.602(b).
[50] 42 C.F.R. § 422.602(a).
[51] 42 C.F.R. § 422.602(b).
[52] 42 C.F.R. Part 405, Subparts A and B.
[53] 42 C.F.R. § 422.608.

- Procedural rules of Parts A and B generally apply and are incorporated by reference, i.e., 60 calendar days to file request.

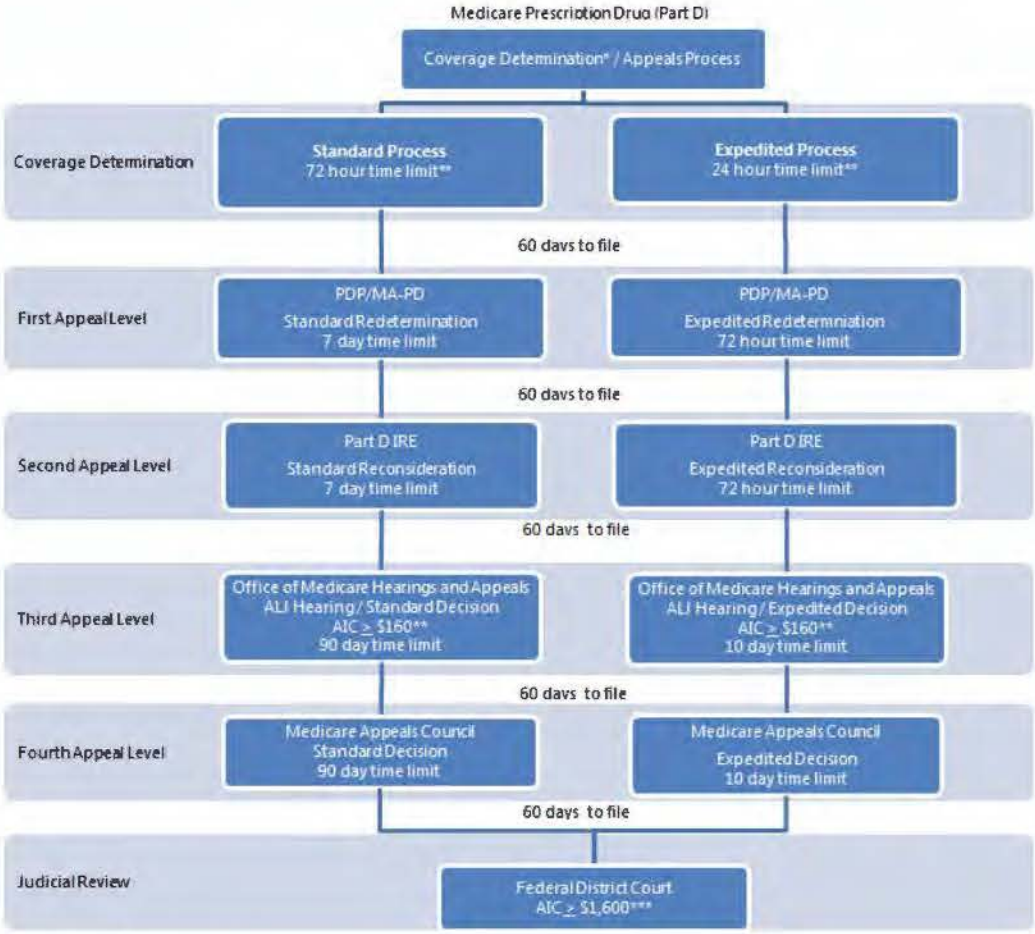
Federal District Court Review

Any party dissatisfied with the Council's action, or when the Council declined the party's request for Council review, may request review by a federal district court.[54]

[SPACE INTENTIONALLY LEFT BLANK]

[54] 42 C.F.R. § 422.612.

Objective 4: Describe the Medicare Part D Appeals Process[55]



AIC: Amount in Controversy
ALJ: Administrative Law Judge
IRE: Independent Review Entity
MA-PD: Medicare Advantage Plan that offers Part D benefits
PDP: Prescription Drug Plan
* A request for a coverage determination includes a request for a tiering exception or a formulary exception. A request for a coverage determination may be filed by the enrollee, by the enrollee's appointed representative or by the enrollee's physician or other prescriber.
** The adjudication timeframes generally begin when the request is received by the plan sponsor. However, if the request involves an exception request, the adjudication timeframe begins when the plan sponsor receives the physician's supporting statement.
*** The AIC requirement for an ALJ hearing and Federal District Court is adjusted annually in accordance with the medical care component of the consumer price index. The chart reflects the amounts for calendar year (CY) 2018.

Coverage Determinations[56]

A coverage determination is a decision made by the Part D plan sponsor regarding:

- Refusal to provide or pay for a Part D drug that an enrollee believes may be covered;
- A tiering or formulary exception request;
- The amount the plan sponsor requires an enrollee to pay for a Part D drug;
- A limit on the quantity (or dose) of a requested drug and the enrollee disagrees with the requirement or dosage limitation;

[55] 42 C.F.R. §§ 423.558–423.638, and 423.1968–423.2140.
[56] 42 C.F.R. § 423.566(b).

- A requirement that an enrollee try another drug before the plan sponsor will pay for the requested drug and the enrollee disagrees with the requirement; and
- A decision whether an enrollee has, or has not, satisfied a prior authorization or other utilization management requirement.

Note: Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health is also an action that constitutes a coverage determination.[57]

An enrollee, an enrollee's prescriber, or an enrollee's representative may request a standard or expedited coverage determination by filing a request with the plan sponsor. Standard or expedited requests for benefits may be made orally or in writing directly to the Part D Plan.[58]

- Standard requests for payment must be made in writing, unless the plan sponsor accepts requests orally.[59]
- For an expedited request, an enrollee or an enrollee's prescribing physician or other prescriber on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the determination, as directed by the Part D plan sponsor.[60]
- Standard timeframe and notice requirements for coverage determinations can be found at 42 C.F.R. § 423.568. Expedited timeframe requirements can be found at 42 C.F.R. § 423.572.

Redetermination by the Part D Plan Sponsor

Following an adverse coverage determination, the enrollee, enrollee's prescriber, or enrollee's representative may appeal the decision to the plan sponsor by requesting a standard or expedited redetermination.[61] A request for standard redetermination must be made in writing.[62] An expedited redetermination request may be made orally or in writing.[63]

A request for redetermination must be filed within 60 calendar days from date of the notice of coverage determination.[64]

- Timeframe information for Part D redeterminations can be found at 42 C.F.R. §§ 423.582 and 423.590.

Reconsideration by an IRE

If a Part D plan sponsor issues an adverse redetermination decision, the enrollee or the enrollee's representative may appeal the decision to the IRE, sometimes called the Part D QIC, by requesting reconsideration.[65] The enrollee must file a written request for reconsideration with the IRE within 60 calendar days of the date of the redetermination by the Part D plan sponsor.[66]

[57] 42 C.F.R. § 423.566(b)(2).
[58] 42 C.F.R. § 423.566(c).
[59] 42 C.F.R. § 423.568(a).
[60] 42 C.F.R. § 423.570(a).
[61] 42 C.F.R. § 423.582.
[62] 42 C.F.R. § 423.582(a).
[63] 42 C.F.R. § 423.584(b).
[64] 42 C.F.R. § 423.582(b).
[65] 42 C.F.R. § 423.600.
[66] 42 C.F.R. § 423.600(a).

Request for an ALJ Hearing

Following an adverse decision by the IRE, only the enrollee or the enrollee's representative may file a request for an ALJ hearing.[67] Standard requirements for ALJ hearing apply:

- Amount in controversy
  - Calculation of Amount in Controversy
    - If the basis for the appeal is the Part D plan's refusal to provide prescription drug benefits, the amount remaining in controversy will be calculated by subtracting any allowed amount under Part D, and any deductible, co-payments, and coinsurance amounts applicable to the Part D drug at issue, from the projected value of the drug benefits in dispute. Projected value includes any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.[68]
    - If the enrollee is seeking reimbursement for out-of-pocket costs incurred in obtaining a disputed Part D drug, the amount remaining in controversy will be calculated by subtracting any allowed amount under Part D, and any deductible, co-payments, and coinsurance amounts applicable to the Part D drug at issue, from the actual amount charged the enrollee or a third party for the Part D drug.[69]
- The ALJ hearing request generally must be made in writing within 60 calendar days of the date of notice of IRE reconsideration.[70]
  - An enrollee may make an expedited request, the enrollee meets the amount in controversy requirements, and if the appeal involves:
    - A denial of a Part D drug, failure to provide coverage in a timely manner, an exceptions request, or a decision on the amount of cost sharing; and
    - A written or oral request for an expedited ALJ hearing within 60 calendar days of the date of the written notice of an IRE reconsideration determination.[71]

Timeframe Information for OMHA Appeals

When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's notice of reconsideration.[72]

If an ALJ or attorney adjudicator accepts a request for expedited hearing, the ALJ or attorney adjudicator issues a written decision, dismissal order, or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period

[67] 42 C.F.R. § 423.1970.
[68] CMS, *Medicare Prescription Drug Benefit Manual (MPDBM) (Internet-Only Manual Publ'n 100-18)* ch. 18, § 90.2.
[69] *Id.*
[70] 42 C.F.R. § 423.1972(a)–(b).
[71] 42 C.F.R. § 423.2002(b).
[72] 42 C.F.R. § 423.2016(a).

beginning on the date the request for hearing is received by the office specified in the IRE's written notice of reconsideration.[73] CMS, the IRE, and/or the Part D plan may participate in an ALJ hearing.[74]

Medicare Appeals Council Review

An enrollee may request that the Council review an ALJ's or attorney adjudicator's decision or dismissal.[75] A written request must be filed within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision.[76] The Council will make a decision or remand it back to OMHA.[77]

Review by Federal District Court

An enrollee may obtain review of a Council decision by a federal district court.[78] The district court can issue a decision or remand the case back to the Council, who can then issue a decision or remand it back to OMHA.[79]

Objective 5: Identify web-based resource links to OMHA applicable statutes, regulations and policies

The CMS website provides access to Medicare manuals, Local Coverage Determinations (LCDs) and their policy articles, CMS/Heath Care Financing Administration (HCFA) Rulings, and some coding resources (e.g., the National Correct Coding Initiative). Additionally, OMHA provides access to most statutory compendia (e.g., Micromedex (formerly DRUGDEX), AHFS Drug Information, United States Pharmacopeia National Formulary, and National Comprehensive Cancer Network (NCCN)).

A comprehensive web based resource available to OMHA attorneys is MediRegs. MediRegs is an online database that contains access to Medicare statutes, regulations, manuals, LCDs, supplier manuals, and various medical coding compilations (e.g., Current Procedural Terminology, ICD-9, ICD-10, Healthcare Common Procedure Coding System (HCPCS) Level II, National Correct Coding Initiative, etc.).

To gain access to MediRegs, an OMHA attorney need only register with the site using their HHS email address. The MediRegs site can be found at: https://www.wkmediregs.com/

[73] 42 C.F.R. § 423.2016(b)(5).
[74] 42 C.F.R. § 423.2010.
[75] 42 C.F.R. § 423.1974.
[76] 42 C.F.R. § 423.2102(a)(1).
[77] 42 C.F.R. § 423.2128.
[78] 42 C.F.R. § 423.2136.
[79] 42 C.F.R. § 423.2138.

Here is a list of web-based resources that are useful in the adjudication process:

Social Security Act, Title XVIII	https://www.ssa.gov/OP_Home/ssact/title18/1800.htm
US Government Publishing Office: Electronic Code of Federal Regulations	https://www.ecfr.gov/cgi-bin/ECFR?page=browse
CMS Federal Register	https://www.federalregister.gov/agencies/centers-for-medicare-medicaid-services
MediRegs	https://www.wkmediregs.com/
CMS NCD Index	https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx
CMS Medicare Coverage Database	https://www.cms.gov/medicare-coverage-database/
CMS Internet-Only Manuals	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html
SSA Program Operations Manual System	https://secure.ssa.gov/apps10/
CMS Transmittals	https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html
CMS MLN Matters	https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Index.html
Medicare Appeals Council Decisions	www.hhs.gov/dab/divisions/medicareoperations/macdecisions/mac_decisions.html
DAB Board and DAB ALJ Decisions	http://www.hhs.gov/dab/decisions/
CMS Physician Fee Schedule Search	https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx
CMS ICD-9 Lookup	https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html
CMS ICD-10 Lookup	https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD10.html
CPT Code Search	http://www.findacode.com/search/search.php
US Food & Drug Administration	https://www.fda.gov/
National Correct Coding Initiative (NCCI)	https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html?redirect=/NationalCorrectCodInitEd/
Micromedex	www.micromedexsolutions.com
HHS Digital Library	https://nihlibrary.nih.gov/resources/hhs-digital-library
Clinical Pharmacology	https://clinicalpharmacology.com/forms/login.aspx

Module 5:
Procedural Rules and Policies

After this session, you will be able to:

1. Identify the procedural rules that govern appeals to OMHA;
2. Apply the jurisdictional concepts of timeliness and amount in controversy;
3. Distinguish the roles of parties and non-party participants;
4. Discuss adjudication time frames, tolling, and waivers;
5. Describe the standard of review and scope of review;
6. Understand the administrative hearing process, including conducting pre- and post-hearing conferences, creating the record, and scheduling and conducting hearings; and
7. Explain when discovery applies.

Required Reading/Reference:

- ✓ 42 C.F.R. part 405, subpart I (§§ 405.900–405.1140)
- ✓ 42 C.F.R. part 422, subpart M (§§ 422.560–422.626)
- ✓ 42 C.F.R. part 423, subparts M and U (§§ 423.558–423.638, 423.1968–423.2140)
- ✓ 42 C.F.R. part 478, subpart B (§§ 478.10–478.48)
- ✓ CMS, *Medicare Claims Processing Manual* (*MCPM*) (*Internet-Only Manual Publ'n 100-4*) ch. 29
- ✓ OMHA Case Processing Manual (OCPM)

BACKGROUND

OMHA adjudicators decide appeals under different statutory provisions. While the matters appealed to OMHA are similar, the path that they took to get to OMHA may differ, and the associated procedural rules may have important distinctions that must be observed. The vast majority of appeals to OMHA are appeals of claims for items or services furnished to Medicare beneficiaries under Medicare Parts A and B. Consequently, this module will focus on the procedural rules for those appeals, which are at 42 C.F.R. part 405, subpart I, while highlighting significant distinctions when other rules apply.

This module is a broad overview, and the specific rules that apply to a particular appeal must be consulted in all instances, to ensure compliance with binding authorities and OMHA policy. We have intentionally not provided a comprehensive discussion of the applicable rules and policies in this section because we want you to get into the habit of looking them up. Regulations may change from year to year, and OMHA policies are evolving. This module is meant to serve as an introduction, not a comprehensive and ongoing resource.

⊗ *CAUTION:* The Department of Health and Human Services (HHS) Departmental Appeals Board, Civil Remedies Division also uses Administrative Law Judges. These Administrative

Law Judges conduct hearings and adjudicate matters, including Medicare matters such as Local Coverage Determination (LCD) challenges and provider and supplier enrollment appeals, under other authorities and delegations. The rules that apply to these other matters, such as part 426 and part 498 rules, cannot be applied to OMHA adjudications.

Claims for Items or Services under Medicare Parts A and B

Section 1869 of the Social Security Act (Act) and implementing regulations establish a process for making determinations with respect to benefits under Medicare Parts A and B and appealing these determinations when a claim for benefits is denied in whole or in part. The appeals process created under § 1869 of the Act offers up to five levels of review under which individuals (which as explained in our regulations includes beneficiaries, certain providers and suppliers, State Medicaid agencies, and applicable plans) may challenge an adverse initial determination.

An initial determination can be a determination regarding whether a claim for items or services furnished to a Medicare beneficiary is covered by the Medicare program. These initial determinations are made by a Medicare Administrative Contractor (MAC), and may be initiated based on a review by another contractor, such as Recovery Auditor Contractor (RAC), Program Safeguard Contractor (PSC), Zone Program Integrity Contractor (ZPIC), or Comprehensive Error Rate Testing (CERT) contractor. Following an adverse initial determination, an individual may request that the MAC make a redetermination with respect to the claim. This is sometimes referred to as a Level 1 appeal because it is the first level of the appeals process. Redeterminations generally must be concluded no later than 60 calendar days after the day the MAC receives the request for a redetermination.

ⓘ *NOTE:* Contractor types have changed over the years. If you hear people referring to a Fiscal Intermediary or Carrier, those are outdated references to the current MACs.

Individuals who are dissatisfied with a redetermination may file a request for reconsideration. This is sometimes referred to as a Level 2 appeal. Pursuant to § 1869(c) of the Act, reconsiderations are conducted by Qualified Independent Contractors (QICs). Reconsiderations must also be processed within 60 calendar days after a QIC receives a timely request for a reconsideration (certain events may add to the 60 calendar day period to conduct the reconsideration, as specified in the regulations). If a party is dissatisfied with the QIC reconsideration, the party may request review by an OMHA Administrative Law Judge or attorney adjudicator, which is sometimes referred to as a Level 3 appeal. If a QIC does not complete its reconsideration within 60 calendar days, the appealing party may escalate the appeal to OMHA.

ⓘ *NOTE:* You may hear some refer to a "Part B of A" appeal. This is contractor jargon for Part B items or services that were furnished in an institutional setting, and the claim for which was processed by a "Part A" contractor. It is a Part B appeal.

Eligibility, Entitlement, and Premiums

An initial determination under § 1869 of the Act can also be a determination regarding a beneficiary's eligibility or entitlement to the Medicare Part A and/or Part B program, a Part B late enrollment penalty, or a Part B (and if the beneficiary is enrolled in a Part D prescription drug plan, a Part D) income-related monthly adjustment amount (IRMAA) premium. These initial determinations are made by the Social Security Administration (SSA). After SSA makes an initial determination, a beneficiary may request a reconsideration by SSA. If the beneficiary does not agree with SSA's reconsideration, the beneficiary may then request a hearing before an OMHA Administrative Law Judge.

ⓘ *NOTE:* Part D late enrollment penalties and subsidy determinations cannot be appealed to a OMHA because they are not Part D coverage determinations appealable to an Administrative Law Judge under § 1860D-4(h) of the Act (discussed further below).

ⓘ *NOTE:* You may hear some refer to these as "Part E" appeals. The parts being referenced in Part A, Part B, Part C, and Part D contexts, are statutory divisions of Title XVIII of the Act. Part E contains the miscellaneous provisions, thus referring to these as "Part E" appeals is not accurate. For example, a Part B entitlement appeal is a Part B appeal.

ⓘ *NOTE:* While appeals of SSA reconsiderations do not have a time frame in which they must be decided under that statute or regulations, OMHA policy requires that beneficiary appeals be prioritized, with the objective that they are completed within 90 calendar days after receiving a timely request for an Administrative Law Judge hearing.

Termination of Coverage

Section 1155 of the Act provides for the right to appeal a provider's determination that services being furnished to a beneficiary are no longer covered by Medicare. When this occurs, the beneficiary may request that a Quality Improvement Organization (QIO) conduct a review of the provider's action. In this instance, the QIO conducts the initial determination. In reviewing the provider's action, the QIO may also review the services that the provider did believe were covered by Medicare, and the initial determination may also include the claim for those services. The initial determination may be appealed to the same QIO for a reconsideration, and a QIO reconsideration may then be directly appealed to OMHA. The regulations for this process are at 42 C.F.R. part 478, subpart B. Pursuant to 42 C.F.R. § 478.40(c), the provisions of subpart I of part 405 apply to QIO hearings and appeals unless they are inconsistent with specific provisions in subpart B of part 478.

ⓘ *NOTE:* QIOs also conduct diagnosis-related group (DRG) validations. DRGs are a system to classify inpatient stays into groups for purposes of payments. A reconsideration of a QIO DRG validation may be requested under part 478, subpart B, but no further review is available after the QIO reconsideration. See 42 C.F.R. § 478.15(c).

ⓘ *NOTE:* While appeals of QIO reconsiderations do not have a time frame in which they must be decided under that statute or regulations, OMHA policy requires that beneficiary appeals be prioritized, with the objective that they are completed within 90 calendar days after receiving a timely request for an Administrative Law Judge hearing.

Section 1869(b) of the Act also provides that an individual may request an expedited determination or expedited reconsideration of an initial determination if an individual receives a notice that a provider of services plans to: (1) terminate all services to an individual (and a physician certifies that failure to continue the provision of services likely places the individual's health at significant risk), or (2) discharge the individual from the provider. In this process, a QIO conducts the initial determination, but the reconsideration is conducted by a QIC. The regulations for this process at the QIO and QIC levels are at 42 C.F.R. part 405, subpart J, and after the QIC reconsideration, the general claim appeals process at part 405, subpart I apply.

Part C Medicare Advantage Organization (MAO) Determinations

Section 1852(g) of the Act and implementing regulations establish a process for making determinations regarding whether an individual enrolled in an MAO is entitled to receive health services and the amount (if any) that the individual is required to pay for such services. The appeals process created under § 1852(g) of the Act offers up to five levels of review under which an enrollee (which is the equivalent of a beneficiary under Parts A and B) may challenge an adverse organization determination.

Following an adverse organization determination, an enrollee may request that the MAO reconsider the organization determination. While termed a "reconsideration" under Part C, this is the equivalent of a redetermination under Parts A and B.

If an MAO affirms its adverse organization determination in whole or part, the issues that remain in dispute are reviewed and resolved by an independent outside entity. The independent outside entity issues a reconsidered determination.

ⓘ *NOTE:* The independent outside entity is an Independent Review Entity (IRE), and refers to itself as the "Part C QIC."

If a party is dissatisfied with the IRE's reconsidered determination, the party may request review by an OMHA Administrative Law Judge or attorney adjudicator. Pursuant to 42 C.F.R. §§ 422.562(d) and 422.608, the provisions of subpart I of part 405 apply to Part C hearings and appeals unless they are inconsistent with specific provisions in subpart M of 42 C.F.R. part 422.

ⓘ *NOTE:* You will see references to Medicare+Choice in the statutory provisions. Medicare+Choice was the initial Part C program established in the 1990s. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the name to Medicare Advantage, as well as making other revisions to the program.

ⓘ *NOTE:* You may hear references to § 1876 of the Act, which was a program that preceded Medicare+Choice and offered beneficiaries an option to join a Cost Plan, such as a health

maintenance organization or competitive health plan. To the extent that these plans continue to exist, § 1876(c)(5) of the Act effectively mirrors § 1852(g) of the Act, and the implementing appeals regulation at 42 C.F.R. § 417.600 makes the Medicare Advantage appeal provisions applicable to § 1876 appeals. Any reference to a Part C appeal or MAO should be assumed to have an equivalent application to Cost Plans, unless specified otherwise.

ⓘ *NOTE:* If a request for an Administrative Law Judge hearing is filed, the MAO or Cost Plan is a party to the Administrative Law Judge hearing pursuant to §§ 1852(g)(5) and 1876 (c)(5) of the Act.

ⓘ *NOTE:* While appeals of IRE reconsidered determinations do not have a time frame in which they must be decided under that statute or regulations, OMHA policy requires that beneficiary appeals, which include Part C enrollee appeals, be prioritized, with the objective that they are completed within 90 calendar days after receiving a timely request for an Administrative Law Judge hearing.

ⓘ *NOTE:* When an MAO discharges an enrollee from an inpatient hospital, a QIO reviews the action and the QIO determination may be immediately appealable to an Administrative Law Judge under 42 C.F.R. § 422.622(g)(2). When an MAO terminates covered home health services or services in a skilled nursing facility or comprehensive outpatient rehabilitation facility, a QIO serves as the IRE under 42 C.F.R. § 422.626, and the QIO's reconsidered determination may be appealed to an Administrative Law Judge under 42 C.F.R. § 422.626(g)(3).

Part D Plan Sponsor Coverage Determinations

Section 1860D-4(h) of the Act and implementing regulations establish a process for making determinations regarding whether an individual enrolled in a prescription drug plan is entitled to coverage for prescribed drugs under the plan and the amount (if any) that the individual is required to pay for such drugs. The appeals process created under § 1860D-4(h) references § 1852(g) of the Act and thereby offers up to five levels of review under which an enrollee may challenge an adverse coverage determination.

Following an adverse coverage determination, an enrollee or the prescriber may request that the Part D plan sponsor conduct a redetermination of its coverage determination. If the enrollee is dissatisfied with the redetermination, the enrollee or prescriber may request a reconsideration by an IRE.

ⓘ *NOTE:* The IRE refers to itself as the "Part D QIC."

If the enrollee is dissatisfied with the IRE's reconsideration, the enrollee may request review by an OMHA Administrative Law Judge or attorney adjudicator.

ⓘ *NOTE:* A prescriber must be an appointed representative to request a hearing before an OMHA Administrative Law Judge.

ⓘ *NOTE:* Unlike Part C appeals, the plan is not a party in a Part D appeal.

ⓘ *NOTE:* The regulations provide that expedited appeals be completed within 10 calendar days and standard appeals be completed within 90 calendar days. Under OMHA policy, expedited appeals receive top priority and Part D standard appeals are prioritized as beneficiary appeals because they are filed by, or on behalf of, Part D enrollees.

Reviews of Dismissals

Separate from requests for a hearing before an Administrative Law Judge following a reconsideration, a dismissal of a request for a reconsideration by a prior adjudicating entity (such as a QIC, QIO, SSA, or IRE) may be appealed for a review by an OMHA adjudicator. A hearing is not required, and the possible outcomes are limited to: (1) affirming the dismissal; (2) vacating the dismissal and remanding the request for reconsideration to the prior adjudicating entity and (3) dismissing the request to review the dismissal (for example, if it was not timely filed or did not meet the amount in controversy requirement).

Reviews of dismissals are not subject to further review. For example, an OMHA adjudicator's decision to affirm a QIC's dismissal is not appealable to the Medicare Appeals Council (Council), nor is an OMHA adjudicator's determination to vacate a dismissal and remand a request for reconsideration to the prior adjudicating entity subject to review by the Chief Administrative Law Judge or designee under 42 C.F.R. § 405.1056(g). Similarly, a QIC's decision to affirm a MAC's dismissal cannot be appealed to OMHA.

Rules and Policies

The regulations that apply to appeals before OMHA are promulgated under the Secretary's authority to establish rules for hearings conducted under the Administrative Procedure Act (APA) and to implement more specific requirements under the Act. See 5 U.S.C. § 556(c) ("Subject to the published rules of the agency and within its powers, employees presiding at hearings may. . ."). The procedural regulations, like all regulations that apply to the Medicare program, are binding and are themselves not subject to review in the administrative appeals process. As in most administrative proceedings, the Federal Rules of Civil Procedure and Rules of Evidence do not apply.

The procedural rules at 42 C.F.R. part 405, subpart I (§§ 405.900–405.1140) became effective in 2005 to implement the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and the MMA. The rules apply directly to most Part A and B appeals, and are the fallback provisions for most other appeal provisions when the specific part does not have a rule on point and applying the part 405 provision is appropriate (see, for example, 42 C.F.R. §§ 422.562(d) and 422.608 for Part C appeals and § 478.40(c) for QIO appeals directly appealable to OMHA).

ⓘ *NOTE*: Sections 422.562(d), 478.40(c), and 422.608 (through reference to 422.562(d)) specifically provide that the following provisions of the part 405 regulations do not apply to part 422, subpart M or part 478, subpart B appeals:

- Section 405.950 (time frames for making a redetermination);
- Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level);
- Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council);
- The option to request that an appeal be escalated from the OMHA level to the Council as provided in § 405.1100(b), and time frames for the Council to decide an appeal of an Administrative Law Judge's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in § 405.1100(c) and (d).;
- Section 405.1132 (request for escalation to Federal court).; and
- Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

ⓘ *NOTE:* BIPA unified the Part A and Part B appeals processes, the rules for which were under 42 C.F.R. part 405, subparts G and H, respectively. Before BIPA, Part A claims were processed by Fiscal Intermediaries, and an appeal to an Administrative Law Judge was available as a second-level appeal (a $100 amount in controversy applied, and provider appeal rights were more limited). Part B claims were processed by Carriers, and a Fair Hearing Officer conducted a second-level review that included a discussion with the appellant, with a subsequent appeal right to an Administrative Law Judge if the amount in controversy was $500 or more. Among other things, BIPA:

- Established the QIC level for Part A and replaced the Fair Hearing Officer level with the QIC for Part B;
- Made the amount in controversy for an Administrative Law Judge hearing a uniform $100 across Part A and Part B appeals under § 1869 of the Act; and
- Established adjudication time frames and the right to escalate at the QIC, OMHA, and Council levels of appeal.

Additional changes to the appeals process were made by the MMA:

- Replaced Fiscal Intermediaries and Carriers with MACs;
- Increased the QIC's adjudication time frame from 30 days under BIPA, to the current 60 days;
- Indexed the amounts in controversy required for an Administrative Law Judge hearing and judicial review;

- Limited new evidence submitted for the first time at the OMHA level by requiring good cause to prompt appellants to submit documentation at lower levels of appeal, with the objective of resolving disputes at the lower levels of appeal; and
- Transferred responsibility for the Administrative Law Judge hearing process on Medicare appeals from SSA to HHS, for which HHS established OMHA.

Other rules that apply to OMHA proceedings:

- Part C appeals: 42 C.F.R. part 422, subpart M (§§ 422.560–422.626)
- Part D appeals: 42 C.F.R. part 423, subparts M and U (§§ 423.558–423.638, 423.1968–423.2140)

  ⓘ *NOTE:* Subpart U, with its more comprehensive rules for the OMHA, Council, and judicial review levels was promulgated in 2009. Prior to that, part 423, subpart M was similar to part 422, subpart M.

- QIO appeals directly appealable to OMHA: 42 C.F.R. part 478, subpart B (§§ 478.10–478.48)

In addition to the regulations, OMHA has established policies that provide day-to-day instructions for carrying out adjudications under the controlling rules. These policies are made through Chief Judge Bulletins (CJBs) and the OMHA Case Processing Manual (OCPM). OMHA policies provide consistency for the public, and serve to enhance adjudication quality and customer service. The newest chapters of the OCPM are mandatory and OMHA adjudicators and support staff must adhere to OMHA policies contained therein.

OCPM chapters are updated on an ongoing basis. We highlight new chapters and updates in our quarterly newsletter, but the most current version of an OCPM chapter on the OMHA portal (also referred to as the OMHA SharePoint) should be consulted.

1. Should it be before OMHA (i.e., is there jurisdiction and were filing requirements met)?

Is there an appealable determination?

There must be an action for which a hearing before an Administrative Law Judge or a review of a dismissal may be requested.

- Examples of actions for which review by an OMHA adjudicator may be requested:
  - Part A QIC reconsideration of an initial determination
  - Part B QIC reconsideration of an initial determination
  - QIO reconsidered determination of an initial determination
  - Part C IRE ("Part C QIC") reconsidered determination of an organization determination
  - Part D IRE ("Part D QIC") reconsideration of a coverage determination
  - SSA reconsideration of a Medicare eligibility or entitlement matter
  - SSA reconsideration of a Part B late enrollment penalty

- SSA reconsideration of a Part B (and if enrolled, Part D) IRMAA

See 20 C.F.R. §§ 404.930 (limited to Medicare-specific reconsiderations), 418.1350, 418.2350; 42 C.F.R. §§ 405.1002, 422.600, 423.1970, 423.2002, 478.40.

- Examples of actions for which a review of a dismissal may be requested:
  - QIC dismissal of a request for a reconsideration
  - IRE dismissal of a request for a reconsideration

See 42 C.F.R. §§ 405.1004, 423.2004.

- Examples of actions for which review by an OMHA adjudicator may not be requested:
  - MAC redetermination
  - QIC review of a MAC's dismissal of a request for a redetermination
  - QIC declination to reopen a reconsideration
  - QIO diagnosis-related group validation
  - Part D late enrollment penalty
  - Part D subsidy determinations
  - Quality of care complaints
  - Part C grievance
  - Part D grievance

Who filed it?

A request may be filed by a party (or the party's representative).

- The party does *not* have to be the same party that requested the reconsideration, unless the party is escalating a request for reconsideration from the QIC to OMHA.
  - For example, an ambulance provider may request a QIC reconsideration, and the beneficiary may request the hearing before an Administrative Law Judge. The critical factor is whether the appellant is a party. (However, only an appellant can request an escalation, and the QIC should reject a non-appellant party's attempt to escalate a request for reconsideration to OMHA.)
- An "authorized representative" is one who has the authority to act on behalf of the party under State or other applicable law. For example, someone who has a healthcare proxy or power of attorney can file appeals on behalf of a beneficiary as an authorized representative. See 42 C.F.R. § 405.902.
  - The record must contain documentation of the representative's authority in order for us to be able to share information about the appeal with the individual—this documentation may have already been filed and be in the administrative record.
- An "appointed representative" is one who is appointed by the party to represent the party in a Medicare claim or claim appeal. An appointment may be filed for up to one

year from the date it is signed, and when filed with respect to a claim remains valid for all appeals of the claim unless the party revokes the appointment or the party dies (a limited exception applies to the latter). See 42 C.F.R. §§ 405.902 and 405.910.

- ➢ The record must contain documentation of the representative's appointment in order for us to be able to share information about the appeal with the individual—this documentation may have already been filed and be in the administrative record.

ⓘ *NOTE:* Multiple parties to a reconsideration may separately file requests for hearing on the same claim. The appeal is of the claim and they are each parties to the claim (regardless of who filed the appeal), so there is one appeal with co-appellants. See 42 C.F.R. § 405.1000(h).

Was the request timely, or is there good cause for an untimely request?

A request must be timely filed, or good cause must be found for an untimely request.

- A timely request generally means 60 days after receipt of a notice of reconsideration (or its equivalent). Assume a party received the reconsideration notice 5 days after the date of the reconsideration unless there is evidence to the contrary in the administrative record. See 42 C.F.R. §§ 405.1002, 405.1004, 405.1014, 422.602, 423.1972, 423.2002, 423.2004, 423.2014, 478.42.
- A timely request is considered filed on the date the entity specified in the reconsideration notice receives the request.
  - ⊗ *CAUTION:* If a request was timely "filed" with an incorrect entity, the date OMHA Central Operations receives it is the date of filing and the date the adjudication time frame begins, and the request may not be dismissed as untimely.

A request for an extension of time to file a request must: (1) be made in writing; (2) state the reason(s) why the request for hearing was not timely filed; (3) be filed with the request for hearing or request for review of a QIC dismissal with the office specified in the notice of reconsideration or dismissal. See 42 C.F.R. §§ 405.1014(e)(2), 423.2014(e)(2)-(3).

- ☐ *FORM:* (non-mandatory) OMHA-103 (Request for Extension of Time to File a Request for an Administrative Law Judge (ALJ) Hearing or Review of Dismissal)

- If the OMHA adjudicator finds there was good cause for missing the filing deadline, the 60 calendar day time period is extended. The request for hearing is considered filed on the date the OMHA adjudicator determines whether there is good cause to extend the 60 days. See 42 C.F.R. §§ 405.1014, 422.602, 423.2014, 478.42.
- 42 C.F.R. § 405.942(b)(2) and (b)(3) provide guidance on determining good cause for an untimely filing:
  - ➢ Considerations for determining good cause for an extension:

(1) The circumstances that kept the party from making the request on time;
(2) If the contractor's action(s) misled the party; and
(3) 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.

➢ Examples of good cause for an extension:

(1) The party was prevented by serious illness from contacting the hearing office in person, in writing, or through a friend, relative, or other person;
(2) The party had a death or serious illness in his or her immediate family;
(3) Important records of the party were destroyed or damaged by fire or other accidental cause;
(4) The contractor gave the party incorrect or incomplete information about when and how to request a hearing before an Administrative Law Judge;
(5) The party did not receive notice of the determination or decision; or
(6) The party sent the request to a Government agency in good faith within the time limit, and the request did not reach OMHA Central Operations until after the time period to file a request expired.

ⓘ *NOTE:* If the party sent the request to an office other than the office specified in the reconsideration (for most appeals, that is the OMHA Central Operations), and the request was timely when it was received by that office but untimely when the correct office received the request, the request is considered timely for filing purposes but any applicable adjudication time frame begins on the date the correct office received the request. See 42 C.F.R. §§ 405.1014(c)(2), 423.2014(d)(2).

⊗ *CAUTION:* The list of examples is not exhaustive; the OMHA adjudicator must consider the individual circumstances of the case.

⊗ *CAUTION:* While either an Administrative Law Judge or an attorney adjudicator may find that an appellant had good cause for missing the filing deadline, only an Administrative Law Judge may find that an appellant did not have good cause for missing the filing deadline.

Was the request filed in the right place?

A request should be filed with the entity identified in the notice of reconsideration. See 42 C.F.R. §§ 405.1014, 422.602, 423.2014.

- For Part A and Part B QIC reconsiderations, Part D IRE reconsiderations, and most QIO reconsiderations, the identified entity is OMHA Central Operations.
- For Part C IRE reconsiderations, the request is filed with the IRE, which forwards the request and case file to OMHA Central Operations.

- For SSA reconsiderations, the request is filed with an SSA office, which forwards the request and case file to OMHA Central Operations.
- For some QIO reconsiderations, the request is filed with the QIO, which forwards the request and case file to OMHA Central Operations.

ⓘ *NOTE:* Central Operations has "mail stops" for appellants to direct special requests, such as beneficiary requests for hearing (the "Beneficiary Mail Stop").

ⓘ *NOTE:* If a request is filed with an OMHA field office, the request must be immediately routed to OMHA Central Operations. If you see a request for hearing that is filed with the field office, alert your Hearing Office Director.

⊗ *CAUTION:* A misrouted request is not in itself a basis for dismissal, and the timeliness of the request is assessed on when it was filed, even if that was with an incorrect entity or office. See 42 C.F.R. §§ 405.1014(c)(2), 423.2014(d)(2).

If a request is filed with an incorrect entity (a "misrouted" request), an acknowledgement letter identifying when OMHA received the request and when an applicable time frame began is required for Part A and Part B QIC reconsideration, and Part D IRE reconsideration appeals. See 42 C.F.R. §§ 405.1014, 423.2014.

- OMHA Central Operations sends the acknowledgement letter.
  - ☐ *FORM:* OMHA-318 (Acknowledgement of Request for Hearing When Sent to Incorrect Entity)

ⓘ *NOTE:* While not required under the regulations, OMHA Central Operations sends general acknowledgement letters. If an appeal is assigned to an OMHA adjudicator when the request is processed (for example, a beneficiary's request for hearing is assigned when it is received), the letter will also include a notice of assignment. If an appeal is held for assignment due to workload volume, a notice of assignment is sent when the appeal is assigned to an OMHA adjudicator.

Does the claim meet the amount in controversy (AIC) threshold?

The statutory provisions establish a minimum AIC for obtaining a hearing before an Administrative Law Judge. The same AIC is used for a right to review of a prior adjudicating entity dismissal. See 42 C.F.R. §§ 405.1002, 405.1004, 422.600, 423.1970, 423.2002, 423.2004, 478.40.

The AIC is adjusted annually and rounded to the nearest $10, except QIO reconsidered determinations that are directly appealable to OMHA under 42 C.F.R. § 478.40. The AIC for the following calendar year is generally announced by CMS in September, and is published in the Federal Register. The AIC applies based on the date a request is filed (for example, if you have a request filed in 2017, the 2017 AIC applies).

- The AIC for a QIO reconsidered determination that is directly appealable to OMHA under 42 C.F.R. § 478.40 is $200. See 42 C.F.R. § 478.40. However, be aware that an appealable

action by a QIO may come to OMHA through other channels, and the $200 would not apply (for example, a QIO may serve as an IRE and issue a reconsideration under 42 C.F.R. § 422.626).

- The AIC for all other appeals is available in the OCPM. See OCPM II-3-4, III-3-4, IV-3-4, V-3-4.
  - For requests filed in 2018, the AIC is $160.

The AIC calculation will depend on the matter that is appealed.

- In Part A and Part B claim appeals, the AIC is based on the claim (that is, not multiple claims in one appeal, or individual components of items or services in a claim). The general rule is:

  Amount charged to the beneficiary for the items or services in the disputed claim
  – Any payment made or awarded for the items or services
  – Any deductible and co-insurance amounts that may be collected
  =AIC

See 42 C.F.R. § 405.1006.

- ⊗ *CAUTION:* The "amount charged" is the amount billed by the provider or supplier. It is not the amount that Medicare would pay if the claim were covered (for example, the Medicare payable amount). If you use the Medicare payable amount and dismiss for lack of AIC on that basis, the Council will vacate the dismissal and the case will be remanded.
- ⊗ *CAUTION:* The AIC is not based on the appealing party's liability or financial responsibility for the claim. For example, if the reconsideration states that the beneficiary is not liable or financially responsible for the denied claim, the beneficiary can still request the hearing if the AIC is met for the claim because the beneficiary is a party to the claim. The AIC calculation does not make an adjustment for the liability or financial responsibility of the appealing party.
- ⊗ *CAUTION:* While an Administrative Law Judge or attorney adjudicator may determine the minimum AIC was met, only an Administrative Law Judge may determine the minimum AIC was not met.

The rules at 42 C.F.R. § 405.1006(d)(2) to (d)(6) provide for five exceptions to the general AIC calculation methodology above:

- Section 405.1006(d)(2) provides that when payment is made for items or services under § 1879 of the Act or 42 C.F.R. § 411.400, or the liability of the beneficiary is limited under 42 C.F.R. § 411.402, the AIC is computed as the amount the beneficiary would have been charged for the items or services in question if those expenses were not paid under 42

C.F.R. § 411.400 or if that liability was not limited under 42 C.F.R. § 411.402, reduced by any deductible and/or coinsurance amounts that may be collected for the items or services.

- Section 405.1006(d)(3) provides that for item or service terminations, where the beneficiary did not elect to continue receiving the item or service, the AIC is computed as it would be under 42 C.F.R. § 405.1006(d)(1), except the amount charged the beneficiary and any deductible and/or coinsurance amounts that may be collected are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services and Medicare payment were not made.

- Section 405.1006(d)(4) provides that for appeals involving an identified overpayment, the AIC is the amount of the overpayment specified in the demand letter for the items or services in the disputed claim.

  ⓘ *NOTE:* If a case involves an estimated overpayment based on an extrapolation of a sample, the AIC is the total amount of the extrapolated overpayment, not the value of the sampled claim(s).

- Section 405.1006(d)(5) provides that, for appeals filed by beneficiaries challenging only the computation of a coinsurance amount or the amount of a remaining deductible, the AIC is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct.

- Section 405.1006(d)(6) provides that, for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected on the published fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the AIC is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services.

  ⊗ *CAUTION*: If an appellant is appealing a paid claim and challenging only a fee schedule or contractor-priced amount of general applicability (that is, not determined on a case-by-case basis), an OMHA adjudicator does not have jurisdiction to decide the issue (see 42 C.F.R. § 405.926(c)). However, the appellant still has a right to request an Administrative Law Judge hearing because there was an initial claim determination. Therefore, the appropriate disposition is an unfavorable decision, not a dismissal.

The following rules apply to other appeal types:

- For eligibility, entitlement, Part B late enrollment penalty, and IRMAA appeals, the rules do not provide an explicit calculation, but the aggregate amounts involved (for example,

the value of entitlement to the Medicare program, the current value of a Part B late enrollment penalty, and the year-long extra payments that an IRMAA imposes) will in all but the most unusual circumstances meet the AIC.

- Part C organization determination appeals follow the same general rule as Part A and Part B claim appeals, but Part C explicitly addresses instances in which the basis of the appeal is the MAO's refusal to provide a service (the projected value of the services is used). See 42 C.F.R. § 422.600.
- Part D coverage determinations use the projected value of the denied drugs, including refills prescribed for the drug in dispute for the plan year. See 42 C.F.R. § 423.1970.

Claims (or their equivalent if in a different Part) can be "aggregated" to meet the AIC. This essentially means that claims that would otherwise not meet the AIC requirement can be appealed if the appellant has other claims to appeal, and the combined AIC of those claims meets the AIC threshold. Multiple appellants can also aggregate claims to meet the AIC. Standards must be met to aggregate claims. See 42 C.F.R. §§ 405.1006, 422.600, 423.1970.

ⓘ *NOTE:* Claims may be aggregated to meet the amount in controversy requirement. Aggregation is not applicable to entitlement/eligibility, late enrollment penalty, and IRMAA appeals.

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

ⓘ *NOTE*: Both Part A and Part B items and services can be considered together as long as the OMHA adjudicator finds that the following criteria has been met:

- The claims have been reconsidered by a QIC or were the subject of the same escalated request for reconsideration;
- The appellant requests aggregation of claims appealed in the same request for hearing, or in multiple requests for hearing filed with the same request for aggregation, and the request is filed within 60 calendar days after receipt of all of the reconsiderations being appealed, or the request for escalation requests aggregation; and
- The OMHA adjudicator determines that the claims involve the delivery of similar or related services (that is, like or coordinated services or items provided to one or more beneficiaries).
  - ⓘ *NOTE:* For Part D appeals, the appeals to be aggregated must involve the delivery of prescription drugs to a single enrollee.

Claims of multiple appellants may be aggregated if:

- The claims have been reconsidered by a QIC or were the subject of the same escalated request for reconsideration;

- The appellants request aggregation of claims appealed in the same request for hearing, or in multiple requests for hearing filed with the same request for aggregation, and the request is filed within 60 calendar days after receipt of all of the reconsiderations being appealed, or the request for escalation requests aggregation; and
- The OMHA adjudicator determines that the claims involve common issues of fact and law (that is, the claims were denied or reduced for similar reasons and involve a similar fact pattern that is material to the reason the claims were denied or reduced).
  - ⓘ *NOTE:* For Part D appeals, the appeals to be aggregated must involve the delivery of the same prescription drugs to multiple enrollees.

⊗ *CAUTION:* While either an Administrative Law Judge or attorney adjudicator may determine the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, only an Administrative Law Judge may determine that the claims do not meet these standards for aggregation.

A request to aggregate should indicate:

- The claims to be aggregated; and
- The reason the appellant(s) believes the claims involve similar or related services, or common issues of fact and law.
  - ⊗ *CAUTION:* A request for aggregation may be inferred by the filing. The Council has noted the word "aggregate" does not have to be present so long as the intent is reasonably evident. While the burden is on the appellant to demonstrate a basis for aggregation, the Council is generally more lenient when beneficiaries are involved and will often accept a minimal showing for why the claims are similar or related, especially when the claims were considered together in the same reconsideration. In contrast, the Council has upheld a more strict application of the aggregation provision for provider/supplier-appellants because they have actual or constructive knowledge of the applicable rules, and are therefore presumed to be more familiar with the requirements.

If the minimum AIC is not met because the request for aggregation is invalid, the reason must be included in the dismissal. See OCPM II-3-4.

If aggregation is granted, the OMHA adjudicator's determination should be documented in the record (for example, in an order addressing the aggregation request, or as part of the decision to make clear that there is jurisdiction to issue a decision on the claims).

Are the request requirements met?

There is basic information that must be provided in a request. This information helps us to identify the appealed action and ensure that the correct parties, or their representatives, are contacted and made part of the hearing process. However, only requests appealing a Part A or Part B QIC or Part D IRE reconsideration or dismissal have content requirements.

A request must be in writing. See 42 C.F.R. §§ 405.1002, 405.1004, 405.1014, 422.602, 423.1970, 423.2002, 423.2004, 423.2014.

- ☐ *FORM:* (non-mandatory) OMHA-100 (Request for Administrative Law Judge (ALJ) Hearing or Review of Dismissal)

- Oral requests are allowed for Part D expedited hearing requests made to the OMHA toll-free Part D expedited request line, after a written reconsideration is issued. See 42 C.F.R. § 423.2014(b). If an enrollee requests an expedited hearing orally, OMHA **must** document the oral request in the record and maintain the documentation.

- For Part A and Part B QIC reconsideration appeals, a complete request must contain or provide a means to ascertain:

  (1) The name, address, and Medicare health insurance claim number (HICN)[1] of each beneficiary whose claim is being appealed;
  (2) The beneficiary's telephone number, if the appellant is an unrepresented beneficiary;
  (3) The name, address, and telephone number of the appellant (when the appellant is not the beneficiary);
  (4) The name, address, and telephone number of the representative (if applicable);
  (5) The QIC case number (if applicable);
  (6) The dates of service of the claim(s) being appealed, if applicable;
  (7) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed; and
  (8) A statement of any additional evidence to be submitted and the date it will be submitted.

  ⓘ *NOTE:* For appeals of statistical samples and/or extrapolations, the elements of a complete request must be included for each sample claim the appellant wishes to appeal, along with any reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted. See 42 C.F.R. § 405.1014(a)(3).

- For Part A and Part B QIC reconsideration appeals, the appellant must send a copy of the request for hearing to the other parties who were sent a copy of the QIC reconsideration (this does not include CMS contractors because they are not parties). See 42 C.F.R. § 405.1014(d).

  ➢ If additional materials submitted with the request are necessary to provide the information required for a complete request (including a brief statement explaining

[1] Section 501 of the Medicare Access and CHIP Re-Authorization Act (MACRA) requires that the Department of Health and Human Services remove Social Security Numbers (SSNs) from beneficiaries' Medicare cards by April 2019. CMS is issuing new Medicare cards that will contain a randomly generated Medicare Beneficiary Identifier (MBI) for each beneficiary rather than a HICN tied to his/her SSN beginning in April 2018. By 2020, the MBI will fully replace the HICN for Medicare transaction. Pursuant to CJB 18-001, OMHA adjudicators must accept either a HICN or MBI in satisfaction of any regulatory or sub-regulatory requirements pertaining to a HICN.

the reasons why the appellant disagrees with the QIC's reconsideration), a copy of the materials must be sent to the parties as well.

- If the appellant is submitting additional evidence, the appellant must also send a copy of the evidence, or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request.

- For Part D IRE reconsideration appeals, a complete request must contain or provide a means to ascertain:

  (1) The name, address, telephone number, and HICN[2] of the enrollee;
  (2) The name, address, and telephone number of the representative (if applicable);
  (3) The IRE case number (if applicable);
  (4) The prescription drug in dispute;
  (5) The plan name;
  (6) The reasons the enrollee disagrees with the IRE's reconsideration;
  (7) A statement of any additional evidence to be submitted and the date it will be submitted; and
  (8) A statement that the enrollee is requesting an expedited hearing (if applicable).

The request must contain the information identified in 42 C.F.R. §§ 405.1014(a)(1) and 423.2014(a)(1) to be a "complete request." See 42 C.F.R. §§ 405.1014(b), 423.2014(b), If there is missing information in the request for hearing or review, the appellant must be provided with an opportunity to complete the request. Any adjudication time frames will not begin until a complete request is submitted. If the appellant fails to complete the request within OMHA policy provides that the defect must be identified in a letter to the appellant, 60 calendar days must be provided to cure the defect, and the letter must inform the appellant that if the defect is not cured, the request is subject to dismissal.

In Part A and Part B appeals, a defect in the request for hearing would include failure to send a copy of the request to the other parties to a Part A or Part B QIC reconsideration. See 42 C.F.R. § 405.1014(d). Parties must be given a reasonable opportunity to cure this defect in the request before the appeal is subject to dismissal, unless the appellant is an unrepresented beneficiary who failed to send a copy of the request to the other parties, in which case OMHA will notify the other parties of the beneficiary's request for hearing or review. See 42 C.F.R. § 405.1014(d)(3). OMHA policy provides that the defect must be identified in a letter to the appellant, 60 calendar days must be provided to cure the defect, and the letter must inform the appellant that if the defect is not cured, the request is subject to dismissal.

ⓘ *NOTE:* Failing to send a copy of the request to the other parties affects the adjudication time frame, unless the appellant is an unrepresented beneficiary.

[2] Pursuant to CJB 18-001, OMHA adjudicators will accept a valid MBI in place of a HICN until these regulations are revised.

ⓘ *NOTE:* The copy requirement does not apply to Part D appeals. See 42 C.F.R. § 423.2014.

⊗ *CAUTION:* The Council's has consistently held that a *de minimis* or technical defect in the request for hearing is not a basis for dismissal. A request that does not satisfy the applicable elements of 42 C.F.R. §§ 405.1014(a),(d) and 423.2014(a)(1) may be cured by obtaining the missing information from the case file or seeking clarification from the appellant.

For example, if a copy of the appealed reconsideration is sent with the request, the information in the reconsideration must be considered in determining whether the request is complete. See also 42 C.F.R. §§ 405.1014(b)(2), 423.2014(c)(2).

Is it an escalation from a QIC?

Escalation may be requested for Part A and Part B QIC requests for reconsideration, if the QIC has not met its time frame to issue the reconsideration (or dismissed it). The party who filed the request for reconsideration must request escalation through the responsible QIC (note that QICs send a notice when the time frame is not met). See 42 C.F.R. § 405.970.

- If the QIC cannot issue a reconsideration within 5 calendar days of a timely filed request for escalation, the QIC will forward the request and case file to OMHA Central Operations(If a reconsideration is issued, the standard rules apply).
- The amount in controversy requirement for an Administrative Law Judge hearing still applies, and aggregation is still available (the request for aggregation should be in the request for escalation). See 42 C.F.R. § 405.1006.
- A separate request for an Administrative Law Judge hearing is not required when an appellant has requested escalation from the responsible QIC and the QIC is unable to issue the reconsideration.

ⓘ *NOTE:* Escalation is not available in Part C and Part D appeals, and appeals of QIO and SSA reconsiderations.

2. Who are the players in an appeal?

Part A and Part B

In a Part A or Part B eligibility, entitlement, or premium appeal, the beneficiary is the only party because it is the beneficiary's interests in the program or the amount he or she has to pay in premiums at stake.

In a Part A or Part B claim appeal, there is a natural tendency to relate the parties or their standing to file an appeal to financial interest. However, in most instances, an individual's or entity's financial responsibility for a denied claim is a separate inquiry from whether that individual or entity is a party and can pursue appeals and is due notices.

- Parties to a Part A or Part B claim appeal include all of the following that apply in a given appeal:
  - The beneficiary who files a claim or has had a claim filed on his or her behalf under Part A or Part B, unless the beneficiary has assigned his or her appeal rights; or if the beneficiary is deceased, the beneficiary's estate; or if the beneficiary is deceased and there is no estate, any person obligated to make or entitled to receive payment;
  - A provider who filed the claim for items or services furnished to the beneficiary, and who had in effect an agreement to participate in Medicare;
  - A supplier who has accepted assignment of the claim for items or services furnished to the beneficiary;
  - An applicable plan when Medicare is directly pursuing a recovery under the Medicare Secondary Payer provisions from the applicable plan, in which case the applicable plan is the only party;
  - A Medicaid State agency that timely filed a request for a redetermination, and has made payment or may be liable for payment for items or services furnished to a dually eligible (in Medicare and Medicaid) beneficiary;
  - A provider or supplier who is not otherwise a party and who accepted an assignment of appeal rights from the beneficiary in accordance with 42 C.F.R. § 405.912;
  - A non-participating physician who has not taken assignment and who may be liable under § 1842(l) of the Act to refund the amount collected because the service was not reasonable and necessary under § 1862(a)(1) of the Act;
  - A non-participating supplier of durable medical equipment that has not taken assignment and who may be liable to refund the amount collected under §§ 1834(a)(18) or 1834(j)(4) of the Act because the supplier did not have a supplier number or the item was furnished after an unsolicited contact, denied in advance, or not reasonable and necessary; and
  - A provider or supplier who is not otherwise a party, furnished services to a beneficiary who subsequently dies, and appealed the initial determination.

See 42 C.F.R. §§ 405.902, 405.906, 405.908, 405.912.

ⓘ *NOTE:* While not explicit in the above, a beneficiary who is the subject of a Medicare Secondary Payer recovery action (directly against the beneficiary) is a party to the Medicare Secondary Payer action. In a Medicare Secondary Payer action, the recoupment is against the individual who received a payment from a third party for the same items or services that Medicare covers, it is not an action denying claims. Therefore, the providers and suppliers involved are not parties (because the claims are not being denied, and recoupment is not sought from the providers and suppliers—the recoupment is sought against the beneficiary's recovery from a third party payer).

ⓘ *NOTE:* A family member, including the spouse of a deceased beneficiary, may not act on behalf of a beneficiary unless the individual is an authorized or appointed

representative. Providing non-representative family members, including spouses, with personally identifiable information (PII) or protected health information (PHI) about the beneficiary is not permitted. Appropriate time should be provided to family members to obtain the necessary authorization or appointment.

ⓘ *NOTE:* CMS and its contractors are not initial parties to the appeal and are discussed in a subsequent section on potential parties.

ⓘ *NOTE:* A CMS contractor's or SSA's treatment of an individual or entity as a party will not be revisited by OMHA, unless the evidence of record raises a question of party status. OCPM I-4-1. If there is a question of party status regarding the individual or entity that submitted the request for hearing that cannot be resolved after review of the record or the record is missing information, the prospective party must be contacted for further information, in accordance with OCPM I-4-6.

A beneficiary may transfer (that is, assign) his or her appeal rights to a provider or supplier that is not already a party. There are specific requirements for this transfer, and form CMS-20031 must be used.

⊗ *CAUTION:* Do not confuse assignment of a claim with assignment of appeal rights. They are mutually exclusive; by taking an assignment of a claim, a supplier is a party to an initial determination and appeals thereof, and a supplier that is already a party cannot take an assignment of appeal rights from a beneficiary.

- An assignment of appeal rights must:

  (1) Be executed using the CMS standard form;

  ☐ *FORM:* (mandatory) CMS-20031 (Transfer of Appeal Rights)

  (2) Be signed by the beneficiary assigning his or her appeal rights;
  (3) Be signed by the assignee (the provider or supplier);
  (4) Indicate the item or service for which appeal rights are being assigned;
  (5) Waive the assignee's right to collect payment from the beneficiary for the item or service that is the subject of assignment, except for coinsurance or deductible amounts and any payment for which a valid Advanced Beneficiary Notice was signed; and
  (6) Be submitted at the same time the request for redetermination or other appeal is filed.

- An assignment of appeal rights is valid for the duration of the administrative and judicial process on the item or service.

  ➢ The beneficiary may revoke the assignment at any time in writing.

    - The revocation is effective when it's received by the adjudicator.
    - The assignee's waiver of the right to collect payment is no longer valid if the beneficiary revokes the assignment.

- An assignment of appeal rights is revoked if the assignee does not appeal an unfavorable decision.
  - The assignee's waiver of the right to collect payment is still valid.
- An assignment of appeal rights may also be revoked by the adjudicator for an act or omission that is contrary to the financial interest of the beneficiary.
  - The assignee's waiver of the right to collect payment is still valid.

- With a valid assignment of appeal rights, the assignee takes the place of the beneficiary and has all of the rights and responsibilities of a party, including:

  (1) Obtaining information about the claim;
  (2) Submitting evidence;
  (3) Making statements about facts or law; and
  (4) Making any request, or giving, or receiving any notice about appeal proceedings.

See 42 C.F.R. §§ 405.902, 405.906, 405.912.

Substitution of party

If a beneficiary dies while a request for hearing is pending with OMHA and the beneficiary has not assigned his or her appeal rights pursuant to 42 C.F.R. § 405.912, the beneficiary's estate or other person obligated to make or entitled to receive payment who would qualify as a party under 42 C.F.R. § 405.906(a)(1), may enter the OMHA proceedings as a substitute party.

ⓘ *NOTE:* Substitution of a party is only required when the beneficiary dies while a request is pending. It is not required if the beneficiary dies before the request is filed.

☐ *FORM:* (non-mandatory) OMHA-106 (Request for Substitution of Party upon Death of Beneficiary or Enrollee).

Employees acting on behalf of a party

Providers and suppliers may designate employees to pursue administrative appeals and appear on their behalf. An employee acting on behalf of an employer that is a party to the proceedings is the point of contact for the party, and has the authority to make representations and speak on behalf of the employer. See OCPM I-4-1.

ⓘ *NOTE:* The employee is not considered an "authorized" or "appointed" representative. Therefore, documentation of representation is not necessary.

Part C

In Part C organization determination appeals, the MAO is always a party (this is a statutory requirement), and one of the following is also a party:

- The enrollee;

- An assignee of the enrollee (that is, a physician or other provider who has furnished a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service);
- The legal representative of a deceased enrollee's estate; or
- Any other provider or entity (other than the MAO) determined to have an appealable interest in the proceeding.

ⓘ *NOTE:* Unlike Part A and Part B, the list of potential parties uses the disjunctive "or"—therefore, a party is one of those listed. Most often, it will be the enrollee.

⊗ *CAUTION:* The provision that allows a physician or other provider to be a party is for non-contract physicians or other providers to appeal MAO organization determinations. Physicians or other providers who have a contractual relationship with the MAO must resolve disputes with the MAO in accordance with their contracts.

See 42 C.F.R. §§ 422.574, 422.582, 422.602; see also CMS, *Medicare Managed Care Manual* (MMCM) (*Internet-Only Manual Publ'n 100-16*) ch. 13, § 60.1.1.

Part D

In Part D coverage determination appeals, the enrollee is the only party.

ⓘ *NOTE:* Unlike an MAO in a Part C appeal, a Part D plan sponsor is not a party to the appeal, and as discussed below, a Part D plan sponsor may only be a "participant" in an appeal (it cannot be made a party).

⊗ *CAUTION:* At prior levels of appeal, the prescriber may request an appeal on behalf of an enrollee, but may not do so at the OMHA level. In order to file a request for an Administrative Law Judge hearing or review of a dismissal, a prescriber must be appointed as the enrollee's representative and file the request in his or her capacity as a representative. The prescriber does not have party status. Ensure that if a prescriber has submitted an appeal to OMHA that the appropriate form is within the file. Appropriate time should be provided to prescribers to obtain the necessary authorization or appointment.

Compare 42 C.F.R. § 423.2008, with §§ 423.580, 423.600 (allowing the prescriber to request the redetermination and reconsideration, respectively, on behalf of the enrollee, upon providing notice to the enrollee).

Representatives

There are two types of representatives in our appeals process: authorized and appointed representatives.

ⓘ *NOTE:* The two types of representatives are separately defined in the part 405, subpart I rules (see 42 C.F.R. § 405.902), but in part 422, subpart M the two are grouped under the definition of "representative" (see 42 C.F.R. § 422.561), and in part 423, subpart M the

two are grouped under the definition of "appointed representative" (see 42 C.F.R. § 423.560). Despite the nomenclature in part 423 appeals, an authorized representative would not also need to be appointed.

- An authorized representative acts on behalf of a party under the authority of a State or other applicable law (for example, a court appointed guardian or an individual with a healthcare proxy or power of attorney). An authorized representative has all the rights and responsibilities of the represented party throughout the appeals process.
- An appointed representative is an individual appointed by a party to represent the party in the claim or claim appeal (for example, a family member or attorney).
  - An appointed representative can be any individual who is not disqualified, suspended, or otherwise prohibited by law from acting as a representative in proceedings before HHS, or in entitlement appeals, before SSA.
  - A valid appointment must:

    (1) Be in writing;
    (2) Be signed and dated by the party;
    (3) Be signed and dated by the individual agreeing to be the representative;
    (4) Provide a statement appointing the representative to act on behalf of the party, and in the case of a beneficiary, authorizing the adjudicator to release identifiable health information to the appointed representative;
    (5) Include a written explanation of the purpose and scope of the representation;
    (6) Contain the party's name, phone number, and address;
    (7) Contain the appointed representative's name, phone number, and address;
    (8) Identify the beneficiary's or enrollee's HICN[3], if the beneficiary or enrollee is the represented party; or the provider's or supplier's National Provider Identifier (NPI), if the provider or supplier is the represented party;

    ⓘ *NOTE:* No unique identifier is required for an appointment when a Medicaid State agency is the represented party.

    (9) Include the appointed representative's professional status or relationship to the party; and
    (10) Be filed with the entity processing the party's initial determination or appeal.

    ☐ *FORM:* (non-mandatory) CMS-1696 (Appointment of Representative)

    - If any of the elements are missing, the individual must be provided with a reasonable opportunity to cure the defective appointment. If an adjudication time frame applies, the time from the later of the date that a defective appointment of representative was filed or the current appeal request was filed

[3] Pursuant to CJB 18-001, OMHA adjudicators will accept a valid MBI in place of a HICN until these regulations are revised.

by the prospective appointed representative, to the date when the defect was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative does not count towards the adjudication time frame. The individual may not act on behalf of a party until the appointment is valid.

⊗ *CAUTION:* Without a valid appointment, there can be no disclosure of protected information.

⊗ *CAUTION:* An appointment of representative is *not* an assignment of appeal rights.

- An appointment is valid to initiate an initial determination or an appeal of a claim for 1 year from the date of signature. When an appointment is used to initiate an initial determination or appeal, the appointment is valid for the duration of the administrative process on the claim (that is, the appointment is valid for all subsequent appeals, even if they extend beyond the 1 year).
  - A party may revoke an appointment at any time and it is effective when the adjudicator receives written notice of the revocation.
  - The death of the party terminates the appointment unless an appeal is in progress and another individual or entity may be entitled to receive payment or obligated to pay for the items or services at issue, except in Medicare Secondary Payer recovery claims.
- An appointment may only be delegated if:
  (1) The representative provides written notice of the delegation indicating the name of the designee and the designee's acceptance of the appointment obligations to the party; and
  (2) The party accepts the delegation in writing (not required if delegating between attorneys in the same law firm or organization).
- An appointed representative must:
  (1) Keep the party informed;
  (2) Always act in the interest of the party;
  (3) Disclose any financial risk or liability a beneficiary may have on a non-assigned claim (if applicable);
  (4) Comply with all laws and CMS regulations, CMS Rulings, and instructions; and
  (5) If a provider or supplier is representing a beneficiary, sign a statement affirming it will not represent the beneficiary on § 1879(a)(2) of the Act issues or waiving the right to collect payment from the beneficiary on those issues, and not charge for the representation.

- Appointed representatives do not have party status—they only take actions on behalf of the individual or entity that they represent. An appointed representative may, to the same extent as a party:

  (1) Obtain appeals information about the claim;
  (2) Submit evidence;
  (3) Make statements about facts and law; and
  (4) Make any request, or give, or receive, any notice about the appeal proceedings.

  ⓘ *NOTE*: Notices and other correspondence must be sent to the representative. In Medicare Secondary Payer cases in which the beneficiary is the represented party, the notices and other correspondence must also be sent to the represented party (that is, the beneficiary).

- Fees for representing a *beneficiary* at the OMHA level for most types of appeals must be approved by the OMHA adjudicator. Fee arrangements made for the purpose of pursuing third-party payment (that is, Medicare Secondary Payer cases) may not be reviewed by the OMHA adjudicator.

  - Representative fees are paid by a beneficiary to the representative; they do not come from the Medicare trust fund.
  - A provider or supplier that furnished the items or services on appeal may not charge a beneficiary for representation.
  - The OMHA adjudicator may *not* use § 206(a)(2) and (a)(3) of the Act to determine the reasonableness of fees.

  ⓘ *NOTE:* These provisions do not apply to representatives of non-beneficiaries.

  ⓘ *NOTE:* In considering the reasonableness of fees, an OMHA adjudicator may consider the hourly rate in the surrounding area (if the fee is charged by the hour) or the percentage (if the fee is charged on a contingency basis).

See 42 C.F.R. §§ 405.902, 405.910; see also MCPM, *supra* ch. 29, § 270.1.2.

CMS / contractors / plans

In Part A and Part B appeals, CMS and its contractors may elect to be participants in the proceedings on a request for an Administrative Law Judge hearing or, unless the request was filed by an unrepresented beneficiary, parties to the hearing.

- There are two opportunities in which CMS or a CMS contractor may file an election:
  - Within 30 calendar days of notification that a request for hearing was filed (non-party participant elections only); or

- If a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing (party or non-party participant elections).

- ⓘ *NOTE*: CMS contractor notification that a request for hearing was filed comes *after* the request is filed. Do not use the request filing date to determine whether an election was timely.

- Elections must be sent to the OMHA adjudicator (or OMHA Central Operations' CMS Contractor Elections Mail Stop for unassigned cases), and to the parties who were sent a copy of the notice of reconsideration.

  - ☐ *FORM:* (non-mandatory) OMHA-105 (Notice of Intent to Participate in Proceedings on a Request for an Administrative Law Judge (ALJ) Hearing or to be a Party to an ALJ Hearing)

- An Administrative Law Judge may request CMS or a CMS contractor to participate or be a party to a hearing, but may not require it and may not draw negative inferences if CMS or the CMS contractor elects not to participate or be a party.

- Only one entity (CMS or a contractor) is generally permitted to attend the oral hearing, determined as follows:

  - If only one entity elected to be a party to the hearing, only that entity is permitted to attend.

  - If more than one entity elected to be a party to the hearing, only the first entity to respond to the notice of hearing is permitted to attend, and remaining entities are made non-party participants.

  - If no entity elected to be a party to the hearing, only the first entity to file an election to be a non-party participant may attend.

  - ⓘ *NOTE*: The Administrative Law Judge has discretion to allow additional entities to attend the oral hearing. If leave is not granted, an entity that is precluded from participating may still be called as a witness by CMS or a CMS contractor that is a party to the hearing. However, doing so allows the other parties to cross-examine the precluded entity.

- Participants may file position papers and provide testimony, but may *not* call witnesses or cross-examine or question the parties or witnesses.

- Parties may file position papers, provide testimony, call witnesses, cross-examine witnesses, and submit additional evidence.

- If a CMS or CMS contractor election is invalid (not timely, or not sent to the correct parties), the OMHA adjudicator sends written notice to the entity that filed the election and the parties who were entitled to receive notice of the election. The notice must be

sent prior to the hearing, and oral notice must also be given if the notice would be sent fewer than 5 calendar days prior to the scheduled hearing.

⊗ *CAUTION:* The Administrative Law Judge should not allow CMS or a CMS contractor acting as a *participant* to question the parties or their witnesses.

ⓘ *NOTE:* When CMS or a CMS contractor elects *party* status, discovery can occur.

See 42 C.F.R. §§ 405.1000(c), 405.1010, 405.1012.

In Part C appeals, the MAO is a party to the appeal pursuant to the statute, and has all of the rights and responsibilities of a party.

- The part 405, subpart I provisions could be used for the Administrative Law Judge to request participation by the IRE or QIO involved in the levels below and for such an entity to elect a status in the appeal, except that the IRE or QIO could not elect party status if the appellant is an unrepresented enrollee.

See 42 C.F.R. §§ 422.562, 422.602.

In Part D appeals, the Part D plan sponsor, the IRE, or CMS may request to be a participant in an appeal.

- The request to participate must be made:

  (1) Within 30 calendar days after notification that a standard request for hearing was filed, or within 2 calendar days after notification that a request for an expedited hearing was filed; or

  (2) No later than 5 calendar days after receiving the notice of hearing for a non-expedited hearing, or 1 calendar day after receiving the notice of an expedited hearing.

  ⓘ *NOTE*: IRE and Part D plan sponsor notification that a request for hearing was filed comes *after* the request is filed. Do not use the request filing date to determine whether an election was timely.

- The OMHA adjudicator determines whether to grant the Part D plan sponsor's, the IRE's, or CMS's request to participate, and must notify the entity and the enrollee within the following time frames:

  (1) At least 20 calendar days before the ALJ or attorney adjudicator issues a decision, dismissal, or remand, if no hearing is scheduled;
  (2) 5 calendar days of receiving a request to participate in a non-expedited hearing; or
  (3) 1 calendar day of receiving a request to participate in an expedited hearing.

- If the OMHA adjudicator determines that the Part D plan sponsor's, the IRE's, or CMS's request to participate is invalid, a written notice must be sent to the entity within the following time frames:
    (1) No later than the date of the notice of decision, dismissal, or remand is mailed, if no hearing is scheduled or the request was made after the hearing occurred;
    (2) Prior to a scheduled non-expedited hearing; or
        - If the notice would be sent fewer than five days before the hearing is scheduled to occur, oral notice must be provided to the entity followed by a written notice as soon as possible.
    (3) Prior to a scheduled expedited hearing.
        - Oral notice must be provided to the entity followed by a written notice as soon as possible.

- An Administrative Law Judge may also request the participation of the Part D plan sponsor, the IRE, or CMS, but may not require it and may not draw negative inferences if CMS or its contractor elects not to participate or be a party.

- The Part D Plan Sponsor, the IRE, and CMS are limited to the non-party "participant" role—they may not be made parties to the appeal.

See 42 C.F.R. § 423.2010.

3. What is the standard and scope of review in an appeal?

Standard of review / scope of review

OMHA adjudicators conduct *de novo* reviews and issue decisions based on the administrative record. That means that it is a new look at the claim without regard to what the other levels of appeal decided.

However, it is a qualified *de novo* review because the issues are based on what the lower levels of review decided—the default issues (those that must be decided) are those issues that were not decided entirely in a party's favor.

ⓘ *NOTE:* The rule uses "party" rather than "appellant" because the appellant may be pursuing an appeal even though the lower level decisions have decided the liability issue in his or her favor by deciding the appellant is not liable.

ⓘ *NOTE*: The term "party" in this context does not include a representative of CMS or one of its contractors that may be participating in a hearing pursuant to 42 C.F.R. § 405.1010.

ⓘ *NOTE:* "Affirming" or "sustaining" a lower level decision is not appropriate because OMHA adjudicators do not conduct appellate review except when reviewing QIC dismissals.

In addition to the default issues, "new issues" can be identified and addressed, but only by an Administrative Law Judge. A new issue can be a favorable portion of a prior claim determination (for example, the determination that a skilled nursing facility (SNF) claim may not have met the 3-day qualifying hospital stay requirement), or a new and different basis for a denial (for example, the item is not reasonable and necessary for a different reason than was identified by the contractors).

⊗ *CAUTION:* A review of a dismissal by a prior adjudicating entity is not a review of the underlying claim. It is only a review of whether the dismissal was proper.

ⓘ *NOTE:* New issues may only be considered if the Administrative Law Judge notifies the parties that were or will be sent the notice of hearing about the new issue before the start of the hearing.

⊗ *CAUTION: New issues may only be considered by an Administrative Law Judge and not attorney adjudicators. 42 C.F.R. § 405.1032(b).*

See 42 C.F.R. §§ 405.1000, 405.1004, 405.1032, 423.2000, 423.2004, 423.2032.

Appealable issues

Generally. OMHA adjudicators only exercise jurisdiction over Part A and Part B initial determinations, Part C organization determinations, and Part D coverage determinations. These determinations are defined in the rules, and sometimes what is not an appealable determination is also defined:

- Part A and Part B initial determinations:
  - 42 C.F.R. §§ 405.924, 478.14 for entitlement, claims, and QIOs.
  - 20 C.F.R. §§ 418.1301, 418.2301 for IRMAAs.
  - What are NOT initial determinations include, but are not limited to, those actions described in 42 C.F.R. § 405.926, and 20 C.F.R. §§ 418.1305 and 418.2305.
- Part C organization determinations:
  - 42 C.F.R. § 422.566(b).
  - What are NOT organization determinations: everything else (see 42 C.F.R. § 422.561 definition of "grievance").
- Part D coverage determinations:
  - 42 C.F.R. § 423.566(b).
  - What are NOT organization determinations: everything else (see 42 C.F.R. § 423.560 definition of "grievance").

The issues also include related issues regarding financial responsibility for a denied claim.

- Section 1879 of the Act is a provision that allows liability for a claim to be limited for specific types of denials, when a party did not know and could not reasonably have known an item or service would not be covered. Liability is analyzed with respect to the beneficiary first because he or she derived a benefit by receiving the item or service. If liability is limited with respect to both the beneficiary and the provider or supplier, payment for the item or service is made.

- Section 1870 of the Act is a provision that allows an overpayment to be waived. If § 1879 analysis applies, it must be conducted first because if there is no overpayment because payment can be made under § 1879 notwithstanding the denial, no overpayment exists. Section 1870 analysis has some similarities to § 1879 analysis, but differs in important ways. The analysis is looking at who was at fault in causing the overpayment, and with regard to the beneficiary, allows considerations of equity.

See CMS, *Medicare Financial Management Manual (MFMM) (Internet-Only Manual Publ'n 100-6)* ch. 3, §§ 70 through 110.

Statistical Sampling/Overpayment Challenges. If a determination involves an extrapolated overpayment and the appellant challenges the validity of the sampling methodology, the issues involve the merits of the appealed sample claims as well as the methodology used to extrapolate the overpayment amount. For background on how the PSC / ZPICs use statistical sampling to estimate overpayments, see *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n* 100-8) ch. 8, § 8.4.

ⓘ *NOTE:* The use of sampling is not subject to review because the prerequisite findings are not appealable initial determinations. See 42 C.F.R. § 405.926.

When a party asserts a disagreement with how a statistical sample and/or extrapolation was conducted in the request for hearing, the OMHA adjudicator must base his or her decision on a review of the entire sample to the extent appropriate to decide the issue. See 42 C.F.R. § 405.1032(d)(2).

Payment Amount Challenges. A finding on the amount of payment may not be made unless the actual amount of payment is at issue. See 42 C.F.R. § 405.1046.

- The amount of payment is generally controlled by payment systems and schedules developed in accordance with statutory provisions, and under the exclusive authority of CMS. These payment amounts cannot be varied from and CMS contractors will not effectuate decisions that find an alternate payment amount is due. However, in order to challenge the payment system or schedule amount in Federal court, the provider or supplier has to exhaust administrative remedies.

- When the payment amount is calculated (for example, it is a contractor priced item or service), the CMS standards established for contractors to determine the amount of payment must be applied.

ⓘ *NOTE:* When an OMHA adjudicator makes a finding on the amount of payment, the contractor may make a subsequent adjustment to the amount of payment due. The contractor's determination on the amount of payment in effectuating the OMHA adjudicator's decision constitutes an initial determination and may be appealed on the amount of payment issue.

⊗ *CAUTION:* The payment amount should not be confused with the possibility of down-coding the level of service.

- A down-code will affect the amount paid on the claim but is not itself a determination on the amount of payment due.
- Down-codes are appropriate when the OMHA adjudicator finds the level of service performed meets the criteria of a code different than the code billed.

ⓘ *NOTE:* The down-code must be one the provider or supplier is qualified to bill for and the item or service meets the criteria for. For example, an Inpatient Rehabilitation Facility (IRF) that performed skilled therapy but not at the level of service required for IRF billing may not be down-coded to a SNF code.

What is not at issue in an appeal. Beyond actions that are not initial determinations, organization determinations, or coverage determinations, the following are not at issue in the appeal:

- Fraud. (Although the reviewer may not make a finding of criminal or civil fraud, the OMHA adjudicator should review the claim to see if there is sufficient documentation and evidence supporting that the items or services were actually furnished or were furnished as billed. In addition, the OMHA adjudicator may make credibility determinations of the evidence. If there are concerns about potential fraud, they should be referred to OMHA's Program Integrity staff (see CJB 17-001);
- Whether requests for lower level appeals were valid;
- The quality or logic of the lower level determinations (unless the appellant requested review of a QIC's dismissal of a reconsideration request; or the OMHA adjudicator finds that the QIC issued a reconsideration that addressed coverage or payment issues, but no redetermination was issued or the redetermination request was dismissed); and
- The validity of regulations and coverage and payment policies.

ⓘ *NOTE:* While we use the term "appeal," OMHA adjudicators are not conducting appellate reviews of the redetermination or reconsideration (or their equivalents in other Parts), or Medicare regulations or policies. OMHA adjudicators do not "affirm" or "reverse" the redetermination or reconsideration, and it is not appropriate to opine on whether the OMHA adjudicator believes those decisions were flawed—we are all a part of HHS. Only the Medicare Appeals Council acts as a more traditional appellate body in reviewing the decision or dismissal of an OMHA adjudicator.

New issues

An Administrative Law Judge (but not an attorney adjudicator) has the authority to review the favorable portions of the determination or review issues that were not previously identified as "new issues."

- If a claim was denied as not reasonable and necessary, and something in the record causes the Administrative Law Judge to question whether the technical coverage criteria are met, the technical coverage criteria would be a favorable portion of the determination. This is because the technical criteria must be met before reasonableness and necessity are examined, and the contractors did not indicate there was an issue with the technical coverage criteria and therefore it was a favorable portion of the determination.

The Administrative Law Judge must find two criteria are met when considering new issues:

(1) Resolution of the new issue(s) could have a material impact on the claim(s) or appealed matter; and

ⓘ *NOTE:* A material impact would render the claim payable or not payable, or payable at a different level of service.

(2) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion, or the evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

Notice that the new issue that will be considered *must* be given so that the parties and potential parties are made aware of the issue and can adequately prepare.

- A detailed statement of the issues in the notice of hearing will generally be regarded as sufficient notice.

See 42 C.F.R. §§ 405.1032, 423.2032.

Adding claims or issues to a pending appeal

Claims that were not part of a reconsideration specified in the request for hearing would be "new claims" to the appeal. New claims may not be added to a pending appeal because they may not have been reconsidered (thus, there is not right to a hearing on the claims), and if they were reconsidered, the appellant must file a request for hearing to exercise the rights to a hearing in accordance with the regulations.

Claims that were adjudicated in the same reconsideration that was appealed can be added to the appeal if the appellant did not specify them in the request for hearing, but only if the 60-day period to request an ALJ hearing has not expired or the adjudicator finds good cause to extend the time period to request a hearing on those claims.

⊗ *CAUTION:* A claim may not be considered if the time to request a hearing has expired (unless the OMHA adjudicator extends the filing time frame) or the claim does not meet the AIC requirement (unless properly aggregated).

See 42 C.F.R. §§ 405.1032(c), 423.2032(c).

Refunds owed to a beneficiary

If, as the result of a denial, a provider or supplier is required to make a refund to a beneficiary for amounts collected from the beneficiary for the items or services at issue, then the contractor must include the language in the redetermination indicating the refund is due and how to obtain a refund if the beneficiary paid the provider or supplier. The contractor must also send the provider or supplier an adjusted remittance advice (RA). This occurs when:

- A nonparticipating physician not accepting assignment who, based on the redetermination, now has a refund obligation under § 1842(l)(1) of the Act;
- A nonparticipating supplier not accepting assignment who is determined to have a refund obligation pursuant to § 1834(a)(18) of the Act, due to a denial under either § 1834(a)(17)(B) or § 1834(j)(4) of the Act; or
- A denial based on § 1879(h) of the Act of an assigned claim submitted by a supplier, where it is determined under § 1834(a)(18) of the Act that the supplier must refund any payments (including deductibles and coinsurance) collected from the beneficiary.

See *MCPM, supra* ch. 30, §§ 140, 150.

Application of equity

There are no equity powers in Medicare administrative appeals, apart from one provision related to whether an overpayment can be waived for a beneficiary.

Application of *res judicata*

Res judicata (also known as claim preclusion) should only be applied when a decision has been made on the same claim with respect to an unchanging fact pattern.

- When the issue involved in the claim has been decided by a QIC, an OMHA adjudicator, or the Council and the decision has become final by administrative or judicial action, application of *res judicata* is appropriate.
  - A determination that items or services are reasonable and necessary for different dates of service is not appropriate for an application of *res judicata* because the beneficiary's circumstances and condition must be independently assessed for each date of service.
  - When a contractor's effectuation of an OMHA adjudicator's finding on the amount of payment due is appealed, *res judicata* would apply to the underlying merits of the

claim because the OMHA adjudicator's findings on the merits of the claim were final whereas the findings on the amount of payment were subject to subsequent actions by the contractor in effectuating the OMHA adjudicator's decision.

See 42 C.F.R. §§ 405.1046, 405.1052(a)(5), 423.2052(a)(5).

Application of estoppel

Estoppel has no application when the Federal government and monetary benefits (or the items or services that may be provided in lieu of direct monetary exchanges) are involved.

- A provider's, supplier's, or beneficiary's reliance on a government publication or the oral advice provided by government personnel may not be used to direct payment for or the provision of items or services, or stop a government recoupment action.

Review of QIC or IRE dismissal

An OMHA adjudicator's review of a QIC or IRE dismissal of a request for reconsideration is limited to determining whether the dismissal was appropriate under applicable rules (the request for reconsideration rules must be applied).

- If the dismissal was appropriate, the OMHA adjudicator *affirms*[4] the QIC dismissal.[5]
- If the dismissal was not appropriate, the OMHA adjudicator *remands*[6] to the QIC for reconsideration on the merits.
- If the request for review is invalid, the OMHA adjudicator *dismisses* the request for review.

ⓘ *NOTE:* The OMHA adjudicator does not have jurisdiction to review a QIC's review of a redetermination dismissal—when a request for administrative review is dismissed, only one level of review is permitted.

See 42 C.F.R. §§ 405.974, 405.1004, 423.2004.

Burden of proof

The proponent of coverage has the burden of proof. Generally, the proof must be in the form of documentation to support coverage and payment criteria were met.

See 5 U.S.C. § 556(d) ("Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof.").

---

[4] "Affirmed is used only in the context of a request for review of a dismissal and means that the [adjudicator] upheld the dismissal of the reconsideration request." CJB 16-001 § II(B)(2).

[5] In this situation, the disposition in the order would be "Decision Affirming Dismissal" and the disposition in MAS would be "Unfavorable." See *id.* §§ II(D)(2), E(6).

[6] "Remanded means the ALJ determined the dismissal of the reconsideration request was in error, vacated the dismissal, and returned the case to the prior-level adjudicator for the requested reconsideration." Id. § II(B)(2).

4. What authorities apply?

Applicable statutes and regulations are binding authority and may not be set aside, declared invalid, or otherwise not followed.

ⓘ *NOTE:* Only an Article III court can review the validity of an HHS regulation, and the effect of the court's review is limited unless the decision is by the U.S. Supreme Court. A District Court decision is limited to the specific case before the court; a Circuit Court of Appeals' decision applies to future cases in the circuit unless HHS elects to exercise nonacquiescence.

CMS Rulings are binding on all HHS components that adjudicate matters under the jurisdiction of CMS, including OMHA adjudicators and the Council.

National coverage determinations (NCDs) are binding on OMHA adjudicators and the Council.

- An OMHA adjudicator may review whether an NCD or CMS Ruling was appropriately applied to a claim (for example, whether the claim falls under the topic covered by the NCD/CMS Ruling) and correctly applied to the claim (that is, whether the standards articulated in the NCD/CMS Ruling were correctly applied).

LCDs and CMS program guidance (including memoranda, instructions, and manuals) are not binding on OMHA adjudicators but must be considered and given substantial deference.

- An OMHA adjudicator may review the applicability of LCDs or CMS program guidance to a claim and whether the LCD or CMS programs guidance was correctly applied to the claim, similar to an NCD/CMS Ruling.
- An OMHA adjudicator may decline to follow an LCD or CMS program guidance for a particular claim but must explain in the decision why the policy was not followed.

⊗ *CAUTION:* A determination with respect to an LCD or CMS program guidance in a claim appeal is limited to the claim; the validity of the LCD or CMS program guidance may not be reviewed.

ⓘ *NOTE:* Reviews of LCDs and CMS program guidance must be conducted independent of any claims to which they are applied under 42 C.F.R. Part 426. These reviews are conducted by Administrative Law Judges within the Departmental Appeals Board Civil Remedies Division.

ⓘ *NOTE:* The regulation includes local medical review policies (LMRPs) as authorities that are owed substantial deference, but we have not included a reference to them because they are now obsolete and have been replaced by LCDs.

For Part C appeals, the evidence of coverage (EOC) document can also be relied upon to assess whether an item or service may have been covered as a supplemental benefit (that is, it would

not be covered under Medicare Part A or Part B, but the plan offers it as a supplemental benefit under the terms and conditions of the EOC).

For Part D appeals, the EOC document can also be relied upon to assess whether a drug was on the plan formulary and if so, at what cost tier, and what other drugs had to be tried before moving to higher tiers or non-formulary drugs.

See 42 C.F.R. §§ 401.108, 405.1060, 405.1062, 405.1063, 423.2062.

5. What is the administrative record?

The administrative record and exhibits

Generally. The administrative record is the complete record of the HHS 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 appellant pursues further appeals, the administrative record created at OMHA is forwarded to the Council, and then to Federal district court.

All materials forwarded to OMHA in the case file must be maintained in the record unless otherwise specified. See OCPM II-4-1.

- Removal or disposal of materials in the case file (for example, removing and disposing of duplicative records filed by a party) is not permitted.
- The administrative record includes both exhibited and not exhibited materials.

The administrative record includes:

- The appealed determinations;
- All documents and other evidence used in making the appealed determinations and the OMHA adjudicator's determination;
  - The administrative record includes all of the documentation relating to the reconsideration, even if the material does not pertain to the specific issues being addressed by the OMHA adjudicator (for example, claims decided favorably at the QIC or a lower level).
- Additional evidence submitted at the OMHA level, regardless of whether such information is admitted by the OMHA adjudicator;
- All filings by parties and participants, and potential parties and participants (for example, responses to hearing notices, waivers, hearing memoranda, motions, stipulations, etc.);
- All notices and orders issued by or at the direction of the OMHA adjudicator;
- All reports of contact by OMHA staff with parties and participants, potential parties and participants, and others; and
  - ☐ *FORM:* OMHA-101 (Report of Contact)

- Audio recordings of all hearings or conferences conducted for the case.

The administrative record does not include:

- Case file requests;
- Case file transmittal sheets;
- Internal OMHA deliberative (working) documents (for example, hearing notes, drafts, research, and communications within the adjudication team);
- Blank pages; and
- Materials for the incorrect beneficiary inadvertently included in the case file at the lower levels and forwarded to OMHA (that is, the beneficiary's claim was not at issue or addressed at any prior level of appeal).

Exhibiting the Record. The administrative record must be exhibited for all cases that result in a decision or dismissal, though simplified exhibiting may be permitted for certain dismissals.

The record is exhibited based on the categories identified within OCPM II-4-2. Categories containing documents become exhibits that are numbered sequentially. See OCPM II-4-3.

Example:

- Category 1 (Initial, Redetermination and Reconsideration procedural documents) becomes Exhibit 1.
- Category 2 (Medical Records/Evidence received by CMS contractors) becomes Exhibit 2.
- Category 3 (Request for Administrative Law Judge Hearing) becomes Exhibit 3.
- Category 4 (OMHA proceedings (procedural documents), such as the notice of hearing, response to the notice of hearing, CMS or contractor elections / requests, etc.) becomes Exhibit 4.
- Category 5 (Evidence and briefs after the Request for Administrative Law Judge Hearing) becomes Exhibit 5.

All of the documents in the prior level case file and any additional documentary evidence the OMHA adjudicator admits or otherwise considers in making the decision or any determination in adjudication process must be exhibited for identification purposes.

- Exhibit in a manner that makes identifying the contents of the exhibit easy and understandable so the parties can determine whether they have the documents or need to request copies.
- Exhibit using arithmetic natural numbers (1, 2, 3, etc.); do not use letters.
- The record should be exhibited in reverse chronological order, to the extent possible, so the highest numbered exhibit is the newest document.

- Each exhibit must be paginated so every page is marked for identification (for example, if Exhibit 3 is 19 pages, the exhibit is paginated so a specific page or page range can be cited, such as "Exh. 3, p. 9" or "Exh. 3, pp. 12–15").

ⓘ *NOTE:* As set forth in OCPM II-4-5, 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 OCPM II-4-3.

Materials not marked as exhibits. The following materials must be kept with the administrative record, but are not marked as exhibits:

- Duplicates (optional—these can be marked as exhibits);
- Materials relating to beneficiaries whose claims are related but no longer at issue (for example, a case in which claims for 30 beneficiaries were involved in the lower levels of appeal, but claims for only 10 of the beneficiaries remain at issue in the OMHA proceeding) (optional—these can be marked as exhibits);
- New evidence that is excluded from consideration, when applicable (that is, a Part A or Part B provider or supplier, or beneficiary represented by a provider or supplier, did not establish good cause for introducing the evidence for the first time at the OMHA level) (optional—these can be marked as exhibits);
- The audio record of the hearing and any prehearing or posthearing conferences; and
- Final disposition documents, including any orders, the notice of decision, decision, and final exhibit list.

Creating the Exhibit List. A list of the exhibits must be created—the list must detail the exhibit number, a reasonable description of the exhibit to sufficiently inform the parties of its contents, and the exhibit page range or number of pages (depending upon which pagination method you are using).

☐ *FORM:* OMHA-156 (Exhibit List)

- If an exhibit contains documents that were excluded from consideration, the description should note the evidence was excluded (for example, a party submission the OMHA adjudicator excluded under 42 C.F.R. § 405.1028).

- The exhibit list should be sent to the parties with the notice of hearing or at the earliest opportunity before the hearing so the parties are aware of the evidence that may be considered by the Administrative Law Judge.

- The exhibit list should be finalized at the time of decision.

- The exhibit list should have no hand markings.

- Only the most recent list should be in the administrative record (except older lists attached to or enclosed with other documents, such as a notice of hearing, may remain in the record as attachments or enclosures).

- A copy of the final exhibit list should be sent to the parties with the notice of decision, remand, or dismissal, if the case was exhibited. See OCPM 19.2.2.

See 42 C.F.R. §§ 405.1042, 423.2042.

Party access to the record

Parties may request and must be provided upon that request (to the extent the party is authorized) at any time prior to issuance of the decision:

- A list of the exhibits;
- A copy of the documentary administrative record, or any portion thereof; and
- Copies of any conference or hearing recordings, or any portion thereof.
  - ☐ *FORM:* (non-mandatory) HHS-719 (Request for Copy of the Record(s) in the Case File)
  - ☐ *FORM:* (non-mandatory) HHS-720 (Request for Copy of the Record(s): Third-Party with the Individual Appellant's Consent) & HHS-721 (Individual Appellant's Consent to Third-Party for Copies of the Individual Appellant's Record(s))

ⓘ *NOTE:* Copies of any materials that contain PII must be furnished in a manner than adheres to government-wide and HHS information security policies.

ⓘ *NOTE:* At this time, OMHA does not charge for copies of the record.

If a party requests an opportunity to comment on the record, the OMHA adjudicator should grant the party a reasonable time to review the record and provide a written response.

☐ *FORM:* (non-mandatory) HHS-724 (Request to Correct, Amend, or Delete a Record(s))

ⓘ *NOTE:* When a party requests an opportunity to comment on the record, the adjudication period is tolled from the receipt of the request through the expiration of the time granted for the party's response.

See 42 C.F.R. §§ 405.1042, 423.2042.

Proffering evidence & ensuring parties are copied

The parties must be provided with copies of all evidence that will be considered by the OMHA adjudicator.

- OMHA assumes the parties have copies of the contents of the reconsideration (or equivalent) case file until they request a copy of all or part of the record, or statements or submissions by the parties suggest they may be missing a document.
  - ➢ If a party may be missing a document, the OMHA team should clarify whether the party has the document and provide a copy if appropriate.

- Parties (and participants) should copy the other parties on any submission after the request for hearing is filed (42 C.F.R. § 405.1014 controls for evidence submitted with the request for hearing).
  - If it is not clear in the record that a submission was copied to the other parties, the OMHA team must provide the appellant with an additional opportunity to clarify with the submitting party (or participant) whether the item was copied or send the request, materials, and/evidence or summary thereof to the other parties. OMHA policy is to give appellants 60 days to cure this defect.
  - If the appellant is an unrepresented beneficiary and fails to provide a certificate of service or other proof of service to another party, or it is not practical to determine whether copies were sent, the team should send the appropriate copies to the other parties.
  - If an appellant, other than an unrepresented beneficiary, fails to send a copy of the request for hearing or request for review of a QIC dismissal, any additional materials, or a copy of submitted evidence or a summary thereof after being given an opportunity to do so, the appellant's the appellant's request for hearing or request for review of a QIC dismissal should be dismissed.
- If evidence was produced at the direction of the OMHA adjudicator (for example, by an OMHA contracted expert), the OMHA adjudicator is responsible for proffering the evidence to the parties and providing a reasonable opportunity for comment (as appropriate).

See 42 C.F.R. §§ 405.1014, 405.1018, 405.1030, 423.2014, 423.1018, 423.1030.

6. What is the deal with new evidence?

When evidence may be submitted

Documentary evidence should be submitted by the parties:

- With the request for hearing;
- By the date the appellant stated it would be submitted in the request for hearing;
- Within 10 calendar days of receiving the notice of hearing;
- At the hearing;
- During a continuance of the hearing if the Administrative Law Judge identified and requested material missing evidence; or
- At a reopened (supplemental) hearing at the Administrative Law Judge's discretion.

☐ *FORM:* (non-mandatory) OMHA-115 (Filing of New Evidence)

ⓘ *NOTE:* If a party (other than an unrepresented beneficiary) submits evidence later than 10 calendar days after receiving the notice of hearing, the adjudication period is

extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

For example, if a notice of hearing is issued on March 1 for a March 30 hearing, the parties should submit any evidence they wish to have considered by March 16 (assume the notice was received 5 days after it was issued unless there is evidence to the contrary). If a party submits evidence at the March 30 hearing, the adjudication period retroactively tolls for 13 days (the time between March 16 and March 30).

ⓘ *NOTE:* The evidence provisions described in this section do not apply to oral testimony.

See 42 C.F.R. §§ 405.1014, 405.1018, 405.1030, 423.2014, 423.2018, 423.2030.

Examining evidence for good cause

Section 1869(b)(3) of the Act (42 U.S.C. § 1395ff(b)(3)) specifically limits the introduction of new evidence at the OMHA level by providers and suppliers in Part A and Part B appeals by requiring a finding that there was good cause that precluded the introduction of the evidence at or before the QIC reconsideration. This limitation is extended by regulation to beneficiaries represented by providers and suppliers, to prevent providers and suppliers from getting around the limitation by introducing new evidence in a representational capacity.

⊗ *CAUTION*: This limitation does not apply to new evidence submitted by unrepresented beneficiaries, Medicaid State agencies, CMS and its contractors, applicable plans, or beneficiaries represented by someone other than a provider or supplier in Part A and Part B appeals. It also does not apply to Part C and Part D appeals. See 42 C.F.R. § 405.1018(d)(2).

⊗ *CAUTION*: If you use SSA's compilation of the Social Security Laws website to access Title XVIII provisions, (b)(3) is not there, but it is in the official versions of the U.S. Code.

- Any new evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier in a Part A or Part B appeal must be examined to determine whether there is good cause for submitting the evidence for the first time at the OMHA level.
  - ➢ The good cause examination must occur regardless of when the evidence was submitted and regardless of whether the OMHA adjudicator requested the evidence.
  - ➢ The OMHA adjudicator determines whether there is good cause based on the circumstances of the case, such as:
    - The new evidence is material to an issue addressed in the QIC's reconsideration and the issue was not previously identified as an issue in the administrative appeal process;
    - The new evidence is material to a new issue that will be considered by the Administrative Law Judge;

- The party was unable to obtain the evidence before the QIC issued its reconsideration, but there is evidence that reasonable attempts were made;
- The party submits evidence to show that the evidence was previously submitted to the QIC or another contractor; or
- Any other circumstance where the OMHA adjudicator determines the party could not have obtained the evidence before the QIC issued its reconsideration.

- If the OMHA adjudicator finds good cause for submitting the evidence for the first time at the OMHA level, the OMHA adjudicator may consider the evidence in deciding the case.

- If the OMHA adjudicator does not find good cause for submitting the evidence for the first time at the OMHA level, the evidence is excluded from consideration in deciding the case.

  - If a hearing is conducted and the evidence was submitted prior to the hearing, the Administrative Law Judge must notify the parties of the exclusion no later than the start of the hearing.

  - If the evidence was submitted during or after the hearing, the Administrative Law Judge may notify the parties of the exclusion at a reasonable time.

ⓘ *NOTE:* The good cause determination must be made in the record. For any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination, the OMHA adjudicator's decision must include a discussion of the new evidence and the good cause determination that was made.

See 42 C.F.R. §§ 405.1018, 405.1028, 405.1030, 405.1042, 405.1046.

7. How is a case developed?

Obtaining Additional Evidence

An Administrative Law Judge may request evidence from the parties at any time before the decision is issued.

- A request for additional evidence may be sent, or if missing material evidence is identified at a hearing, it may be requested at that time.

- If the evidence is requested from a provider, supplier, or beneficiary represented by a provider or supplier, in a Part A or Part B appeal, a statement explaining why the evidence was not submitted prior to the OMHA level is required and the OMHA adjudicator must conduct a good cause examination.

See 42 C.F.R. §§ 405.1018, 405.1028, 405.1030, 423.2018, 423.2030.

Requesting Information from the QIC, QIO, or IRE

If the record is missing information that is:

- Essential to resolving the issues on appeal; and
- Can be provided only by CMS, its contractors, or the Part D plan sponsor.

  ⓘ *NOTE*: Information that is publically available via the internet or a printed location, or that is in the possession of one of the parties to the appeal, is not information that can only be provided by CMS, its contractors, or the Part D plan sponsor. This includes, but is not limited to, information available on a CMS, contractor, or plan website and information in an official CMS or HHS publication.

  ⓘ *NOTE*: Official copies of redeterminations and reconsiderations are information that can only be provided by CMS, its contractors, or the Part D plan sponsor. However, if an electronic copy of the missing redetermination or reconsideration was uploaded in MAS, the OMHA adjudicator must accept the electronic copy as an official copy, and should not issue a request for information.

Then, the OMHA adjudicator may retain jurisdiction of the case and request the missing information from the prior adjudicating entity. The entity then has 15 calendar days from receipt of the request to furnish the information or otherwise respond. If an adjudication period applies to the appeal, that period is extended by the period between when the request was sent and the date the prior adjudicating entity responds (or 20 calendar days, whichever is less).

ⓘ *NOTE*: If the missing information or a response is not received within 20 calendar days, and the request was for an official copy of a missing redetermination or reconsideration, the OMHA adjudicator may remand the case (discussed further below).

See 42 C.F.R. §§ 405.1034, 423.2034.

Subpoenas

Generally. An Administrative Law Judge may issue subpoenas for the appearance and testimony of witnesses; and for a party or Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying.

☐ *FORM:* OMHA-140 (Subpoena)

- An Administrative Law Judge may issue a subpoena on her or his own motion.
- An Administrative Law Judge may issue a subpoena at the request of a party, but only when:

  (1) Discovery has been initiated in the case;
  (2) The party filed a motion to compel;

(3) The Administrative Law Judge granted the motion to compel;
(4) The requested discovery has not been produced pursuant to the motion to compel; and
(5) The party's request:

(a) Is in writing;
(b) Identifies the witness or document;
(c) Sufficiently identifies the address or location of the witness or document to find them;
(d) States the important facts the witness or document is expected to prove;
(e) Explains why the important facts can't be proven without subpoenaing the witness or document; and
(f) Is filed no later than the end of the discovery period established by the Administrative Law Judge.

⊗ *CAUTION:* An Administrative Law Judge may not on his or her own motion, or at the request of a party, issue a subpoena to CMS or its contractors to compel an appearance, testimony, or the production of evidence. For Part D appeals, section 423.2036 also provides that the Part D plan sponsor cannot be compelled to appear or testify, but an Administrative Law Judge may issue a subpoena to the Part D plan sponsor for the production of material books, records, correspondence, papers, or other documents.

See 42 C.F.R. §§ 405.1036, 423.2036.

Interlocutory Appeals of Subpoena Rulings. An Administrative Law Judge ruling on a subpoena request generally may only be reviewed during the course of the Council review of the claim at issue. However, an interlocutory Council review of a subpoena (or any portion thereof) may occur when an Administrative Law Judge overrules an objection to a subpoena where the basis of the objection is that the subpoena:

(1) Compels disclosure of material protected from disclosure, such as privileged or confidential material; or
(2) Presents an undue burden.

- When the Administrative Law Judge is notified that a party (or non-party) intends to seek an interlocutory Council review of the subpoena, the proceedings affected by the subpoena are stayed.

- Upon notice that a party or non-party intends to seek Council review of the subpoena, the Administrative Law Judge must stay the proceedings affected by the subpoena (or the portion of the subpoena if only a portion will be reviewed by the Council) until the Council issues a written decision on the Administrative Law Judge's action.

- The Administrative Law Judge determines the initial length of the stay for the party (or non-party) to seek Council review but must make the stay at least 15 calendar days from the day the Administrative Law Judge received notice of the intent to seek review.

- If the Council does not grant the review request or review the Administrative Law Judge action on its own motion within the time allotted by the Administrative Law Judge for the stay to seek review, the stay is lifted and the Administrative Law Judge's action stands.

Enforcement of Subpoenas. If the Administrative Law Judge determines that a party or non-party has refused to comply with a subpoena, the Administrative Law Judge may request the Secretary to consider enforcing the subpoena in accordance with § 205(e) of the Act.

- A request for enforcement must:
  - Be written;
  - Describe in detail the Administrative Law Judge's findings of non-compliance;
  - Describe in detail the Administrative Law Judge's specific request for enforcement;
  - Include a copy of the subpoena;
  - Include evidence the party (or non-party) subject to the subpoena received it by certified mail; and
  - Be sent with the related documents to the party (or non-party) subject to the subpoena, the other parties in the case, and any affected non-parties.
- Requests for enforcement are routed through the office Associate Chief Administrative Law Judge, then to the OMHA Program Evaluation and Policy Division for Department review.

See 42 C.F.R. §§ 405.1036, 423.2036.

Discovery

Generally. Discovery is only permitted when CMS or a contractor is a party in the case.

ⓘ *NOTE:* Discovery is not permissible when CMS or a contractor elects, or requests and is granted, non-party participant status.

Scope of Discovery. The Administrative Law Judge may permit discovery on matters that are relevant to the issues being considered by the Administrative Law Judge, provided:

- The matters are not privileged or otherwise protected from disclosure; and
- The Administrative Law Judge determines the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate.

Length of Discovery. When a party seeks discovery, the Administrative Law Judge establishes a time limit to request discovery and a time limit to conduct discovery.

- All requests for discovery must be received by the party subject to the request no later than the date specified by the Administrative Law Judge for requesting discovery.

- All discovery must be completed by the date specified by the Administrative Law Judge for conducting discovery.
- Extensions to the discovery time limits may be granted by the Administrative Law Judge upon request of a party and after a reasonable opportunity is provided for the other parties to respond to the request.
- Discovery must be completed at least 45 calendar days before the hearing.

Limitations on Discovery. Discovery is limited by the requirements of 42 C.F.R. § 405.1037 and any additional limits placed on it by the Administrative Law Judge.

- A party may request the reasonable production of documents by another party for inspection and copying.
- A deposition may only be taken if:
  (1) The proposed deponent agrees to the deposition; or
  (2) The Administrative Law Judge finds the deposition is necessary and appropriate to secure the deponent's testimony.
- A party may not request admissions.
- A party may not send interrogatories.
- A party may make a motion to compel discovery or a motion for a protective order from discovery (the other parties may file a response to any such motion).
  - A motion to compel or response to a motion to compel must describe the party's efforts to resolve or narrow the discovery dispute.
  - The Administrative Law Judge must rule on the motion and send the ruling to the parties.
  - In the ruling, the Administrative Law Judge may grant or deny the motion in whole or in part, and may impose any additional limitations on discovery that the Administrative Law Judge deems necessary and appropriate.

Interlocutory Appeals of Discovery Rulings. An interlocutory Council review of a discovery or disclosure ruling (or any portion thereof) may occur when the party seeking review believes the ruling:

(1) Authorizes discovery or disclosure of privileged or confidential material; or
(2) Presents an undue burden.

- When the Administrative Law Judge is notified that a party intends to seek an interlocutory Council review of the ruling, the ruling is stayed.

- The Administrative Law Judge determines the initial length of the stay for the party to seek Council review but must make the stay at least 15 calendar days from the day the Administrative Law Judge received notice of the intent to seek review.
- Upon notice that a party intends to seek Council review, the Administrative Law Judge must stay all proceedings affected by the ruling.
- If the Council does not grant the review request or review the ruling on its own motion within the time allotted by the Administrative Law Judge for the stay to seek review, the stay is lifted and the ruling stands.

See 42 C.F.R. § 405.1037.

OMHA procured experts

Generally. OMHA may obtain an expert to aid in the adjudication of an appeal when an Administrative Law Judge determines an expert is necessary to adjudicate the matters on appeal (for example, a statistical expert may be helpful to address issues related to how a sample and extrapolation were conducted).

- Experts may be used to provide oral testimony during the hearing, to answer written questions for the record, and/or to perform tasks related to their expertise, such as conducting a statistical sample.
- The OMHA Expert Witness Procurement (EWP) system must be used to obtain an expert.

When Expert Will Not Be Present at the Hearing. When an OMHA-procured expert will not be available for testimony at a hearing (either due to the expert's unavailability or because a hearing will not be held in the case), the parties must be provided with opportunities to:

(1) Provide comments and suggestions on any questions asked of the expert;
(2) Respond to the expert's responses to any questions asked of the expert; and
(3) Request follow-up questions be posed to the expert.

- When interrogatories are used:
  - The proposed interrogatories must be proffered to the parties with a reasonable opportunity for comments and suggestions.
  - The Administrative Law Judge must consider the comments and suggestions but retains discretion to determine the most appropriate interrogatories to pose to the expert. If changes are made to the interrogatories, they must be proffered again before being sent to the expert.
  - The expert's responses must be proffered to the parties with a reasonable opportunity for comments and the ability to request follow-up questions or clarifications from the expert.

- The Administrative Law Judge must consider the parties' comments and requests but retains discretion to determine their appropriateness and value to the proceedings.

When Experts Will Be Present at the Hearing. When an expert will be available for questioning at the hearing, responses to any interrogatories must be proffered to the parties.

- The hearing will provide the parties with an opportunity to object to questions asked of the expert, ask additional questions of the expert, and ask follow-up questions to the expert's responses.

8. Does it have to go to a hearing?

In general, a hearing is required to adjudicate a request for hearing unless the request is dismissed or remanded, or a decision can be issued based on the record. See OCPM II-7-1.

ⓘ *NOTE:* Recall that a hearing does not have to be conducted to adjudicate a request for a review of a dismissal issued by a prior adjudicating entity (even if the appellant filed a request for a hearing in appealing the dismissal).

Decisions on the record (fully favorable)

If a decision that is fully favorable to the appellant on every issue can be made based on the record alone, and no other party to the appeal is liable for claims at issue, the decision can be issued without conducting the hearing.

See 42 C.F.R. §§ 405.1038, 423.2038.

On-the-record decisions (hearing waived)

If all of the parties who would be sent a notice of hearing waive the oral hearing (for example, the appellant and a non-appellant party who was held liable for the denied claim after the initial determination), the decision can be issued without conducting the hearing (regardless of the outcome).

☐ *FORM:* (non-mandatory) OMHA-104 (Waiver of Right to an Administrative Law Judge (ALJ) Hearing)

- Even if the parties have waived the oral hearing, an Administrative Law Judge may still conduct the hearing if he or she believes a hearing is necessary to decide the case.
- The parties have the right to withdraw the waiver of the oral hearing. If a waiver is withdrawn before a decision is issued, a hearing must be scheduled (unless a fully favorable decision can be issued on the record alone).

  ☐ *FORM:* (non-mandatory) OMHA-114 (Withdrawal of Waiver of Right to an Administrative Law Judge (ALJ) Hearing

⊗ *CAUTION:* The appellant may not be the only party who would be sent a notice of the hearing, thus additional inquiry is needed when an appellant waives the oral hearing.

See 42 C.F.R. §§ 405.1038, 423.2038.

On-the-record decisions (appellant outside the United States)

A decision based on the record alone may be issued if the appellant lives outside the United States and does not state that he or she wishes to appear for a hearing, and no other parties who would be sent a notice of hearing (for example, a non-appellant party who participated in the reconsideration or was held liable for the denied claim after the initial determination) want to appear at the hearing.

ⓘ *NOTE:* The "United States" in this instance includes the 50 states and Puerto Rico, the U.S. Virgin Islands, the District of Columbia, American Samoa, the Northern Mariana Islands, and Guam).

See 42 C.F.R. §§ 405.1038, 423.2038.

On-the-record decisions (stipulated decisions)

If CMS or a contractor submits a written statement, or makes an oral statement at a hearing, indicating an item or service should be covered or payment should be made, an OMHA adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on this basis. No findings of fact, conclusions of law, or further explanation of the reasons for the decision are required.

ⓘ *NOTE:* If the amount of payment is an issue before the OMHA adjudicator, the statement from CMS or a contractor must also agree to the amount of payment the parties believe should be made.

Dismissing the request for hearing

If a request for a hearing is going to be dismissed, a hearing does not have to be conducted.

- However, an Administrative Law Judge may conduct a hearing if he or she wishes.

See 42 C.F.R. §§ 405.1046, 423.2046.

Remands

If a request for a hearing is going to be remanded, a hearing does not have to be conducted.

- However, an Administrative Law Judge may conduct a hearing if he or she wishes.

9. What happens if it does need to go to a hearing?

Consolidated hearing

Before scheduling a hearing, consider whether the appellant has other requests for hearing pending before the same Administrative Law Judge, and if so, whether a consolidated hearing on those requests would be appropriate.

- A consolidated hearing may be held for multiple cases when the cases are before the same Administrative Law Judge and one or more of the issues in the cases are the same. The Administrative Law Judge should consider the efficiency of conducting a consolidated hearing and the adjudication deadlines of the cases involved.
- A consolidated hearing may only be held for appeals that were filed by the same appellant, unless multiple appellants aggregated claims to meet the minimum AIC requirement and all beneficiaries have authorized disclosure of their PII and PHI to the other parties and participants.
- An appellant may request a consolidated hearing. The Administrative Law Judge may require the appellant to waive the adjudication deadline for one or more appeals as a condition of granting the request if the Administrative Law Judge determines that consolidation would otherwise prevent the Administrative Law Judge from timely deciding all of the appeals at issue. See 42 C.F.R. § 405.1044(a)(2),CJB 11-003.
- An Administrative Law Judge may conduct a consolidated hearing on her or his own motion. However, if the consolidation is done on the Administrative Law Judge's own motion, the Administrative Law Judge may *not* require the appellant to waive the adjudication time frame.
- If a consolidated hearing is conducted, the Administrative Law Judge must determine how the decision and administrative records in the cases will be maintained:
  - The records may be separately maintained and separate decisions issued; or
  - The records may be consolidated and a single decision issued.
  - ⓘ *NOTE:* The rules do not explicitly permit a consolidated decision without a consolidated record, and vice versa ("make either a consolidated decision *and* record or a separate decision *and* record").
- The Administrative Law Judge must issue a notice of consolidated hearing.
  - The notice should inform the parties and CMS contractors of the case numbers that will be heard together (and, in the case of a consolidated decision and record, the case number by which the appeal will proceed).

- The notice of consolidated hearing must be sent with or as part of the notice of hearing.
- If appeals are consolidated for hearing, but the Administrative Law Judge elects to maintain separate administrative records, a single notice of hearing may be issued for the consolidated hearing. Notice of the consolidated hearing must be provided with the notice of hearing, and the notice of hearing (or an attachment thereto) must list the individual appeal numbers involved in the consolidated hearing. *See* OCPM I-6-C for further information on notices of consolidation.
- Where possible, staff should group the information by MAC jurisdiction prior to issuing the consolidated hearing notice so the notice of hearing can be timely transmitted to the respective MACs (redaction of PII is necessary). See OCPM II-7-3.

  Example. The Administrative Law Judge decides to consolidate hearings for a nationwide DME supplier, and the claims arise from multiple MACs because the subject beneficiaries reside in different jurisdictions. The beneficiaries' claims should be grouped and identified by MAC on the consolidated hearing notice.

ⓘ *NOTE:* When a notice of hearing is sent to an individual beneficiary or to any other party to a consolidated or multiple-beneficiary hearing that is not authorized to receive PII for all of the beneficiaries involved, the notice of hearing must be redacted to display only the information pertaining to that beneficiary or party.

If the decision and administrative record will be consolidated, the MAS and administrative records must be combined. A single OMHA appeal number will be used to identify the case, and notices must reflect that appeal number.

If the decision and administrative record will not be consolidated, common evidence must be copied and placed in each record, and the consolidated hearing recording must be labeled appropriately (including a warning that it contains PII from other appeals) and a copy of the recording placed in each record.

- Care should be taken during the hearing to clearly identify when statements and testimony are general in nature or specific to an individual case to assist in identifying when individual appeals are being discussed.

ⓘ *NOTE:* For cases involving one or more of the same issues that are before an OMHA adjudicator and will be decided without a hearing, the OMHA adjudicator may make a consolidated decision and record at the request of the appellant or on the OMHA adjudicator's own motion.

See 42 C.F.R. §§ 405.1044, 423.2044; CJB 11-005.

Prehearing conferences

A prehearing conference may be conducted to facilitate the hearing (for example, refine the factual disputes and issues for a more efficient hearing).

- A conference may be held on the Administrative Law Judge's own motion or at the request of a party.
- Conferences should not be used to take testimony and resolve factual disputes.
- Conferences may be conducted by the Administrative Law Judge or by an OMHA attorney.

  ⊗ *CAUTION*: Although an OMHA attorney advisor may conduct a conference for a case that is assigned to an Administrative Law Judge, an attorney adjudicator may not conduct a conference for a case that is assigned to the attorney adjudicator because there is no hearing to facilitate.

A notice of prehearing conference must be sent (or faxed if a party requests a facsimile) to the parties who will be noticed for the hearing.

- The notice of prehearing conference must inform the parties of the:
  - Time of the conference;
  - Place of the conference; and
  - Purpose of the conference.

☐ *FORM:* OMHA-153 (Notice of Prehearing/Posthearing Conference)

- The parties must be informed of the conference at least 7 calendar days before the conference.

  ⓘ *NOTE:* Assuming 5 calendar days for delivery by mail, the notice of prehearing conference should be sent at least 12 calendar days before the conference.

  ⓘ *NOTE:* The regulations do not require sending notice to CMS or a contractor unless they are parties at the time of the conference, but the Administrative Law Judge may elect to do so.

An Administrative Law Judge (but not an OMHA attorney) may consider matters beyond the stated purpose of the conference if the parties consent, either before or during the conference, and the consent is reduced to writing.

An audio recording of the conference must be made part of the administrative record.

The Administrative Law Judge must issue a prehearing conference order that states all of the agreements and actions that result from the conference.

☐ *FORM:* OMHA-154 (Prehearing/Posthearing Conference Order)

- The Administrative Law Judge must proffer the order to the parties and provide them an opportunity to object to the order, or portions thereof.
- If the parties do not object to the prehearing conference order within 10 calendar days of receipt, or any additional time granted by the Administrative Law Judge, the order becomes binding on all parties.

Scheduling hearings

Generally. Hearings may be scheduled with or without party input as to the date and time of the hearing (that is, a coordination call may be made before scheduling the hearing if the Administrative Law Judge so requires).

- The notice of hearing must be mailed, or otherwise transmitted, at least 20 calendar days before the hearing date to the parties and other potential participants at their last known address. A waiver of the 20 calendar day requirement may be obtained, if necessary, but note that the waiver only applies to that individual or entity (for example, the waiver does not limit a CMS contractor's right to elect party or participant status within 10 calendar days after receiving a notice of hearing).
- Sufficient time after the hearing must be provided to allow for the decision instructions and decision to be drafted and signed before any applicable adjudication time frame elapses.

Place of Hearing (Hearing Format). The "place of hearing" is where the hearing will occur for the parties, and the place may not be the same for all parties and witnesses.

- If a video-teleconference (VTC) hearing is conducted, it is the physical site of the VTC vendor.
  - VTC is the default format for appearances by unrepresented beneficiaries and if VTC technology is available, it must be provided if it is requested in the request for hearing, or in an objection to a telephone format.
  - For appearances by other individuals, VTC may be provided if the Administrative Law Judge determines that VTC is necessary to examine the facts or issues in the appeal.
  - Certain travel expenses for the parties may be covered if the VTC site is more than 75 miles from the party.
- If an in-person hearing is conducted, it is the physical site of the hearing (for example, an OMHA field office).
  - In-person hearings may be conducted if VTC and telephone technology are not available (or, in the case of an unrepresented beneficiary, VTC or telephone technology is not available) or the Administrative Law Judge determines the circumstances of the case make an in-person hearing necessary.

- An in-person hearing in an OMHA field office is generally permitted, provided the parties agree to travel at their own expense and security is available in the office on the hearing date (check with the Hearing Office Director).
- An in-person hearing at a remote site requires the concurrence of the office Associate Chief Administrative Law Judge. Certain travel expenses for the parties may be covered if the hearing site is more than 75 miles from the party.

- If a telephone hearing is conducted, it is the phone number (where the party chooses to be at the time of the hearing will be up to the party).
  - A telephone hearing is the default format for appearances by all appellants other than unrepresented beneficiaries. For all other appellants, a telephone hearing may be "offered" by initially scheduling the hearing by VTC, unless the request clearly conveys that another format is desired.

Time of Hearing. Hearings must be scheduled with a specific start time that must be within normal business hours for the parties and any representatives, unless all parties and representatives who will be appearing agree to other times before the hearing is scheduled.

- Normal business hours are 8:00 a.m. to 4:30 p.m. in the time zone where the party or representative is appearing. Where there are parties or representatives in multiple time zones who will be appearing, every effort will be made to ensure that the hearing is scheduled within normal business hours in all time zones. See OCPM II-7-1.
- Non-specific start times (for example, advising appellants that a hearing will begin sometime between 8:00 a.m. and 4:00 p.m.) are not permitted, as 5 U.S.C. § 554(b) requires that the convenience and necessity of the parties or their representatives is considered when setting the time, place, and nature of the hearing.

See 42 C.F.R. §§ 405.1000, 405.1020, 423.2000, 423.2020.

Notice of hearing

A notice of hearing must be issued using the approved OMHA notice of hearing form.

☐ *FORM:* OMHA-1024T (Notice of Hearing) or OMHA-624T (Notice of Expedited Part D Hearing)

- The form contains standard language designed to satisfy legal requirements (such as informing parties that they may designate a representative, they should respond by acknowledging the notice of hearing, how to object to the issues or time and place of the hearing, and the request may be dismissed if the appellant or representative fails to appear at the hearing), but additional information specific to the appeal must be added to:
  - Inform the parties of the date and time of the hearing;

- Inform the parties of the "place" of the hearing (if a VTC site, that must be indicated as the place for the individual party);
- State the general issues and any specific new issues to be decided in the case; and
- Inform the parties that an expert witness will be called by the Administrative Law Judge, if applicable.

- The notice of hearing must be sent with:
  - A response to the notice of hearing
    - ☐ *FORM:* (non-mandatory) OMHA-102
  - The OMHA Travel Policy, if the party is travelling to a location for the hearing.
    - ☐ *FORM:* OMHA-026
  - Information on VTC hearings, when the hearing will be conducted via VTC
    - ☐ *FORM:* OMHA-025
  - A copy of the exhibit list should be sent with the notice of hearing.
    - ☐ *FORM:* OMHA-156
    - ⓘ *NOTE:* If the exhibit list is not sent with the notice of hearing, it should be sent at the first available opportunity before the hearing to provide the parties and participants with sufficient time to review and, if necessary, request any documentary evidence they do not have.

A notice of the hearing must be sent to:

- The parties (recall, that includes the MAO in Part C appeals), unless the party did not participate in the reconsideration and was not found liable after the initial determination. Put in a positive manner, the notice of hearing must be sent to:
  - Any party who filed a request for hearing;
  - Any party who participated in the reconsideration (for example, the party requested the reconsideration);
  - Any party who has been found liable for the items or services at the redetermination or reconsideration level (regardless of whether the party requested an appeal at any level);
  - Any party whose interest may be adversely affected by the outcome of the case (that is, a party who may be potentially liable based on the Administrative Law Judge's initial review of the case file even when liability had not previously been imposed on the party subsequent to the initial determination);

  ⊗ *CAUTION:* Whether a notice of hearing has to be sent to a party does not impact their status as a party or right to a hearing. If they evidence a desire for a hearing,

they should be included in the hearing. Ultimately, the Council could remand an appeal for a new hearing if a party is not provided with an opportunity for a hearing.

- CMS contractors and plans, depending on the type of appeal;
  - For Part A and Part B claim appeals, the notice must be sent to the QIC or QIO that issued the reconsideration (or if escalated from a QIC, the QIC with which the request for reconsideration was filed), as well as CMS or a contractor that elected to participate in the proceedings within 30 calendar days after notification that a request for hearing had been filed. For Part D coverage determination appeals, the notice must be sent to the IRE and Part D plan sponsor.

ⓘ *NOTE*: The Administrative Law Judge may also, at his or her discretion, send the notice to other CMS contractors if the Administrative Law Judge believes they would be helpful or is requesting their participation in the hearing (for example, the PSC or ZPIC that conducted the statistical sampling in an overpayment appeal).

- Expert witnesses whose services the Administrative Law Judge has procured (following OMHA's policy on the use and disclosure of PII); and
- Any other participant whose presence at the hearing is requested by the Administrative Law Judge.

The notice of hearing is mailed to the parties and other potential participants at their last known address, given by personal service, or otherwise transmitted at least 20 calendar days before the hearing. However, notice does not have to be sent to a party or potential participant who indicates in writing that it does not wish to receive this notice.

ⓘ *NOTE:* The rules only require the notice to be *sent* at least 20 days before the hearing, the parties do *not* have to *receive* the notice 20 days before the hearing.

- A waiver of the notice of hearing or the 20-day notice period may be made, but must be in writing and made part of the record, and it only applies to the individual or entity who waived the notice or 20-day period.

  ☐ *FORM:* OMHA-142 (Waiver of 20-Day Advance Written Notice of Hearing)

  ☐ *FORM:* (non-mandatory) OMHA-104 (Waiver of Right to an Administrative Law Judge (ALJ) Hearing)

  ⊗ CAUTION: A waiver is effective *only* for the waiving party—a waiver does not impact the rights of the other parties or potential parties or participants.

- Notices may be faxed if the party or representative requests that the notice is sent by facsimile. To protect PII, the contact should be called to alert them that the fax is being sent immediately before it is sent. A confirmation of a successful transmission should be maintained in the record.

42 C.F.R. §§ 405.1020, 405.1022, 423.2020, 423.2022.

Responses to the notice of hearing

Generally. Each party who is sent a notice of hearing should file a response to the notice of hearing within 5 days after receipt, to acknowledge the notice and, if applicable, object to the time or place of the hearing, the issues, or other information contained in the notice.

☐ *FORM:* (non-mandatory) OMHA-102 (Response to Notice of Hearing)

- If the appellant or any party to the reconsideration, or a representative thereof, does not file a response to the notice of hearing, the Administrative Law Judge must attempt to contact the party or representative for an explanation why a response was not filed. Failure to acknowledge a notice of hearing is not a basis to dismiss a request for hearing.

ⓘ *NOTE:* CMS and its contractors and plans are not required to file a response unless they have elected party status.

ⓘ *NOTE:* Assume the party received the notice 5 days after it was sent unless there is evidence to the contrary.

Objection to the time or place. If a party objects to the time or place (which includes the format) of the hearing, the party must notify the Administrative Law Judge at the earliest opportunity before the hearing. The notification must:

  - Be in writing;
  - State the reason(s) for the objection; and
  - Provide a preferred time or place (or format).

- Upon notification of an objection to the time or place of the hearing, the Administrative Law Judge should evaluate the request, the facts, and the impact on the hearing process to determine if good cause exists to change the time or place.

  ➢ Reasons that could support a good cause finding include, but are not limited to:

    - The party or the party's representative is unable to attend or travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family;
    - Severe weather conditions make it impossible to travel to the hearing;
    - The party has attempted to obtain a representative but needs additional time;
    - The party's representative was appointed within 10 calendar days of the scheduled hearing and needs additional time to prepare for the hearing;
    - The party's representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;
    - A witness who will testify to facts material to a party's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;
    - Transportation is not readily available for a party to travel to the hearing;

- The party is unrepresented and is unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language);
- The party or representative has a prior commitment that cannot be changed without significant expense; or
- The party or representative asserts that he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

ⓘ *NOTE:* If the hearing is rescheduled at the request of a party with good cause, the adjudication time frame is tolled for the time between the original hearing date and the rescheduled hearing date.

- If a party objects to a VTC or telephone hearing and requests an in-person hearing, the Administrative Law Judge may grant the in-person hearing with a finding of good cause and the concurrence of the office Associate Chief Administrative Law Judge.

- If an unrepresented beneficiary objects to an initial offer of a telephone hearing and instead requests a VTC hearing, the VTC hearing must be granted because VTC is the default hearing format and a telephone hearing may only be offered, not required, where the appellant is an unrepresented beneficiary.

- If a party other than an unrepresented beneficiary objects to a telephone hearing and requests a VTC hearing, the Administrative Law Judge may grant the request with a finding of good cause.

ⓘ *NOTE*: 42 C.F.R. § 405.1020(i)(5) requires the concurrence of the Chief Administrative Law Judge (which is delegated to the office Associate Chief Administrative Law Judge) to grant a request for VTC hearing when an appellant other than an unrepresented beneficiary objects to a telephone hearing, but this is inconsistent with the general standard for determining how appearances are made in 42 C.F.R. § 405.1020(b)(2)(i). Therefore, the more flexible standard (no concurrence is required) is used.

Objections to the Issues. If a party objects to the issues stated in the notice of hearing, the party must notify the Administrative Law Judge at the earliest possible opportunity before the time set for the hearing, but no later than 5 calendar days before the hearing. The notification must:

- Be in writing;
- State the reason(s) for the objection; and
- Be copied to the other parties who were provided with notice of the hearing.

- Upon notification of an objection to the issues, the Administrative Law Judge must make a decision on the objection in writing, or on the record at a prehearing conference or at the hearing.

Amended Notice of Hearing. When a party has not responded to the notice of hearing and an inquiry reveals the party did not receive the notice of hearing, a copy of the notice must be issued by certified mail or other means requested by the party and authorized by OMHA procedures.

ⓘ *NOTE:* The hearing may have to be rescheduled if the copy of the notice will be sent fewer than 20 calendar days before the hearing, unless a waiver of the 20 calendar day notice period can be secured from the party. Rescheduling the hearing under these circumstances does *not* toll the adjudication time frame.

- If a hearing is rescheduled or the place of the hearing is changed, an amended notice of hearing must be sent to the parties who received the notice of hearing and any potential party or participant that elected party or participant status pursuant to the initial notice.

  ⓘ *NOTE:* If a hearing is rescheduled, the regular notice of hearing requirements would apply to the amended notice, including mailing the notice at least 20 calendar days before the hearing and requiring a response to the notice.

See 42 C.F.R. §§ 405.1010, 405.1012, 405.1020, 405.1022, 405.1024, 423.2010, 423.2020, 423.2022, 423.2024.

10. What happens at and after the hearing?

Conducting the hearing

Who May Be Present. The hearing is generally open to:

- The parties (including the MAO in Part C appeals, and CMS or contractors that elected party status);
- Party representatives;
- Witnesses called by a party;
- Witnesses called by the Administrative Law Judge (for example, an OMHA expert); and
- CMS, CMS contractors, plans as participants.

- OMHA staff necessary for the hearing proceedings or case processing may also be at the hearing (for example, a legal assistant or the attorney or paralegal who will be drafting the decision).

- If a party requires assistance or monitoring by a caregiver during the hearing, the Administrative Law Judge should use discretion in determining whether the caregiver may be privy to the hearing proceedings.

⊗ *CAUTION:* All parties and witnesses may not have a right to be present for all portions of the hearing.

- When an individual beneficiary's claim is being discussed, parties and witnesses who do not have an interest or authorization to be present for that portion of the hearing should be temporarily excused from the hearing.
- Contractors should only be part of the hearing for claims that the contractor (or the predecessor contractor in the jurisdiction) reviewed or adjudicated—for example a MAC for a jurisdiction may not be part of the hearing for a claim that was processed and adjudicated by another MAC.

Introductory Statement. Though there is no standard script for hearing proceedings, a hearing should generally begin with:

- The title of the case and case number;
- If necessary and as appropriate, a brief explanation of the Administrative Law Judge hearing process, the purpose of the hearing, and acknowledgement that, unless specifically allowed by regulation, a decision will not be made at the hearing but rather will be made by a written decision based upon the documentary record and the testimony provided at the hearing;
- Any preliminary instructions on the course of the hearing and expected decorum during the hearing;
- A roll call of those present for the hearing and, as applicable, those that will be present for some portion of the hearing (for example, a witness that is not present for the introductory statement but will be present at some point during the hearing); and
- As applicable, the Administrative Law Judge's decision on any matter that may affect the course of the hearing (for example, whether there is good cause for the late submission of evidence by a provider or supplier).

- In consolidated hearings when the administrative record will not be consolidated:
  - The introductory statement should include a description of the consolidation, including the case numbers that will be heard during the course of the hearing and when common testimony is expected to be given; and
  - As the consolidated hearing transitions from discussing the claims involved in a specific case to those involved in another, a brief statement noting the title of the case and the individual case number should be read into the record.

Statement of Issues. After the introductory statement is made, it may be helpful to focus the hearing by restating the issues that will be considered by the Administrative Law Judge (that is, restate the issues stated in the notice of hearing).

- If any prehearing case development clarified the issues, such as a prehearing conference, it may be useful to restate those understandings.

- In consolidated hearings where the administrative record and decision will not be consolidated, and if the specific issues vary from case to case, the issues may need to be restated in the transitional statement.

See 42 C.F.R. §§ 405.1030, 405.1036, 423.2030, 423.2036, 405.1044, 423.2044.

Overview of Exhibits/Evidence to Be Admitted into the Record. To help ensure all parties have an understanding of the documentary evidence that may be considered by the Administrative Law Judge in making the decision, it may be useful to briefly review the administrative record and exhibit list with the parties and ask whether the parties have copies of the evidence or any objections to the contents of the record.

- In consolidated hearings where the administrative record and decision will not be consolidated, it may be more efficient to briefly discuss the records of the constituent cases generally at the opening of the consolidated hearing.
  - If there are specific issues or questions regarding an individual case, discussion of that may be better left to the portion of the consolidated hearing that deals with the individual case.

Parties at the Hearing. The parties have a right to present evidence and state their positions, either directly or through a representative.

- In general, parties should be permitted to make a general opening statement of their position and arguments, and then be allowed to present their witnesses or request the introduction of new evidence.
  - The Administrative Law Judge may determine how and when the parties may present evidence and state their positions, and place reasonable limits on the parties' presentations.
  - While the parties should be permitted to present their case, the Administrative Law Judge may find it useful to ask questions to focus on the areas that are at issue in the appeal.
  - The Administrative Law Judge may limit testimony and/or argument that are irrelevant to the issues before the Administrative Law Judge, that are repetitive of evidence or testimony already on record, or that relate to an issue that has been sufficiently developed or on which the Administrative Law Judge has already ruled.
  - The Administrative Law Judge may excuse from the hearing a party or representative that is uncooperative, disruptive, or abusive during the course of the hearing after an initial warning. The excused party or representative must be provided with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and may request a recording of the hearing in order to

respond in writing to statements made by other parties or participants and/or testimony of the witnesses at the hearing.

- Parties that waive their right to appear at an oral hearing do not waive their right to a hearing or their right to receive notice of the hearing.
  - An appellant may withdraw her or his waiver of appearance at any point before the decision is issued.
  - A non-appellant party may withdraw her or his waiver of appearance up to the date of the hearing.

See 42 C.F.R. §§ 405.1000, 405.1010, 405.1012, 405.1030, 405.1036, 423.2000, 423.2010, 423.2030, 423.2036, 405.1044, 423, 2044.

Non-Party Participants at the Hearing. As a participant, CMS, a contractor, or a Part D plan sponsor may file position papers and provide testimony to clarify factual or policy issues, though representatives of the agency or contractor may not be called as witnesses, except under very limited circumstances when CMS or a contractor is precluded from attending the oral hearing, but is called as a witness by CMS or another contractor that is a party to the hearing, in which case the precluded entity may be cross-examined by the other parties.

- As a non-party participant, they may not call or cross-examine witnesses and may not be permitted to question the parties.
- As a non-party participant, they may not be called as a witness during the hearing (the Administrative Law Judge may ask them questions, but parties should not).

Witnesses. All witnesses, whether called by the parties or the Administrative Law Judge should take an oath or affirm they will tell the truth under penalty of perjury.

- Parties and representatives may need to be sworn in if their presentation includes asserting facts not in the record. Merely restating the facts in the record or advancing arguments will generally not require a party or representative to be sworn in. Nevertheless, to avoid a later question it is recommended that parties and representatives be sworn in.
- All witnesses, whether called by the parties or the Administrative Law Judge, are subject to direct examination by the party who called the witness, cross-examination by the other parties, and questioning by the Administrative Law Judge. Redirect and re-cross examination should be permitted as appropriate.
- CMS and its contractors that have elected participant status may not call witnesses or question the witnesses, nor may they be treated as witnesses (questions to participants should be posed only by the Administrative Law Judge).
- The Administrative Law Judge may elect to limit witness participation in the hearing proceedings to the witness' testimony. When excusing a witness, the Administrative Law

Judge may elect to excuse the witness subject to recall pending later testimony or arguments in the hearing.

- When the record does not clearly establish that an "expert witness" qualifies as an expert, expert status should be established at the hearing. With sufficient information in the record and parties or representatives more familiar with the hearing process, the Administrative Law Judge may find it more efficient to ask the parties to stipulate the witness qualifies as an expert.

New Evidence Submitted at the Hearing. New documentary evidence may be submitted at the hearing.

- The Administrative Law Judge may request material evidence that is not in the record during the hearing. If the evidence cannot be readily produced during the course of the hearing, the Administrative Law Judge may stop the hearing and provide the parties with an opportunity to produce the evidence.

- In Part A and Part B appeals of QIC reconsiderations, new evidence submitted at the hearing—even if requested by the Administrative Law Judge—is subject to a good cause showing for evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier.

ⓘ *NOTE:* The new evidence limitation for providers, suppliers, and beneficiaries represented by providers or suppliers does not extend to oral testimony.

Stipulations. Stipulations may be used to make the hearing process more efficient when there is no disagreement among the parties on a factual issue (for example, the parties may agree an OMHA expert witness qualifies as a witness based on a review of the witness' résumé.)

- Stipulations should be limited to cases in which the parties or their representatives have an appreciation of the effect of a stipulation. For parties or representatives who are less familiar with the hearing process, the Administrative Law Judge may choose to explain the effect before allowing a stipulation of facts.

- If CMS or a contractor submits a written statement, or makes an oral statement at a hearing, indicating an item or service should be covered or payment should be made, an OMHA adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on this basis alone.

Continuing the Hearing. Hearings may be continued to develop the record (for example, when an Administrative Law Judge requests evidence during the course of a hearing) or to provide parties with additional time, at the Administrative Law Judge's discretion.

ⓘ *NOTE:* When a hearing is continued based on a request from a party, the adjudication time frame is not tolled, but the Administrative Law Judge may request a waiver of the

adjudication time frame from the appellant or require the appellant to formally request a rescheduled hearing.

See 42 C.F.R. §§ 405.1000, 405.1010, 405.1012, 405.1018, 405.1028, 405.1030, 405.1036, 423.2000, 423.2010, 423.2018, 423.2030, 423.2036.

Posthearing conferences

A posthearing conference may be conducted to facilitate the hearing decision (for example, clarify the issues for decision).

- A conference may be held on the Administrative Law Judge's own motion or at the request of a party.
- Conferences should not be used to take testimony and resolve factual disputes.
- Conferences may be conducted by the Administrative Law Judge or by an OMHA attorney.

  ⊗ *CAUTION*: Although an OMHA attorney may conduct a conference for a case that is assigned to an Administrative Law Judge, an attorney may not conduct a conference for a case that is assigned to the attorney adjudicator because there is no hearing decision to facilitate.

A notice of posthearing conference must be sent (or faxed if a party requests a facsimile) to the parties who were noticed for the hearing.

- The notice of posthearing conference must inform the parties of the:
  - Time of the conference;
  - Place of the conference; and
  - Purpose of the conference.

☐ *FORM:* OMHA-153 (Notice of Prehearing/Posthearing Conference)

- The parties must be informed of the conference at least 7 calendar days before the conference.

  ⓘ *NOTE:* Assuming 5 calendar days for delivery by mail, the notice of posthearing conference should be sent at least 12 calendar days before the conference.

  ⓘ *NOTE:* The regulations do not require sending notice to CMS or a contractor unless they are parties at the time of the conference, but the Administrative Law Judge may elect to do so.

An Administrative Law Judge may consider matters beyond the stated purpose of the conference if the parties consent, either before or during the conference, and the consent is reduced to writing.

An audio recording of the conference must be made part of the administrative record.

The Administrative Law Judge must issue a posthearing conference order that states all of the agreements and actions that result from the conference.

- ☐ *FORM:* OMHA-154 (Prehearing/Posthearing Conference Order)

- The Administrative Law Judge must proffer the posthearing conference order to the parties and provide them an opportunity to object to the order, or portions thereof.
- If the parties do not object to the posthearing conference order within 10 calendar days of receipt, or any additional time granted by the Administrative Law Judge, the order becomes binding on all parties.

See 42 C.F.R. §§ 405.1040, 423.2040.

Supplemental hearings

The Administrative Law Judge may conduct a supplemental hearing any time before a decision is issued to receive new and material evidence, including testimonial evidence, or address a procedural matter.

The procedures for scheduling and conducting a supplemental hearing are the same as a regular hearing but the Administrative Law Judge may limit the hearing to those parties and participants that took part in the original hearing, if appropriate.

- The notice of hearing must indicate that the hearing is supplemental. (OCPM II-7-9).
- Given the adjudication time frame, the Administrative Law Judge may wish to seek waivers of the full 20-day notice requirement. See CJB 11-003 (An Administrative Law Judge may seek waivers with the express approval of the office Associate Chief Administrative Law Judge when the particular circumstances of a case render it reasonably impractical to timely adjudicate the case).

See 42 C.F.R. §§ 405.986, 405.1030, 423.1986, 423.2030.

Closing the record

The record is closed when the hearing is concluded unless the Administrative Law Judge has stated otherwise during the course of the adjudication.

- If the record will not be closed at the conclusion of the hearing, the Administrative Law Judge should establish deadlines for the receipt of additional evidence and the closing of the record.

11. What are the possible outcomes in an appeal?

Decisions

Unless a request for hearing is dismissed or remanded, a written decision must be issued.

- ☐ *FORM:* OMHA-152 (Decision)

- The decision must:
  - Provide the findings of fact, conclusions of law, reasons for the decision, and summarize any clinical or scientific evidence used in making the decision, except in the case of stipulated decisions issued under 42 C.F.R. § 405.1038(c) or 423.2038(c);
  - Be based on (and must reference) the evidence of record, both documentary and testimonial;
  - Be drafted in a manner calculated to be understood by a beneficiary; and
  - Include a discussion of any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination, and a discussion of the good cause determination that was made.
- The decision is binding on the parties, and CMS and its contractors or plans.
- Recommended decisions may only be made when the Council instructs an OMHA adjudicator to issue a recommended decision. Recommended decisions are issued only to the parties in a case. When the decision becomes final, the final decision is issued in accordance with standard procedures or as instructed by the Council.

Notice of the decision must be sent to all parties (this includes the MAO, if it is a Part C appeal, and any CMS contractors that elected party status), except the notice can be sent to only the appellant if: (1) the appeal involves an overpayment; (2) multiple beneficiaries are involved; and (3) the beneficiaries are not liable. The notice is sent with the decision itself. The notice must be the approved OMHA form to ensure appeal rights and other information is provided. A copy of the final exhibit list must be included with the notice to the parties, as well as Form DAB-101 ("Request for Review of Medicare Administrative Law Judge (ALJ) Medicare Decision/Dismissal). However, the Form DAB-101 is not sent to CMS contractors.

- ☐ *FORM:* OMHA-1051T (Notice of Decision)
- ☐ *FORM:* OMHA-150T (Notice of Decision on Request for Review of Dismissal)
- The notice of decision must also be sent to contractors or plans, depending on the type of appeal:
  - Part A and Part B claim appeals: Notice of the decision is sent to the QIC that issued the reconsideration, or from which the appeal was escalated.

- Part C coverage determination appeals: Notice of decision is sent to the QIC or QIO that issued the reconsideration.
- Part D coverage determination appeals: Notice of the decision is sent to the IRE and the Part D plan sponsor.

A decision on a claim or entitlement appeal is binding on the parties, unless:

- The decision is reviewed by the Council or escalated to a Federal District Court;
- The decision is reopened by the OMHA adjudicator;
- The decision is a recommended decision pursuant to a Council order;
- Expedited Access to Judicial Review has been granted; or
- The OMHA adjudicator did not have the authority to issue the decision.

A decision affirming a QIC's, QIO's, or IRE's dismissal of a request for reconsideration is binding on the parties and not subject to further review.

See 42 C.F.R. §§ 405.980, 405.1046, 405.1048, 423.2046, 423.2048, 478.48.

Dismissals

A request for an Administrative Law Judge hearing or request for a review of a prior adjudicating entity dismissal may be dismissed for the following reasons:

⊗ *CAUTION*: An attorney adjudicator may dismiss a withdrawn request for, but only an Administrative Law Judge may dismiss a request for hearing for any other reason. (Bothe Administrative Law Judges and attorney adjudicators may dismiss a request for review of a dismissal for any reason.)

☐ *FORM:* OMHA-173 (Order of Dismissal)

- *Withdrawal of the Request for Hearing*. A request for hearing may be dismissed at any time before the notice of decision, remand, or dismissal is mailed when the party that filed the request submits a written withdrawal or orally withdraws the request at the hearing.

  ➢ No other party may have requested a hearing or review for the same matter.

  ➢ The withdrawal must state or convey the appellant is withdrawing the request for hearing and does not intend to proceed with the appeal.

  ➢ If a legal professional (for example, an attorney) is acting as a representative and files the withdrawal, the OMHA adjudicator may presume the representative has advised the appellant of the consequences of withdrawing the request.

  ☐ *FORM:* (non-mandatory) OMHA-119 (Withdrawal of Request for an Administrative Law Judge (ALJ) Hearing or Review of Dismissal)

- *Failure to Appear at the Hearing*. A request for hearing may be dismissed when neither the appellant nor the appellant's representative, if any, appears at the time and place set for the scheduled hearing if:
    - The record contains documentation that the appellant or representative acknowledged the notice of hearing and the appellant or representative does not contact the hearing office within 10 calendar days of failing to appear, or does contact the Administrative Law Judge, but the Administrative Law Judge determines there was not good cause for the failure to appear; or
    - If the record does not contain documentation that appellant or representative acknowledged the notice of hearing and the Administrative Law Judge sends a notice to the party at the last known address asking why the party did not appear, and the party does not respond to the Administrative Law Judge's notice within 10 calendar days after receiving the notice or does contact the Administrative Law Judge but the Administrative Law Judge determines the party did not demonstrate good cause for not appearing.

    ➢ In determining whether there was good cause for failing to appear, the Administrative Law Judge should consider any physical, mental, educational, or linguistic limitations the party may have.

    ⊗ CAUTION: If multiple appellants or appellant representatives are involved, all have to fail to appear for a dismissal under this provision.

- *No Right to a Hearing*. A request for hearing may be dismissed when the individual or entity filing the request does not have a right to a hearing or review.

    ➢ The individual or entity does not have a right to a review of a QIC's review of a lower-level dismissal.

    ➢ The individual or entity does not have a right to a hearing if the individual or entity is not a party.

    ➢ The individual or entity does not have a right to a hearing if the claims at issue in the request do not meet the minimum AIC and cannot be aggregated.

    ⓘ *NOTE:* If the request for hearing was not timely filed, use the untimely filing basis to dismiss the request.

- *Untimely Request for Hearing or Review*. A request may be dismissed when it was not timely filed and an extension was not requested or no good cause was found to extend the filing deadline.

- *Death of the Beneficiary*. A request may be dismissed when the beneficiary whose claim is being appealed dies <u>while the request is pending adjudication at the OMHA level</u>, provided the following are met:

- The request was filed by the beneficiary or beneficiary representative;
- The beneficiary's spouse or estate has no remaining financial interest in the case (that is, the beneficiary has not been found liable such that payment may be demanded from the estate or the spouse);
- No other parties with a financial interest in the case wish to pursue the appeal; and
- No other parties filed a valid and timely request for hearing.

- *Res Judicata*. A request may be dismissed when the appellant's rights on the same facts and on the same issue(s) or claim(s) involved in the request were decided by a contractor, an OMHA adjudicator, or the Council and the previous determination or decision has become binding by either administrative or judicial action.

- *Abandonment*. A request for hearing may be dismissed if the Administrative Law Judge concludes the appellant has abandoned the request.

  - The Administrative Law Judge may conclude the appellant has abandoned a request when the office attempts to contact the appellant to schedule a hearing and is unable to do so after making reasonable efforts to do so (such as a letter sent to the appellant stating attempts are being made to schedule the hearing and if contact is not made, the request may be dismissed).

  - All attempts to contact the appellant to schedule the hearing should be documented for the record.

  ⓘ *NOTE:* Tracked mail would be appropriate to record the letter was received at the address of record or was undeliverable.

- *Incomplete requests and failure to copy*: A request for hearing or review may be dismissed if, after having been provided an opportunity to correct the deficiency:

  - The request did not contain the elements required for a complete request for hearing or review; or

  ⓘ *NOTE*: If supporting materials submitted with a request clearly provide the information required for a complete request, the request may not be dismissed. For example, if a request is missing the QIC's Medicare Appeal Number, but a copy of the reconsideration is submitted with the request, the request is considered complete.

  - The appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties that received a copy of the QIC's reconsideration or dismissal.

A notice of dismissal must be sent to the appellant and all parties that were sent a copy of the request for hearing or review, as well as any CMS contractor that had participant or party status. The notice must be the approved OMHA form to ensure appeal rights and other information is

provided. The notice is sent with the dismissal order itself. A Form DAB-101 should be included with the notice, as well as an exhibit list if applicable.

- ☐ *FORM:* OMHA-1072T (Notice of Dismissal)
- ☐ *FORM:* OMHA-171T (Notice of Dismissal of Request for Review of Dismissal)

An OMHA adjudicator's dismissal of a request for hearing is binding on the parties, unless the dismissal is vacated by the OMHA adjudicator or the Council. An OMHA adjudicator's dismissal of a request for review of a dismissal issued by a prior adjudicating entity is binding unless vacated by the OMHA adjudicator.

See 42 C.F.R. §§ 405.1052, 405.1054, 423.2052, 423.2054.

- **Remands**

The remand authority is limited. CMS and its contractors or a party may request review of a remand by the Chief Administrative Law Judge if the remand was outside of the scope of these authorities.

- When a remand is issued, the notice and order of remand and case file are sent to the contractor to which the case is being remanded.

See 42 C.F.R. §§ 405.1056, 405.1058, 423.2056, 423.2058.

Review of a dismissal by a prior adjudicating entity

If a review of a dismissal issued by a prior adjudicating entity reveals the dismissal was not proper, the dismissal is vacated and the matter is remanded to the prior adjudicating entity for the requested reconsideration.

See 42 C.F.R. §§ 405.1004,405.1056(d), 423.2004, 423.2056(d).

Missing appeal determination or case record

If an OMHA adjudicator requests an official copy of a missing redetermination or reconsideration, and it is not received within 15 calendar days of the prior adjudicating entity receiving the request (assumed 5 days after it is placed in the mail), or if the prior adjudicating entity does not furnish the case file for an appeal, the OMHA adjudicator may issue a remand directing the prior adjudicating entity to either:

- Reconstruct the record and return the case to OMHA; or
- Initiate a new appeal adjudication.

ⓘ *NOTE*: Although the regulations state that the OMHA adjudicator may issue a remand directing the Part D plan sponsor or a contractor other than the prior adjudicating entity to reconstruct the record or initiate a new appeal adjudication, these remands should still

be sent to the prior adjudicating entity, which will relay the instructions to the plan or other contractor and coordinate the response.

See 42 C.F.R. §§ 405.1034, 405.1056(a), 423.2034, 423.2056(a).

No redetermination

If the OMHA adjudicator finds that no redetermination was conducted, or the redetermination request was dismissed, but the prior adjudicating entity issued a reconsideration on the merits, the OMHA adjudicator remands the case to the prior adjudicating entity to re-adjudicate the request for reconsideration.

⊗ *CAUTION:* QIOs and SSA do not conduct redeterminations.

See 42 C.F.R. §§ 405.1034, 405.1056(b), 423.2034, 423.2056(b)..

Requested remand

If an appellant and CMS or a CMS contractor jointly request a remand to the prior adjudicating entity, the OMHA adjudicator may remand the case if the request includes the reasons why the case should be remanded, and the OMHA adjudicator determines that a remand will likely resolve the matter in dispute (for example, CMS requests a remand in order to reopen the case and pay the claim at issue).

See 42 C.F.R. §§ 405.1056(c), 423.2056(c).

Invalidated LCDs and NCDs

An OMHA adjudicator remands an appeal if the appellant is entitled to relief because the LCD or NCD that was applied was invalidated by the Departmental Appeals Board or a higher tribunal.

See 42 C.F.R. § 405.1056(e).

Part D enrollee change in condition

If an enrollee wishes to introduce evidence on a change in his or her condition after a coverage determination was made by a Part D plan sponsor, the OMHA adjudicator remands the appeal to the Part D IRE to consider the new evidence.

See 42 C.F.R. § 423.2056(e).

When the Medicare Appeals Council says so

The Council can direct OMHA adjudicators to remand cases to contractors for specific information or actions. If the Council orders such a remand, it must be followed. Guidance can be sought from senior attorneys in the field office or the OMHA Program Evaluation and Policy Division.

12. How long do we have to get this done?

Adjudication time frames

There are different adjudication time frames that may operate in the OMHA process, subject to events that may toll or extend the time frame. However, all beneficiary and enrollee-initiated appeals are prioritized and should be treated as 90-day appeals unless another adjudication time frame applies to the appeal.

- A 10-day adjudication time frame applies to expedited appeals of Part D IRE reconsiderations.
- A 90-day adjudication time frame applies to appeals of Part A and Part B QIC reconsiderations, and non-expedited appeals of Part D IRE reconsiderations.
- A 180-day adjudication time frame applies to appeals that are escalated to OMHA because the Part A or Part B QIC did not complete its reconsideration within its 60-day adjudication time frame.

ⓘ *NOTE:* If the deadline for adjudicating a case falls on a day the field office is closed, the deadline will be on the next day the field office is open for business.

ⓘ *NOTE:* If the Council remands a case that was subject to an adjudication time frame, the case will be subject to the same adjudication time frame starting on the date OMHA receives the Council remand.

See 42 C.F.R. §§ 405.1016, 423.2016, CJB 15.002.

Starting the adjudication time frame

Adjudication time frames begin on the date that a timely request for an Administrative Law Judge hearing is filed or an escalation is received by OMHA, unless otherwise provided in the regulations.

ⓘ *NOTE:* If a request is untimely, the adjudication time frame begins on the date the OMHA adjudicator grants the extension to file the request.

ⓘ *NOTE:* If a request for hearing is misrouted (that is, filed with an entity other than OMHA Central Operations), the adjudication time frame begins on the date OMHA Central Operations receives the request.

See 42 C.F.R. §§ 405.1014, 405.1016, 423.2014, 423.2016.

Tolling and extending adjudication time frames

The adjudication period stops on the date a tolling or extension event begins and restarts on the date the event ends; the adjudication deadline is adjusted accordingly. The following are examples:

ⓘ *NOTE:* When multiple events overlap, the adjudication period stops on the date the earliest event begins and restarts on the date the last event ends.

- If the request for hearing or review is not complete, the appellant will be provided with an opportunity to complete the request, and the adjudication time frame does not begin until the request is complete.
- In a Part A or Part B QIC reconsideration appeal, if the appellant (other than an unrepresented beneficiary) did not send a copy of the request for hearing to the other parties to the reconsideration, the adjudication time frame does not begin until the record indicates notice of the request was sent to the other parties.
- If a party submits written evidence more than 10 calendar days after the party receives the notice of hearing , the adjudication time frame is tolled for the time between when the evidence should have been submitted (10 days after receiving the notice of hearing) and when the evidence was submitted. However, this does not apply to evidence submitted by an unrepresented beneficiary or enrollee (except in Part D expedited appeals).
- If a hearing is rescheduled at the request of an appellant, or if the appellant requests a continuance or supplemental hearing, the adjudication time frame is tolled for the time between the original hearing date and the rescheduled, continued, or supplemental hearing date.
- In a Part A or Part B QIC reconsideration appeal, if the Administrative Law Judge identifies missing material evidence at the hearing and continues the hearing to a later date so the evidence can be obtained, the adjudication time frame is tolled for the time between when the evidence should have been submitted (10 calendar days after receiving the notice of hearing, which is assumed to be 5 calendar days after it was sent) and when the evidence is submitted.
- If the OMHA adjudicator requests missing information that is essential to resolving the issues on appeal and that can be provided only by CMS, its contractors, or the Part D plan sponsor, the adjudication time frame is tolled by the period between when the request is made and when the lower adjudicating entity responds to the request or 20 calendar days, whichever is shorter.
- If the OMHA adjudicator remands a case that is missing an official copy of a redetermination or reconsideration, or the case file, and the lower adjudicating entity is able to reconstruct the record, the adjudication time frame is tolled by the period between when the case was remanded and when the case is returned to OMHA.
- If an appellant has waived her or his right to appear at a hearing and subsequently withdraws the waiver, the adjudication time frame is extended for the amount of time necessary to schedule and conduct the hearing.

- The adjudication time frame is tolled for the duration of any discovery under 42 C.F.R. § 405.1037.
- If a party requests access to or copies of the record for review *and* an opportunity to comment on the record, the time between receipt of the request and the expiration of the period to comment on the record (established by the OMHA adjudicator) does not count towards the adjudication time frame. If a Federal court orders the Department, OMHA or an OMHA adjudicator to stay the administrative proceedings, the appeal is administratively tolled for the duration of the stay order.

  ⓘ *NOTE:* A general stay order issued by a Bankruptcy Court does not stay OMHA administrative proceedings because OMHA proceedings relate to whether the services were covered, and not directly to the payment that may or may not result.
- The time from the later of the date that a defective appointment of representative was filed or the current appeal request was filed by the prospective appointed representative, to the date when the defect was cured or the party notifies the OMHA adjudicator that he or she will proceed with the appeal without a representative, does not count towards the adjudication time frame.
- If a party objects to the OMHA adjudicator, and the OMHA adjudicator withdraws, the adjudication time frame is tolled by 14 calendar days.

See 42 C.F.R. §§ 405.1014, 405.1016, 405.1018, 405.1020, 405.1026, 405.1030, 405.1036, 405.1037, 405.1042, 405.1056, 423.2018, 423.2020, 423.2026, 423.2036, 423.2042, 423.2056; CJB A-003-2010.

Time Frame Waivers

An appellant may waive the adjudication time frame for a specific period of time, or in full.

- The appellant may waive the adjudication time frame at any point in the hearing process.

  ⓘ *NOTE:* If multiple appellants are involved, all appellants must agree to the waiver.
- Waivers for specific periods of time may be agreed to by the OMHA adjudicator and the appellant.
- Waivers should be in writing and included in the administrative record.

⊗ *CAUTION:* Waivers of the adjudication time frame may not be solicited except as provided for in OMHA policy, unless authorized by the regulations (for example, an Administrative Law judge may condition an appellant's request for a consolidated hearing on an adjudication time frame waiver—this is not an option if the Administrative Law Judge consolidates a hearing on his or her own motion).

⊗ *CAUTION:* Under the Interim Final Rule, granting a request for an in-person hearing resulted in an automatic waiver of the adjudication time frame. This is no longer true. Pursuant to a change made in the 2009 Final Rule, a party requesting an in-person

hearing may waive the adjudication time frame (in writing), but the waiver is no longer automatic.

See 42 C.F.R. §§ 405.1016, 405.1036, 405.1044, 423.2036, 405.2044; CJB 11-003.

Request for escalation

Escalation is only available for appeals of Part A and Part B QIC reconsiderations, or appeals that were escalated from a Part A or Part B QIC because the QIC did not issue a reconsideration within its 60-day adjudication time frame.

- Only the appellant may request escalation.
- When a request for escalation is filed, there are two options: (1) issue a decision, dismissal, or remand within 5 calendar days; or (2) issue a notice stating that the OMHA adjudicator is unable to issue a decision, dismissal, or remand, and forward the case file to the Council.

See 42 C.F.R. §§ 405.1016, 405.1106.

If a non-appellant files a request for escalation, or an appellant files a request for escalation of an appeal for which escalation is not available, the request for escalation must be denied and a notice must be sent within 5 calendar days of receipt of the escalation request to the individual who requested the escalation, explaining why the request is being denied.

13. What happens after OMHA?

Requests for Review by Medicare Appeals Council

After an OMHA adjudicator issues a decision (except a decision affirming a dismissal issued by a lower adjudicating entity) or dismissal (except a dismissal of a request for review of a dismissal issued by a lower adjudicating entity), a party may request a review by the Council. The Council conducts a more appellate type of review, but ultimately undertakes a de novo review of the claim. If the Council issues a decision, the decision is the final decision of the Secretary from which judicial review may be sought.

- The Council may adopt, modify (further explain the rationale for the decision or correct an error in the decision, but reach the same result), or reverse an OMHA adjudicator's decision, or remand to OMHA for further proceedings.
- The Council may deny review of an OMHA adjudicator's dismissal, or vacate a dismissal and remand to OMHA for further proceedings.
- The Council may dismiss a request for hearing for any reason the OMHA adjudicator could have dismissed it.

See 42 C.F.R. §§ 405.1100, 405.1102, 405.1108, 405.1130, 422.608, 422.612, 423.1974, 423.2100, 423.2102, 423.2108, 423.2130, 478.46.

Medicare Appeals Council Own Motion Review

The Council may undertake a review of an OMHA adjudicator's decision or dismissal on its own motion, and CMS or any of its contractors may refer a case to the Council with a recommendation to do so.

- CMS or a contractor may refer a case if it believes there is an error of law material to the outcome of the claim or the case presents a broad policy or procedural issue that may affect the general public interest.
- If CMS or a contractor participated in an appeal at the OMHA level, CMS or a contractor may also refer a case if it believes the decision or dismissal is not supported by a preponderance of the evidence in the record, or the OMHA adjudicator abused his or her discretion.

⊗ *CAUTION:* When a case is referred to the council, CMS or its contractor is required to send a copy of the referral to the OMHA Chief Administrative Law Judge. However, the OMHA adjudicator is not a party to the appeal and should not respond to the referral letter, or attempt to further explain his or her decision or dismissal—the Council will not consider an OMHA adjudicator's statements regarding the referred decision or dismissal.

See 42 C.F.R. §§ 405.1110, 423.2110.

Vacating a Dismissal

An OMHA adjudicator may vacate his or her own dismissal within 6 months of the date of the notice of dismissal, or the Council may vacate an OMHA adjudicator's dismissal.

Reopening a Decision

An OMHA adjudicator may reopen a decision at the request of a party or on the OMHA adjudicator's own motion.

- A decision may be reopened within 180 calendar days of the date of the decision if there is good cause to reopen the decision.
  - ➢ Good cause may be established when: (1) there is new and material evidence that was not available or known at the time of the decision, and may result in a different conclusion; or (2) the evidence that was considered in making the decision clearly shows on its face that an obvious error was made at the time of the decision.
  - ⊗ *CAUTION:* A change in legal interpretation or policy is not a basis to reopen a decision under the reopening provisions.
- A decision may be reopened at any time if it was procured by fraud or similar fault.
- When a revised decision is issued, notice of the revised decision must be issued to the parties at their last known address.

ⓘ *NOTE:* A decision *not* to reopen a decision is not a reviewable determination.

ⓘ *NOTE:* A decision may not be reopened when an appeal of the decision is pending.

ⓘ *NOTE:* A decision does not have to be reopened to correct scriber's errors—an amended decision may be issued to correct errors such as incorrect beneficiary identifiers.

⊗ *CAUTION:* The reopening provisions apply to decisions, not dismissals or remands.

See 42 C.F.R. §§ 405.980–405.986, 422.616, 423.1980–423.1986, 478.48.

Remand Returned from a Prior Adjudicating Entity

When a remand is issued seeking a case file or an official copy of a missing redetermination or reconsideration, or issued at the direction of the Council, and the contractor is able to reconstruct the record, the case is returned to OMHA. Unless a new reconsideration is issued, the appellant does not have to file a new request for an Administrative Law Judge hearing. The case is no longer remanded, the reconsideration is no longer vacated, and any adjudication time frame that applies to the appeal is extended by the period between when the remand was issued and the date the case is returned to OMHA.

- The appeal is generally assigned to the same OMHA adjudicator.
- The appeal number will have an "R" suffix.

When a remand is issued because a dismissal issued by a prior adjudicating entity was vacated, or the appellant was entitled to relief after an NCD or LCD was invalidated, a new reconsideration will be issued that must be appealed.

- The appeal is generally assigned to the same OMHA adjudicator.
- The appeal number will generally have an "R" suffix.

See 42 C.F.R. §§ 405.1056, 423.2056.

Review of remand is requested

If a party, CMS, a CMS contractor, or the Part D plan sponsor believes a remand was not authorized under 42 C.F.R. §§ 405.1056 or 423.2056, the individual or entity may request that the OMHA Chief Administrative Law Judge review the remand.

- Requests for review of a remand must be filed within 30 calendar days of receiving notice of a remand.
- If the Chief Administrative Law Judge or designee finds the remand was not authorized, the remand order will be vacated and the case will be returned to the OMHA adjudicator that issued the remand.

- If the Chief Administrative Law Judge or designee finds the remand was authorized, the remand stands.

ⓘ *NOTE:* The review of remand procedures are not available when an OMHA adjudicator remands a case after determining that the dismissal of a reconsideration request issued by a lower level entity was in error.

See 42 C.F.R. §§ 405.1056(g), 423.2056(g).

14. What happens when . . .

. . . someone requests Expedited Access to Judicial Review?

Expedited Access to Judicial Review (EAJR) is a mechanism that allows a party to bypass the OMHA hearing and Council review levels of appeal when there is no material fact in dispute and the OMHA adjudicator and the Council do not have the authority to address the issue raised (for example, the statutory provision is unconstitutional, or the regulation, NCD, or CMS Ruling is invalid). See 42 C.F.R. §§ 405.990, 423.1990.

- The review entity is the Departmental Appeals Board (the entity that is the Board, as opposed to the organizational unit that houses the Board (also called the Departmental Appeals Board)).
- Requests for EAJR are filed with the DAB. If a request for hearing has not already been filed, it may be submitted with the EAJR request to the DAB.
- If the Board determines there is a material issue of fact or the OMHA adjudicator and the Council do have the authority to decide the asserted issue of law, the appeal will be returned.

⊗ *CAUTION:* An OMHA adjudicator may not advance a request for an Administrative Law Judge hearing to the DAB under the EAJR provisions—a party must request the action.

. . . the Medicare Appeals Council removes a request for hearing?

The Council may remove a request for an Administrative Law Judge hearing and conduct the hearing itself. See 42 C.F.R. §§ 405.1050, 423.2050. If this happens, follow the Council's instructions.

ⓘ *NOTE:* This is an exceptionally rare action. If you receive a removal order from the Council, please contact the OMHA Program Evaluation and Policy Division.

⊗ *CAUTION:* An Administrative Law Judge may not advance a request for hearing to the Council or request the Council to take a case.

. . . a beneficiary representative wishes to charge fees?

Fees for representing a *beneficiary* at the OMHA level for most types of appeals must be approved by the OMHA adjudicator. Fee arrangements made for the purpose of pursing third-party payment (that is, Medicare Secondary Payer cases) may not be reviewed by the OMHA adjudicator. See the "Representatives" section in Topic 2: "Who are the players in an appeal?" for information on processing a fee approval.

15. Is there a form for that?

OMHA Forms

OMHA has established a number of forms for the adjudication process, mostly forms used by OMHA to create outgoing orders, notices, informational inserts, or other correspondence, or document actions for the record (for example, for a report of contact that should be documented for the record). OMHA forms undergo a Departmental clearance process, including legal review by the Office of General Counsel to help ensure legal standards are met. Where there is an applicable OMHA form, it must be used and approved language in the form cannot be altered unless the form indicates it can be altered, or the circumstances require it (for example, making an alteration to nomenclature because it is a Part C appeal).

The OMHA Intranet Portal (also referred to by the software used, SharePoint) has the most current versions of OMHA forms (which are subject to change). The OMHA Intranet Portal also has the Form DAB-101 (Request for Review of Administrative Law Judge (ALJ) Medicare Decision/Dismissal), which must be included with a notice of decision or dismissal, and HHS forms that are used in the OMHA adjudication process.

OMHA Intranet Portal link: https://omhaportal.hhs.gov/Forms1/Forms/AllItems.aspx

Many commonly used forms are also incorporated into the Medicare Appeals Template System (MATS), which is an OMHA tool that loads MAS data into forms (such as the appeal number, appellant, OMHA adjudicator). MATS templates often have logic to customize a form for the circumstances of a case (for example, the template for the hearing request cure letter will ask what is missing so language can populate in the form). MATS templates may also contain pre-loaded optional language for decisions and dismissals.

HHS Forms

There are a number of HHS forms that were established for the OMHA adjudications before OMHA was established. Many of these forms continue to exist and be used as HHS forms.

Internet link: http://www.hhs.gov/forms/publicuse/index.html

CMS Forms

CMS has an extensive form collection, much of which does not pertain to OMHA adjudications. However, the form for appointing a representative and the form for transferring beneficiary appeal rights are CMS forms (CMS-1696 and CMS-20031, respectively).

Internet link: https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-list.html

Resources

The electronic Code of Federal Regulations (eCFR) is the most up to date version of the C.F.R.. It is available at:
http://www.ecfr.gov/cgi-bin/ECFR?page=browse

The current official C.F.R. and historical versions of the C.F.R. are available at:
https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR

The Federal Register is available at:
https://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR

The CMS manuals are available at:
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html

The OMHA Case Processing Manual (OCPM) is available at:
https://omhaportal.hhs.gov/Pages/OCPM/TOC.aspx

Select Medicare Appeals Council decisions are available at:
http://www.hhs.gov/dab/divisions/medicareoperations/macdecisions/mac_decisions.html

The Medicare Appeals Council Decision Resource (MAC DR), which is a searchable database of most Council decisions, is available at (accessible only on the HHS network):
https://omhaportal.hhs.gov/MACDR/SitePages/main.aspx

Suggested Reading/Reference:

- Medicare Program; Changes in Medicare Appeals Procedures Based on Section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000—Notice of CMS ruling, 67 Fed. Reg. 62478 (Oct. 7, 2002) (implementing portions of BIPA)
- Medicare Program: Changes to the Medicare Claims Appeal Procedures—Interim Final Rule, 70 Fed. Reg. 11472 (Mar. 8, 2005) (implementing regulatory changes pursuant to BIPA and the MMA)

- Medicare Program; Changes to the Medicare Claims Appeal Procedures: Correcting Amendment to an Interim Final Rule—Correcting Amendment, 70 Fed. Reg. 37700 (June 30, 2005) (correcting the Interim Final Rule)
- Medicare Program; Changes to the Medicare Claims Appeal Procedures: Correcting Amendment to a Correcting Amendment—Correcting Amendment, 70 Fed. Reg. 50241 (Aug. 26, 2005) (correcting the Interim Final Rule)
- Medicare Program: Changes to the Medicare Appeals Procedures—Final Rule, 74 Fed. Reg. 65296 (Dec. 9, 2009) (responding to comments to the Interim Final Rule and revising rules)
- Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction—Final Rule, 77 Fed. Reg. 29001, 29016–18 (May 16, 2012) (removing and redesignating portions of part 405, subparts G and H)
- Medicare Program; Right of Appeal for Medicare Secondary Payer Determinations Relating to Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers' Compensation Laws and Plans—Final Rule, 80 Fed. Reg. 10611 (Feb. 27, 2015) (implementing provisions of the SMART Act to provide appeal rights to applicable plans in Medicare Secondary Payer recovery actions)
- Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures—Final Rule, 82 Fed. Reg. 4974 (Jan. 17, 2017) (revising the OMHA level appeals procedures)

Module 6: Administrative Decision Writing

After this session, you will be able to:

1. Understand the Requirements of the Administrative Procedure Act (APA);
2. Identify Statutory and Regulatory Decision Writing Standards;
3. Distinguish Findings of Fact from Conclusions;
4. Identify the Legal Basis for OMHA Decisions;
5. Learn How to Access the Medicare Appeals Template System (MATS);
6. Reference and Use the OMHA Citation Manual;
7. Recognize Common Decision Writing Errors and Issues;
8. Understand the Framework of the OMHA Decision Template.

Required Reading/Reference:

- ✓ Administrative Procedure Act, 5 U.S.C. §§ 551–559, 701–706
- ✓ Policy Directive, PD-2007-002 (April 24, 2007)
- ✓ CJB 12-002 (August 8, 2012)
- ✓ CJB 10-001 (May 19, 2010)
- ✓ 42 C.F.R. § 405.1046
- ✓ 42 C.F.R. §§ 405.1000 and 405.1110
- ✓ *Almy v. Sebelius*, 679 F.3d 297 (4th Cir. 2012)
- ✓ Writing Style Models:
  - The Supreme Court of Ohio, *Writing Manual: A Guide to Citations, Style, and Judicial Opinion Writing*[1]
  - National Labor Relations Board, *NLRB Style Manual: Guide for Legal Writing in Plain English*[2]

The Administrative Procedure Act

The APA is the key piece of federal legislation dealing with the relationship between federal administrative agencies and the public. The APA applies, with certain exceptions, to every agency and authority of the federal government. The APA is based on the dichotomy between rule-making and adjudication.[3] It establishes the minimum standards for federal authorities in the area of rulemaking and adjudication, and codified the judicial review process. The Office of

[1] The Supreme Court of Ohio, *Writing Manual: A Guide to Citations, Style, and Judicial Opinion Writing* (July 2013), at http://www.sconet.state.oh.us/ROD/manual.pdf.
[2] National Labor Relations Board, *NLRB Style Manual: Guide for Legal Writing in Plain English* (Jan. 2000), at https://www.nlrb.gov/sites/default/files/attachments/basic-page/node-1727/stylemanual.pdf
[3] Attorney General's Letter to the Senate Judiciary Committee (Oct. 19, 1945); *see* S. Rep. No. 79-752, 185 at 223–24.

Medicare Hearings and Appeals (OMHA) is bound by the requirements of the APA, as well as Medicare statutes and regulations.

These binding authorities require certain information be provided to an appellant in a decision. Under the APA, all decisions, including initial, recommended, and tentative decisions, are part of the record and shall include a statement of: (1) findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the record; and (2) the appropriate rule, order, sanction, relief, or denial thereof.[4]

Medicare regulations mandate that OMHA Administrative Law Judges (ALJs) and attorney adjudicators issue written decisions which include findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record.[5] The decision must be written in a manner calculated to be understood by a beneficiary and must include:

> (1) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;
> (2) The procedures for obtaining additional information concerning the decision; and
> (3) Notification of the right to appeal the decision to the Medicare Appeals Council (Council), including instructions on how to initiate an appeal under this section.[6]

Additionally, an ALJ or attorney adjudicator has ninety (90) calendar days, beginning from the date of receipt of the request for an ALJ hearing, to issue a decision, dismissal order, or remand to the Qualified Independent Contractor (QIC), unless the 90 calendar day period was waived by the appellant or was extended[7] under 42 C.F.R. § 405.1016.

Key Concepts

Factual Findings

Beyond the importance to the parties understanding the decision, findings of fact play an important role for reviewing bodies. As one court noted, "findings of fact are the polestar for our judicial review. Without them, the court wanders aimlessly through the record."[8]

---

[4] 5 U.S.C. § 557(c)(3).

[5] 42 C.F.R. § 405.1046(a)(1).

[6] *Id.* § 405.1046(a)(2).

[7] *Id.* § 405.1016.

[8] *Perez v. U.S. Steel*, 416 N.E. 2d. 864 (Indiana, 1981).

With respect to factual determinations, the Medicare statute specifies that "the findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive."[9] The Supreme Court has defined substantial evidence as "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."[10]

Conclusions (Analysis)

In order to maintain the integrity of findings of fact, remember:

"The ultimate finding is a conclusion of law or at least a determination of a mixed question of law and fact." *See Helvering v. Tex-Penn Oil Co.*, 300 US. 481, 491 (1937). The Court in Almy noted that, "quite apart from matters of fact, the Secretary's decisions are governed by the APA, which requires courts to determine whether the agency's action was 'arbitrary, capricious, an abuse of discretion, . . . otherwise not in accordance with law, . . . [or] without observance of procedure required by law.'"[11]

Factual Findings versus Conclusions

The findings of fact required by statutes are usually called "basic" facts, and the conclusions are called "ultimate" facts. One court advised that, "(1) from consideration of the evidence, a determination of facts of a basic or underlying nature must be reached; (2) from these basic facts the ultimate facts, usually in the language of the statute, are to be inferred."[12]

Legal Basis for OMHA Decisions

Statutes

Administrative Procedure Act, 5 U.S.C. §§ 551–559, 701–706

The APA was originally enacted in 1946,[13] repealed and revised in 1966, and codified at 5 U.S.C. §§ 551–559, 701–706.

---

[9] 42 U.S.C. § 405(g).

[10] *Almy v. Sebelius*, 679 F.3d 297, 301-302 (4th Cir. 2012), quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229; 59 S.Ct. 206; 83 L.Ed. 126 (1938).

[11] *Almy*, 679 F.3d 297 at 302, quoting 5 U.S.C. § 706(2).

[12] *Saginaw Broadcasting Co. v. FCC*, 96 F.2d 554 (D.C. Cir. 1938), *cert. denied*, 305 U.S. 613 (1938).

[13] Pub. Law 79-404 (1946).

Regulations

***42 C.F.R. § 405.1002* — Right to an ALJ Hearing**

If a party to a QIC reconsideration files a written request for an ALJ hearing within 60 calendar days after receipt of the notice of the QIC's reconsideration, and meets the amount in controversy, the party has a right to a hearing before an ALJ.[14] A party also has a right to an ALJ hearing if the party timely filed its appeal to the QIC and the appeal continues to be pending at the end of the adjudication period, if the claim satisfies amount in controversy requirements, and the party files a written request with the QIC to escalate the appeal to OMHA after the adjudication period has ended and the QIC does not issue a decision or dismissal within 5 calendar days.[15] Note that 42 C.F.R. section 405.1004 also provides a right to review of a QIC notice of dismissal.

***42 C.F.R. § 405.1032* — Issues before an ALJ or attorney adjudicator decision**

The issues before the ALJ or attorney adjudicator include all the issues for claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor.[16]

***42 C.F.R. § 405.1038* — Deciding a case without a hearing before an ALJ**

An ALJ or attorney adjudicator may decide an appeal without conducting an ALJ hearing only when the conditions of 42 C.F.R. section 1038 are satisfied.[17]

***42 C.F.R. § 405.1046* — Notice of an ALJ or attorney adjudicator decision**

The ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The general rules advise:

> (1) Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions. OMHA mails or otherwise transmits a copy of the decision to all the parties at their last known address and the QIC that issued the

[14] 42 C.F.R. § 405.1002(a).

[15] *Id.* § 405.1002(b).

[16] *Id.* § 405.1032(a).

[17] *Id.* § 405.1038(a)–(b).

reconsideration or from which the appeal was escalated. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ or attorney adjudicator may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with the ALJ's or attorney adjudicator's decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.[18]

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination.

(ii) For any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to 42 C.F.R. § 405.1028, a discussion of the new evidence and the good cause determination that was made.

(iii) The procedures for obtaining additional information concerning the decision; and

(iv) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.[19]

OMHA-Specific Guidance

Policy Directive, PD-2007-002 (April 24, 2007)

Requires use of the Decision Template Form (or use of the same subject area headings).

CJB 12-002 (August 8, 2012)[20]

This policy limits the use of beneficiary names and Health Insurance Claim Numbers (HICNs) generated by OMHA to safeguard Personally Identifiable Information (PII).

[18] *Id.* § 405.1046(a)(1).

[19] *Id.* § 405.1046(a)(2).

[20] *See also* CJB 17-002 (February 27, 2017).

Names

All case-related material produced by OMHA staff, including but not limited to, decisions, orders, letters, headers, footers, captions, notices, and claim lists should identify the beneficiary by first initial, full last name.

Example: J. Doe

HICNs and MBI

Use only the last four (4) numeric digits of the HICN and any alphabetical suffix, if appended to the HICN. Filler asterisks should be used for the preceding numbers and letters.

Example: *****1234A

Note: By April 2019, new Medicare cards will be issued containing a randomly generated Medicare Beneficiary Identifier (MBI). Following a transition period during which providers and suppliers may use either a HICN or an MBI, the MBI will fully replace the HICN for Medicare transactions. **CJB 18-001** provides instruction on which identifier should be used in OMHA correspondence and how to protect the beneficiary's PII.

Practical Tips

1) Include Findings of Fact and Conclusions of Law.
2) Include the rationale for all material issues of fact and law presented.
3) Include an appropriate Order.
4) Consider the audience to whom and for whom the decision is written.
5) Address the major point of contention of the appeal.
6) Be frank and candid in the assessment of the evidence.
7) Avoid being insensitive or blunt.
8) Choose the important "hard facts" as the control points and address them in decision. This can be done by including all findings necessary to resolve the issues identified, and which are relevant to the decision.
9) Make specific findings.
10) Avoid conclusory findings.
11) Conclusions of Law:
    a. Need to be the logical result of applying the findings of fact to the law for the stated issue. That is, they must be consistent with the findings of fact.
    b. Address the legal principles applicable to the appeal.

Frequent Causes of Action on OMHA Decisions by the Council

Outcome of Appeals

Comparing sample months in 2014 and 2015 with a sample month in 2017:

Council Action	7/28 – 8/29/2014	6/1 – 6/30/2015	1/3 – 1/31/2016
Dismiss/Deny Request for Review	51	38	88
Adopt ALJ Decision	53	33	14
Modify ALJ Decision	27	17	6
Reverse ALJ Decision	17	21	8
Remand ALJ Decision	37	12	7
Total	185	121	123

Frequent reasons for reversals, modifications, and remands cited by the Council as of November 2015 include:[21]

- The most common reason is failure to address applicable regulation, NCD, LCD, coding edit, manual provision, or CMS ruling, or explain why a policy was not applied.
- Other recurring problems involve incomplete records; decisions granting relief not within the ALJ's authority or scope of review (e.g., on services not addressed at lower levels); procedural flaws such as inadequate service or notice of issues; and confusion about sections 1879 (liability) or 1870 (overpayment) of the Social Security Act (the Act).

Writing Styles and Standards

Use of Plain Language

Congress enacted the Plain Writing Act of 2010,[22] requiring federal agencies to use clear communication that the public can understand and use. Additionally, the law defines plain writing as writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience.[23]

[21] JES-III Training, "The View from the Medicare Appeals Council at the DAB," Leslie A. Sussan, Deputy Chair (November 12, 2015).
[22] 5 U.S.C. § 301.
[23] *Id.*

- The United States Department of Health and Human Services (HHS) Plain Writing Plan can be viewed at: http://www.hhs.gov/open/recordsandreports/plainwritingact/index.html

- Learn more about plain writing at the Plain Language website: http://www.plainlanguage.gov

Common Writing Mistakes

The following are suggestions to improve decision drafting. The common writing mistakes were drawn from the Supreme Court of Ohio's *Writing Manual,*[24] NLRB's *Style Manual,*[25] and *Garner's Modern American Usage*.[26]

A. Hanging Section Headings

If a heading is at the end of a page with no text underneath it, press the "Enter" key until the heading appears at the top of the next page.

B. Wordiness

Wordiness means using more words than necessary to make a point. This includes legalese, multiple syllable words, redundancy, or excessive use of prepositional phrases.

Legalese[27]

In order to convey a professional tone, decision writers will utilize extra clauses, excess verbiage, and Latin phrases that do not add any meaning to the declaratory statements in the Decision. Decision writers should avoid superfluous verbiage because it clouds the meaning of the statement being made and leads to ambiguity.

[24] The Supreme Court of Ohio, *Writing Manual*, at http://www.sconet.state.oh.us/ROD/manual.pdf.
[25] National Labor Relations Board, *NLRB Style Manual* (Jan. 2000), at https://www.nlrb.gov/sites/default/files/documents/44/stylemanual.pdf.
[26] Bryan Garner, *Garner's Modern American Usage* (3rd ed. 2009).
[27] *Garner's Modern American Usage, supra* at 505; *NLRB Style Manual, supra* at 51.

Multiple Syllable Words[28]

Multiple Syllable Words	Simpler Words
Although	Though
Because	Since
Consequently	Thus
Therefore	Thus
Upon	On

C. ***Prepositional Phrases***[29]

Prepositional phrases add to the wordiness of a sentence and slow down the readers. Also, prepositional phrases are commonly used in legalese and detract from the *Federal Plain Language Guidelines*.[30] Some of the most common prepositions include: as, at, by, of, for, from, in, of, on, since, to, through, and with.

Some examples of phrases include:

Complex Preposition Phrases	Simpler Words
Concerning the matter of	About
For the reason that	Because
In spite of the fact that	Though, although
In the amount of	For
In view of the fact that	Because
The question as to whether	Whether

Prepositions: In view of the medical documentation submitted by the appellant, the record supports the argument of the appellant that the services were reasonable and necessary for the beneficiary.

Eliminate some of the prepositions: The appellant's submitted medical documentation supports the appellant's argument that the services were reasonable and necessary for the beneficiary.

[28] *NLRB's Style Manual, supra* at 52. http://www.plainlanguage.gov
[29] *Garner's Modern American Usage, supra* at 654.
[30] *Federal Plain Language Guidelines* (Dec. 2010), at http://www.plainlanguage.gov/howto/guidelines/bigdoc/fullbigdoc.pdf

The writer should not omit all prepositions, but the writer should be mindful that prepositions add to unnecessary wordiness.

D. Grammar

1. Comma Usage[31]

a) To separate coordinated main clauses or independent clauses. Independent clauses can stand alone as a complete sentence.

Incorrect: The lawyer must submit evidence to meet the burden of proof and the jury is required to specify damages. (Ideas not closely related; comma needed).

Correct: The lawyer must submit evidence to meet the burden of proof, and the jury is required to specify damages.

Two Exceptions:

1. If the two main clauses are closely linked.
   For Example: I walked to the bus and I caught it just in time. (Ideas closely linked; no comma needed).

2. If the subject of the second independent clause is the same as the first –not repeated, but understood. This is also called a compound predicate.

   For Example: The appellant submitted a timely request for an ALJ hearing and supplemented the record.

b) Between adjacent parallel items, or series.

Incorrect: The cases involve proceeds of sales, insolvent taxpayers, bankruptcies, or simply do not address the question presented herein.

Correct: The cases involve proceeds of sales, insolvent taxpayers, or bankruptcies. Several cases do not address the question presented here.

[31] *Garner's Modern American Usage, supra* at 676–677; *NLRB's Style Manual, supra* at 35–37.

c) Around parenthetical elements.

Incorrect: Defendants further argue that even if they were in violation of the Act, they would not be liable.

Correct: Defendants further argue that, even if they were violation the Act, they would not be liable.

d) To avoid misreading or for emphasis.

Two Standard Forms:

- Dates: Consider the month and date as an inseparable element—two parts that are never separated by a comma. Then, if a date includes more than two elements, commas are used to separate the elements.

  Incorrect: The Beneficiary received the services between March, 2008 and April, 2008.

  Correct: The Beneficiary received the services between March 2008 and April 2008.

  Incorrect: OMHA received the request for hearing on March 1, 2012, and sent a notice of receipt the next day.

  Correct: OMHA received the request for hearing on March 1, 2012 and sent a notice of receipt the next day.

- Quotations: Commas and periods always go inside quotation marks. Other punctuation goes inside the quotation marks if the words are part of the quoted material, outside if it is not.

2. Semicolons[32]

Semicolons have two uses:

a) To separate independent clauses in place of a conjunction.

Correct: The agency's error was carefully dealt with by the Court of Appeals; this case does not require further attention by this Court.

[32] William Strunk Jr. and E.B. White, *The Elements of Style*, (July 1999), at 3–12; *NLRB's Style Manual*, *supra* at 42.

b) In series with internal commas or compound elements. This often occurs when listing locations, names, dates, and descriptions.

Correct: While I was on vacation, I traveled to Boston, Massachusetts; New York City; Philadelphia, Pennsylvania; and Washington, D.C.

3. Passive Voice[33]

The writer can use passive voice when the identity of the actor must be hidden, the actor is unknown, or when the actor is much less important than the receiver. Otherwise, the writer should avoid passive voice because it obscures the action and buries the subject and verb.

One way of recognizing passive voice is the use of a form of the verb "to be." Also, the action verb usually ends in –ed, -d, -t, -en, or –n. Passive voice also often uses a "by" phrase.

Passive: A telephone hearing was held by Judge X on February 1, 2012.

Active: Judge X held a telephone hearing on February 1, 2012.

4. Use of the Right Word[34]

Affect / Effect:

Affect means to influence, to have an effect on. (Bright lights affect eyes).

Effect means a result or to accomplish. (Her policies had a positive effect.) (Her administration effected radical changes.)

As to: Often superfluous. (There was a question whether—NOT as to whether—they won.) It is misused as a preposition. (There was doubt about—NOT as to—proper conduct for the occasion.)

That/Which: Both "that" and "which" may introduce a restrictive clause, written without commas. (The bridge that [or which] fell was 50 years old.)

"Which" uses commas when introducing a nonrestrictive, or parenthetic, clause. (The bridge, which was over 50 years old, collapsed.)

[33] *Garner's Modern American Usage, supra* at 612–613.

[34] *NLRB Style Manual, supra* at 53–57; *Writing Manual, supra* at 115–121.

Either/Or: Used in sentences in a positive sense, meaning "either one or the other."

Neither/Nor: Used in sentences in a negative sense, meaning "neither this one nor the other."

Then/Than: "Then" is used as a time expression. "Than" is used in the comparative form.

5. **Singular and Plural**[35]

Pronouns

Pronouns must agree in number and in gender with the nouns they replace. If you place a pronoun too far away from the noun it represents, the pronoun may inadvertently make it refer to another noun of the same number and gender. Check the pronoun to make sure it has a prior noun and that the two agree.

Collective nouns, which are nouns that represent groups, are considered singular. A company is considered "it." For example, "jury" becomes "it." "Jurors" becomes "them." Also, watch for errors when switching a genderless noun into a pronoun. A common error occurs when the writer tries to avoid using "he" to represent a singular person. For example, "lawyer" becomes "he or she" not "they." "Everyone" becomes "we" or "they."

Verb Agreement with the subject

Example: The services were reasonable and necessary—NOT the services was reasonable and necessary.

Example: Whether the item provided to the beneficiary on March 17, 2011, meets Medicare coverage criteria—NOT whether the item provided to the beneficiary on March 17, 2011, meet Medicare coverage criteria.

Medicare Appeals Template System (MATS)

The Medicare Appeals Template System (MATS) is a new decision and correspondence writing tool. The pilot contains a letter shell, decision shell, dismissal shell, a decision affirming QIC dismissal shell, and withdrawal and untimely dismissal templates for Part A, B, and C appeals.

Information is either populated from MAS or manually entered into tabulated form fields. Based on the specific selections made, an editable dismissal, decision, or letter outline with

[35] *Garner's Modern American Usage, supra* at 178–180, 663–665.

prompts is created under the MATS format, along with the appropriate notice, exhibit page, and any applicable attachments.

HOW TO ACCESS MATS

MATS can be accessed by navigating to the MATS Folder on the field office's shared drive. Open the folder and select the MATS.exe file in the List View or the Welcome Mat Icon in the Thumbnails View. Open the MATS.exe file and then "Run," to access the folders of categorized templates. Select the appropriate folder and the available templates will be displayed. To select a template, click on the appropriate file. MATS currently has templates available for decisions, dismissals, notices, orders, and letters.

- For more information, review the MATS Use Guide at https://omhaportal.hhs.gov/Forms1/**MATS** User Guide v3.docx.

OMHA Citation Style

OMHA has its own citation system that is a departure from the *Bluebook*[36]. The following is a short summary of some of the most common citations used at OMHA. The complete system is contained within Chief Judge Bulletin 10-001.[37]

1. **The Social Security Act**

Full Citation in Text: Section 1862(a)(1)(A) of the Social Security Act (the Act).
Short Citation in Text: Section 1862(a)(1)(A) of the Act.

Full Citation After Sentence: Social Security Act (Act) § 1862(a)(1)(A).
Short Citation After Sentence: Act § 1862(a)(1)(A).

2. **Code of Federal Regulations (C.F.R.)**

42 C.F.R. § 405.1002

Note: Periods are used between C.F.R.

[36] *Bluebook: A Uniform System of Citation* (20th ed. 2015).
[37] CJB 10-001 (January 2014) at https://omhaportal.hhs.gov/Program%20Evaluation%20and%20Policy/Case%20Processing%20Policy%20and%20Procedure/Chief%20Judge%20Bulletins%20(CJBs)/CJB%2010-001%20Citation%20System.pdf.

When citing multiple sections of the C.F.R. that are under the same Part, use two section symbols (§)'" to signal multiple citations.

For example: 42 C.F.R. §§ 405.1002 and 405.1006.

When citing multiple sections of the C.F.R. that are not under the same Part, use the full citation.

For example: 42 C.F.R. § 424.24(c) and 42 C.F.R. § 410.59.

3. CMS' Policy Manuals

Long form: CMS, *Medicare Benefit Policy Manual* (*MBPM*) (*Internet-Only Manual Publ'n 100-2*) ch. 7, § 40 (May 2011).

After the first long citation, the short form of the citation should be used. This applies even if a different chapter and section is used.

Short Form: *MBPM, supra* ch. 7 § 40

4. National Coverage Determination

When citing the National Coverage Determinations, use the abbreviation "NCD." Make sure to put the abbreviation after the first use of the long form.

For example: National Coverage Determination (NCD).

When citing a specific NCD, use the following long form of the citation:

For Example: CMS, *Medicare National Coverage Determinations Manual (MNCDM) (Internet-Only Manual Publ'n 100-3)* ch. 1, § 280.1.

Note: After citing the long form, use the following short form of the citation: NCD 280.1.

5. Local Coverage Determination

When citing the Local Coverage Determinations, use the abbreviation "LCD." Make sure to put the abbreviation after the first use of the long form.

For example: Local Coverage Determination (LCD).

When citing a specific LCD, use the following long form of the citation:

[Contractor], Local Coverage Determination L[ID number]: [Title] (LCD L[ID number]) (Revision effective dates).

For Example: National Government Services, Local Coverage Determination L26884: Outpatient Physical and Occupational Therapy Services (LCD L26884) (effective Nov. 1, 2011 through Nov. 30, 2011).

After citing the long form, use the following short form of the citation:

LCD L[ID number]

For Example: LCD L26884.

6. Exhibit Citation

Abbreviate "Exhibit" as "Exh." when citing a single exhibit or "Exhs." for multiple exhibits.

For example: Exh. 1 or Exhs. 2 & 3.

When citing after a sentence, place the citation in parenthesis.

For example: (Exh. 1).

When citing exhibit pages, the most common form of citation is as follows:

Single Page: (Exh. 1, p. 1).

Multiple pages:

1. (Exh. 1, pp. 1, 4). – means the decision writer cites documentation on only pages 1 and 4.

2. (Exh. 1, pp. 1–4) – means the decision writer cites documentation on pages 1 through 4.

7. Id.

OMHA Rules:

1. Used to refer to the previous citation clause/sentence. If the previous citation clause/sentence has more than one citation in it and the intent is to only use one citation, "*Id.*" cannot be used. Also, "*Id.*" cannot be used when the previous citation has one sentence in it and the intent is to use more than one citation in the next sentence.

2. Use "at" only when the reference is to a page, not a section in the code. For example, (*Id.* at 3), *Id.* § 405.1002.

When citing "Id.," the most common form is to italicize it and put it in parentheses.

For example: (*Id.*)

8. Medicare Appeals Council Decisions

The Council is now exclusively using docket numbers that begin with "M-" or "E-." The Program Evaluation and Policy Division (PEPD) recommends citing Council decisions as cited in the Program Advisor: M-15-1456 (Sept. 15, 2015).

OMHA Administrative Decision Template

A. General Format

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
_____ Field Office

Appeal of: _____	ALJ Appeal No.: 1-_____
Beneficiary: _____	Medicare Part: _____
HICN: _____	Before: _____ U.S. Administrative Law Judge

DECISION

Procedural History

Issues

Findings of Fact

Legal Framework

I. **ALJ Review Authority**
   - A. *Jurisdiction*
   - B. *Scope of Review*
   - C. *Standard of Review*

II. **Principles of Law**
   - A. *Statutes & Regulations*
   - B. *Guidance*

Analysis

Conclusions of Law

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: _____

_____
U.S. Administrative (Ctrl)

B. Heading

The heading of a decision contains several important sections that provide the reader with basic information regarding the parties, the type of appeal, and the ALJ or attorney adjudicator assigned to the case. The information contained in the heading includes:

(1) the appellant's name;
(2) the beneficiary's first initial, full last name;
(3) the last four numeric digits of the beneficiary's Health Insurance Claim Number (HICN) and any alphabetical suffix;
Note: CMS is developing the New Medicare Card Project, an initiative to remove the Social Security Number-based HICN from Medicare Cards. Beginning on April 1, 2018, beneficiaries will receive new cards with an assigned Medicare Number.[38]
(4) the OMHA Appeal Number;
(5) the relevant Medicare Part or IRMAA; and
(6) the name of the ALJ or attorney adjudicator rendering the decision.

Practice note:
Occasionally, attorneys will use previously issued decisions as a guide in drafting a decision on a similar topic. When using such a decision, be sure to review the heading to ensure that the correct information is noted on the new decision.

C. Decision (Summary)

The purpose of the summary of Decision is to inform the reader of the appeal decision. It should provide the reader with a succinct and precise summation of the decision. The summary must identify whether the decision was Favorable, Partially Favorable, or Unfavorable. Additionally, the summary should note the appellant's name, whether the decision was on-the-record, and the issue being resolved. The writer should ensure that the information in the summary is consistent with the conclusion.

D. Procedural History

The Procedural History establishes a roadmap to demonstrate how the appellant obtained jurisdiction at the OMHA appeal level. An effectively written procedural history will include:

(1) the name of the beneficiary (Note: the appellant is identified in the Decision section above);
(2) the date(s) of service at issue;

[38] CMS: New Medicare Cards, at https://www.cms.gov/Medicare/New-Medicare-Card/index.html.

(3) the dates of the appellant's requests for lower level appeals and the subsequent decisions;
(4) the basis for the unfavorable decision at the lower level of appeal;
(5) any relevant procedural information from the ALJ hearing, such as witness or representative names; and
(6) any relevant procedural issues (such as, the admission of late and/or new evidence, whether the 90 calendar day adjudication period was waived or tolled, or if the decision is issued on-the-record.

Introduction of New Evidence

New evidence is any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that was not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker.[39] Such evidence must be accompanied by a statement explaining why the evidence was not previously submitted.[40] However, these requirements do not apply to oral testimony given at a hearing; evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an applicable plan; or a beneficiary represented by someone other than a provider or supplier.

A good cause analysis must be completed when:[41]

(1) prior to the hearing, the appellant submits additional documentation that was not previously introduced into the record;
(2) at the hearing, the appellant submits additional documentation that was not previously introduced into the record;
(3) at the request of the ALJ, the appellant submits records (medical, billing etc.) or other evidence after the hearing concludes; or
(4) the appellant submits missing documentation that was referenced in the previous decisions but not included in the record *(Note—for missing evidence any analysis would conclude a good cause finding is unnecessary, as the evidence was not in fact new).*

The introduction of new evidence by a provider, supplier, or beneficiary represented by a provider or supplier must be evaluated pursuant to 42 C.F.R. sections 405.1018 and 405.1028. The foregoing regulations serve the interests of orderly decision-making by providing for the proper consideration of evidence. Timely filed and properly introduced evidence results in a more accurate case analysis at all levels of the Medicare appeals process because the medical expertise of the lower levels of claims review can fully develop a payment or non-payment

[39] 42 C.F.R. § 405.1018(c).
[40] *Id.*
[41] 42 C.F.R. § 405.1028.

rationale. Further, timely filed and properly introduced evidence reduces the incidence of fraud and abuse of the Medicare adjudicatory process and helps to eliminate mistakes that potentially occur as a result of bypassing qualified medical expertise.

E. Issues

The statement of issues represents the foundation of the ALJ's or attorney adjudicator's decision because it identifies the points of contention to be clarified at the hearing. The statement should be brief and should succinctly state the issues to be resolved. An effective statement of issues will separate individual issues and not be ambiguous. The issue statement may be in question or statement form. The writer should be consistent if there is more than one issue.

Practice notes:

1. Entitlement to payment, medically reasonable and necessary determinations,[42] limitation on liability provisions,[43] and waiver of overpayment provisions[44] are all separate issues that need to be identified separately in the statement of issues.

2. Review and compare the issues identified in the decision with the issues identified in the notice of hearing to ensure that they are consistent.

F. Findings of Fact

Only facts that are necessary to explain the decision should be included within the findings of fact. Excessive factual detail is distracting to the reader and results in the decision containing analysis of facts irrelevant to the outcome of the appeal. However, a writer must include enough detail to fully explain the decision's rationale. Findings of fact are based upon the entire record, including consideration of testimony, exhibits, official documents, and any other information in the record. Additionally, the findings of fact may be presented in either paragraph or numbered form, depending on the ALJ's or attorney adjudicator's preference.

At a minimum, the findings of fact should include:

(1) the beneficiary's diagnoses, particularly those relevant to the Medicare coverage criteria;
(2) the items or services provided to the beneficiary on the date(s) of service at issue;
(3) any facts relevant to the Medicare coverage criteria (e.g., the facts relevant to the coverage requirements of pneumatic compression devices); and
(4) payment or coverage conditions present or not present in the record.

[42] Act § 1862(a)(1)(A).
[43] *Id.* § 1879.
[44] *Id.* § 1870.

Practice notes:

1. Ensure that the findings are completely factual, not conclusory. Conclusions may mask themselves as factual findings, so it is important to pay close attention to the distinction. A statement such as "the appellant was not qualified" is conclusory, while a statement such as "the appellant was a medical doctor" is factual.

2. Additionally, **specific citation** to the record for ALL relevant facts is required in order for the appellant, CMS, and the Council to verify the information.

G. Legal Framework

The discussion of applicable law provides a roadmap which demonstrates that the ALJ's or attorney adjudicator's conclusion is based on sound reason and logic. This roadmap includes the ALJ's or attorney adjudicator's review authority, the scope and standard of the review, and the underlying principles of law used to make the decision. This section will contain the largest amount of information. Any "boilerplate" language under this section will change depending on (1) the part of Medicare at issue (A, B, C, D, or IRMAA) and (2) the type of service or items at issue.

H. ALJ Review Authority

Jurisdiction

A party to the reconsideration may request a hearing before the Secretary, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner.[45] The Secretary administers the nationwide Medicare hearings and appeals system through OMHA.[46] ALJs and attorney adjudicators within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Council or expedited to judicial review.[47]

In order to be entitled to review, a request for ALJ hearing must meet the amount in controversy requirements of 42 C.F.R. § 405.1006(b).[48] In certain circumstances, if a claim by itself does not meet the amount in controversy, multiple claims may be combined or aggregated to meet the amount in controversy requirement.[49]

[45] Act § 1869(b)(1)(A); 42 C.F.R. § 405.1002.
[46] 70 Fed. Reg. 36386, 36387 (June 23, 2005).
[47] 42 C.F.R. § 405.1048.
[48] *Id.* § 405.1002(a)(2).
[49] *Id.* § 405.1006(e).

In addition, the request for ALJ hearing must be timely filed. A request for hearing is timely if filed within sixty (60) calendar days after receipt of notice of the QIC's reconsideration.[50] The date the party received notice of the reconsideration is presumed to be five (5) calendar days after the date of the reconsideration, unless there is evidence to the contrary.[51]

Scope of Review

All initial determinations by CMS-contracted Intermediaries or Carriers *prior to* January 1, 2006, are governed by the ALJ hearing procedures set forth at 20 C.F.R. §§ 404.929 through 404.961 and 42 C.F.R. §§ 405.720 and 405.855. Initial determinations by MACs *after* January 1, 2006, are governed by the ALJ hearing procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1054.

Issues before the ALJ or attorney adjudicator include all the issues for claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the appellant's favor.[52] In addition, a new issue specified in the request for hearing, may only be considered, if its resolution could have a material impact on the claim or appealed matter, and: (1) there is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; and (2) the evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.[53]

The ALJ or attorney adjudicator may decide an appeal on the record, without conducting a hearing, when: (1) the evidence in the hearing record supports a finding fully in favor of the appellant on every issue, no other party to the appeal is liable for claims at issue, and CMS or a contractor has not elected to be a party to the hearing; (2) all of the parties who would be sent a notice of hearing indicate in writing that they do not wish to appear before an ALJ at hearing; or the appellant lives outside the U.S., does not inform OMHA that he or she wants to appear at a hearing before an ALJ, and there are no other parties who would be sent a notice of hearing and who wish to appear.[54]

Standard of Review

OMHA is staffed with ALJs who are qualified and appointed pursuant to the APA.[55] They act as independent finders of fact in conducting hearings pursuant to section 1869 of the Act. In addition, pursuant to rules promulgated in 2017, OMHA attorney adjudicators, licensed attorneys with knowledge of Medicare coverage and payment laws and guidance, are

[50] *Id,* § 405.1002(a)(1).
[51] *Id.* § 405.1002(a)(3).
[52] *Id.* § 405.1032(a).
[53] *Id.* § 405.1032(b).
[54] *Id.* § 405.1038(a)–(b).
[55] 5 U.S.C. § 3105.

authorized to take action on certain requests for ALJ hearing and requests for review of QIC or Independent Review Entity (IRE) dismissals.[56] Attorney adjudicators have the authority to decide appeals for which a decision can be issued without a hearing, issue remands to CMS contractors, and dismiss requests for hearing when an appellant withdraws the request.[57] OMHA may assign attorney adjudicators to adjudicate claim appeals, subject to the statutory procedures, time limits, and procedural requirements of the APA, Medicare law, and applicable HHS regulations. An ALJ or attorney adjudicator conducts a *de novo* review and issues a decision based on the hearing record.[58]

I. Principles of Law

This section of the decision presents the applicable law and governing policy the ALJ or attorney adjudicator used in making his or her decision.

Statutes and Regulations

The Medicare program is administered through CMS, a component of the HHS. Under the authority of section 1842(a)(1)(a) of the Act, the Secretary of HHS is authorized to enter into contracts with private entities for the day-to-day operations of the program. CMS promulgated regulations at 42 C.F.R. § 400, *et seq.* for the implementation of the Medicare program.

National Coverage Determination (NCD)

An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare.[59] The regulations state that an NCD, if applicable, is binding on MACs, QIOs, QICs, ALJs and attorney adjudicators, and the Council.[60] An ALJ or attorney adjudicator may not disregard, set aside, or otherwise review an NCD.[61] However, an ALJ or attorney adjudicator may review the facts of a particular case to determine whether the NCD applies.[62]

Precedential Decisions

Beginning in 2017, the Chair of the Department Appeals Board (DAB), of which the Council is a component, has the authority to designate certain Council decisions as precedential.[63] Decisions designated as precedential are binding on all CMS components, all HHS components that

[56] 42 C.F.R. § 405.902.
[57] *Id.* §§ 405.1000, 405.1004, 405.1052, and 405.1056.
[58] *Id.* § 405.1000(d).
[59] *Id,* § 405.1060(a); CMS, *Medicare Program Integrity Manual* (MPIM), *(Internet-Only Manual Publ'n 100-8*), ch. 13, § 13.1.1.
[60] 42 C.F.R. § 405.1060(a)(4).
[61] *Id.* § 405.1060(b)(1).
[62] *Id.* § 405.1060(b)(2).
[63] *Id.* § 405.968(b).

adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration (SSA) to the extent that components of the SSA adjudicate matters under the jurisdiction of CMS.[64]

Policy and Guidance

The manuals issued by CMS in administering the Medicare program also are considered by ALJs and attorney adjudicators. Although not binding on an OMHA adjudicator, the respective manuals provide guidance in the administration of the Medicare program. In *Shalala v. Guernsey Memorial Hospital*, the United States Supreme Court concluded that an agency manual section is a valid interpretive rule and that it is reasonable for the agency to follow it.[65]

CMS Medicare Internet-Only Manuals (IOMs)

The IOMs are a replica of CMS' official record copy. The IOMs provide information regarding CMS' program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives.[66] The CMS program components, providers, contractors, Medicare Advantage organizations, and state survey agencies use the IOMs to administer CMS programs.[67]

Local Coverage Determination (LCD)

An LCD is a MAC-specific policy regarding whether to cover a particular item or service in accordance with section 1862(a)(1)(A) of the Act. LCDs specify the clinical circumstances under which an item or service is considered to be reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. An LCD applies only to items and services furnished within the MAC's jurisdiction.

ALJs, attorney adjudicators, and the Council are not bound by LCDs, but must give an LCD substantial deference if it is applicable to a particular case.[68] If an ALJ, attorney adjudicator, or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed.[69] An ALJ, attorney adjudicator, or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.[70]

---

[64] *Id.* § 405.1063(c).
[65] *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 102 (1995).
[66] Centers for Medicare & Medicaid Services (CMS): Internet-Only Manuals (IOMs), at http://www.cms.gov/Manuals/IOM/list.asp.
[67] *Id.*
[68] 42 C.F.R. § 405.1062(a).
[69] *Id.* § 405.1062(b).
[70] *Id.*

Additional Guidance

There are other sources of information that can assist with the decision drafting process. Below are descriptions of some of those sources.

Policy Articles

Policy Articles are published in association with LCDs and assist in defining coverage criteria, payment rules, and documentation requirements for a particular item or service. These articles can be located online at the MAC websites or CMS' Medicare Coverage Database.[71]

Drug Compendia

Within Medicare Part B and D appeals, issues often surface surrounding off-label use of drugs. The term "off-label" refers to prescribing a drug for a use not set forth on approved Food and Drug Administration (FDA) labels. Certain off-label uses for FDA-approved drugs may be covered by Medicare, if the use is supported by one or more citations in the following CMS-approved pharmacological compendia:

- American Hospital Formulary Service Drug Information (AHFS-DI);
- DRUGDEX; and
- United States Pharmacopeia-Drug Information (USP-DI) (or its successor publication).

The following additional compendia apply only to drugs and biologicals used in anti-cancer chemotherapeutic regimens:

- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium;
- Clinical Pharmacology; and
- Lexi-Drugs (effective August 12, 2015).

Approved uses for drugs and biologicals furnished incident to physician services under Medicare Part B are addressed in:

- United States Pharmacopoeia-National Formulary (USP-NF); and
- American Dental Association (ADA) Guide to Dental Therapeutics.

Information about FDA-approved brand name and generic prescription and over-the-counter human drugs and biological therapeutic products can be located at the FDA website. Drugs@FDA includes most of the drug products approved since 1939, and the majority of patient information, labels, approval letters, reviews, and other information are available for drug

[71] CMS, *Medicare Coverage Database*, at https://www.cms.gov/medicare-coverage-database/.

products approved since 1998.[72] The FDA database of approved drug products is updated daily and available online.[73]

Healthcare Guidelines

These support materials act as evidence-based guidelines to aid healthcare providers and suppliers when making determinations regarding observation, inpatient, and other levels of care. Two of the leading providers of this type of material are described below.

Practice note:

1. At this time, OMHA does not have access to these guidelines. However, please note that the Council has given these types of guidelines substantial deference and has analogized them to CMS-issued LCDs.[74]

(1) McKesson's InterQual Criteria

McKesson's InterQual Criteria covers the medical and behavioral health continuums of care. CMS and its contractors use InterQual Criteria for its Medicare inpatient services auditing programs.[75]

(2) Milliman Care Guidelines

CMS and its contractors use Milliman Care Guidelines. These independently developed clinical guidelines are evidence-based care guidelines that support care management.[76]

Additional Information

CMS Demonstration Projects

CMS conducts and sponsors a number of demonstration projects to test and measure the effect of potential program changes. These demonstration projects study the likely impact of new methods of service delivery, coverage of new types of service, and new payment approaches on beneficiaries, providers, health plans, and others involved in the delivery and reimbursement of

[72] U.S. Food and Drug Administration: Drugs@FDA Database, at http://www.fda.gov/Drugs/InformationOnDrugs/ucm135821.htm.
[73] *Id.*
[74] Council, *In re Sacred Heart Hospital* (Nov. 2009).
[75] *See* McKesson, Press Releases, "CMS to Use McKesson's InterQual® Criteria to Support Medicare Initiatives for Twelfth Consecutive Year," at http://www.businesswire.com/news/home/20110929005412/en/CMS-McKesson%E2%80%99s-InterQual%C2%AE-Criteria-Support-Medicare-Initiatives; *see also* McKesson Health Solutions Announcement "CMS Continues Its Long-Standing Use of InterQual," at http://www.mckesson.com/about-mckesson/newsroom/press-releases/2015/cms-continues-its-long-standing-use-of-interqual/.
[76] MCG, "About MCG" at https://www.mcg.com/content/about-mcg; *see also* PR New Wire, Press Releases, "CMS to Provide Healthcare Review Contractors with Access to *Milliman Care Guidelines*," at http://www.prnewswire.com/news-releases/cms-to-provide-healthcare-review-contractors-with-access-to-milliman-care-guidelines-107214098.html.

medical services. Demonstration projects are considered to be critical tools in validating research and helping to monitor the effectiveness of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). For example, from 2011 to 2013, CMS conducted a demonstration project, which impacted a significant number of Medicare claims appeals. The Part A to Part B Rebilling Demonstration allowed hospitals to rebill for 90 percent of the Part B payment when a Medicare contractor denied a Part A inpatient short stay claim as not reasonable and necessary due to the hospital billing for the wrong setting. Before, when outpatient services were billed as inpatient services, the entire claim is denied in full.[77]

Federal Case Law

While the majority of OMHA decision writing focuses on the Act, applicable federal regulations, and Medicare coverage guidance; it is important to remember that some cases will be appealed to the federal courts. The issues on appeal can range from administrative procedure rules to Medicare coverage of a specific claim.

J. Analysis

The analysis section, the most important part of the hearing decision, must demonstrate that the ALJ's or attorney adjudicator's conclusion is based on reason and logic, and derived from the facts in the record. The analysis should not range beyond the issues presented and should only address the issues that need to be resolved to decide the appeal. Additionally, each issue raised in the proceeding must be addressed in the ALJ's or attorney adjudicator's reasoning. Failure to address all the issues could lead to reversal by the Council or remand to consider the issue.

Practice notes:

1. Prior to applying the limitation on liability and waiver of overpayment provisions of sections 1879 and 1870 of the Act, an ALJ or attorney adjudicator should first determine whether services provided to the beneficiaries in each case met the coverage provisions of the Act.[78]

2. Effective analysis does not contain solely conclusory paragraphs. Simply restating the facts, the applicable law, and a concluding paragraph **DOES NOT** equate to successful analysis. The decision writer must fully explain why the facts and the applicable law logically and reasonably equal the conclusion.

[77] CMS, Comprehensive Error Rate Testing (CERT), Part A to Part B Rebilling Demonstration, at https://www.cms.gov/CERT/04_Part_A_to_Part_B_Rebilling_Demonstration.asp; see CMS, Part A to Part B Rebilling Demonstration Ended March 14, 2013, at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Part_A_to_Part_B_Rebilling_Demonstration.html.

[78] *See* Council, *In re Charles Stockwell, O.D.*, (Feb. 14, 2011).

3. Any fact presented in the analysis should have already been stated in either the Findings of Fact or the Legal Framework.

Limitation on Liability: Section 1879 of the Act

Under section 1879 of the Act, the Beneficiary and/or Provider/Supplier liability for non-covered Medicare services may be limited under particular circumstances. In pertinent part, limitation on liability may apply to items or services that are excluded under sections 1862(a)(1)(A) and 1862(a)(9) of the Act, or by reason of a coverage denial described in section 1879(g) of the Act.

However, Medicare payment under the limitation on liability provision cannot be made when Medicare coverage is denied on any basis other than one of the provisions of the law specified above (e.g. a technical denial of ambulance services).[79] Moreover, there are certain claims that may appear to involve a question of medical necessity, as described in section 1862(a)(1)(A) of the Act, but the actual Medicare payment denial is based on a statutory provision other than those enumerated in HCFA Ruling 95-1. Under these circumstances, Medicare payment under the limitation on liability provision cannot be made because the denial is not based on one of the statutory provisions specified above.[80]

Practice note:

1. If section 1879 of the Act is applicable, then the section 1879 determination is made prior to a possible section 1870 analysis because an overpayment does not exist if payment can be made under section 1879 of the Act because there was lack of knowledge by both the beneficiary and the provider.[81]

Waiver of Overpayments: Section 1870 of the Act

CMS, *Medicare Financial Management Manual* (*MFMM*), provides that section 1870 of the Act is not limited to claims denied for being not reasonable and necessary under section 1862(a)(1) of the Act. The *MFMM* further states:

> Section 1870 is the framework for determining who is liable for the overpayment and whether the overpayment recovery can be waived. For providers taking assignment, waiving recovery of an overpayment is appropriate where the provider was without fault with respect to causing the overpayment.[82]

[79] HHS: HCFA Ruling 95-1, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads/hcfar951.pdf.
[80] *Id.*
[81] CMS, *Medicare Financial Management Manual (MFMM) (Internet-Only Manual Publ'n 100-6)* ch. 3, § 70.3 (June 2017); Council, *In re Charles Stockwell, O.D.* (Feb. 2011).
[82] *MFMM, supra,* ch. 3, § 70.3 (June 2017).

The *MFMM* provides that once the MAC has concluded that an overpayment exists (that is, a finding that payment cannot be made under the limitation on liability provisions), the MAC must make a determination pursuant to § 1870 of the Act regarding whether the provider and the beneficiary was without fault with respect to the overpayment.

If a provider was without fault with respect to an overpayment it received, it is not liable for the overpayment. Therefore, it is not responsible for refunding the amount involved. CMS provides that a MAC will consider "a provider, physician, or other supplier without fault, if it exercised reasonable care in billing for, and accepting, the payment." This is demonstrated when the provider, physician, or other supplier:

> • Made full disclosure of all material facts; and
> • On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the contractor's attention.[83]

The *MFMM* sets forth examples in which providers are deemed "at fault" for overpayments. For services that are medically unnecessary or custodial, CMS directs the MAC to apply the Section 1879 limitation on liability criteria in determining whether the provider should have known that the services were not covered and, therefore, whether the provider was at fault for the overpayment.[84]

For services other than those that are medically unnecessary or custodial, CMS states that the provider should have known about a policy or rule if:

> (1) The policy is in the provider manual or Federal regulation;
> (2) The Medicare contractor provided general notice to the medical community concerning the policy or rule; or
> (3) The Medicare contractor gave written notice of the policy or rule to the particular provider.

Generally, a provider's allegation that it was not at fault with respect to payment for non-covered services because it was not aware of the Medicare coverage provisions is not a basis for finding it without fault if any of the above conditions are met.[85]

If an overpaid provider was without fault, and therefore not liable for refund, liability shifts to the beneficiary.[86] If a beneficiary is liable for an incorrect payment, recovery may be waived, if the

[83] *MFMM, supra,* ch. 3, § 90.
[84] *MFMM, supra,* ch. 3, § 90.1.
[85] *MFMM, supra,* ch. 3, § 90.
[86] *MFMM, supra,* ch. 3, § 70.3(B).

beneficiary was without fault with respect to the overpayment and recovery would defeat the purposes of Title II or Title XVIII of the Act (i.e., cause financial hardship) or would be against equity and good conscience. (Where an overpayment is discovered subsequent to the third calendar year after the year the payment was made, recovery is deemed against equity and good conscience if the beneficiary was without fault).[87]

Practice notes:

1. Special rules apply to overpayments that are discovered subsequent to the third year in which notice of payment had been made.[88]

2. Sections 1870(b) and (c) of the Act do not apply to providers on nonassigned, post-payment, medically reasonable and necessary claims. These claims are examined under section 1842(1) of the Act.[89]

K. Conclusions of Law

This section of the decision represents the disposition of the appeal. The conclusion should clearly indicate the ALJ's or attorney adjudicator's decision on the issues and whether the item or service is reimbursable under Medicare.

L. Order

This section contains a single sentence ordering the Medicare contractor to process the claim in accordance with the ALJ's or attorney adjudicator's decision.

M. ALJ or Attorney Adjudicator Signature and Date

This section must be signed and dated by the ALJ or attorney adjudicator issuing the decision.

[87] Act § 1870(c); MFMM, *supra*, ch. 3, § 70.3(C).
[88] *MFMM*, *supra*, ch. 3, § 80.
[89] *MFMM*, *supra*, ch. 3, §§ 70 and 70.3.

Almy v. Sebelius

679 F.3d 297
56 Bankr.Ct.Dec. 100
Monique D. ALMY, Chapter 7 Trustee for the Bankruptcy Estate of BioniCare Medical Technologies, Incorporated, Plaintiff–Appellant,
v.
Kathleen SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, Defendant–Appellee.
No. 10–2241.
United States Court of Appeals,
Fourth Circuit.
Argued: Jan. 26, 2012. Decided: April 26, 2012.

Summaries: Source: Justia

Plaintiff, the Chapter 7 trustee for the bankruptcy estate of BioniCare Medical Technologies, contested determinations of the Medicare Appeals Council (MAC) refusing to provide coverage for the BIO-1000, a device to treat osteoarthritis of the knee. Plaintiff alleged that the Secretary improperly used the adjudicative process to create a policy of denying coverage for the BIO-1000, that the MAC's decisions were not supported by substantial evidence, and that the MAC's decisions were arbitrary and capricious on account of a variety of procedural errors. The court rejected those contentions and affirmed the judgment of the district court.

[679 F.3d 299]

ARGUED: Robert Lloyd Roth, Hooper, Lundy & Bookman, PC, Washington, D.C., for Appellant. Michael Raab, United States Department of Justice, Washington, D.C., for Appellee. **ON BRIEF:** Matthew W. Cheney, Crowell & Moring LLP, Washington, D.C., for Appellant. William B. Schultz, Acting General Counsel, Janice L. Hoffman, Associate General Counsel, Mark D. Polston, Deputy Associate General Counsel for Litigation, Brett Bierer, Janet Freeman, Gerard Keating, Department of Health & Human Services, Washington, D.C.; Tony West, Assistant Attorney General, Irene M. Solet, United States Department of Justice, Washington, D.C.; Rod J. Rosenstein, United States Attorney, Larry D. Adams, Assistant United States Attorney, Office of the United States Attorney, Baltimore, Maryland, for Appellee.

Before WILKINSON, GREGORY, and KEENAN, Circuit Judges.

Affirmed by published opinion. Judge WILKINSON wrote the opinion, in which Judge GREGORY and Judge KEENAN joined.

OPINION
WILKINSON, Circuit Judge:

Medicare Part B is a federal program that, among other things, subsidizes items of durable medical equipment for qualified recipients. Plaintiff Monique D. Almy, the Chapter 7 trustee for the bankruptcy estate of BioniCare Medical Technologies, Inc., contests determinations of the Medicare Appeals Council (MAC) refusing to provide coverage for the BIO–1000, a device to treat osteoarthritis of the knee. Almy alleges that the Secretary of Health and Human Services improperly used the adjudicative process to create a policy of denying coverage for the BIO–1000, that the MAC's decisions were not supported by substantial evidence, and that the MAC's decisions were arbitrary and capricious on account of a variety of procedural errors. We reject those contentions and affirm the judgment of the district court.

I. A.

Medicare is a federal program providing subsidized health insurance for the aged and disabled. *See*42 U.S.C. § 1395 *et seq.* The Secretary of Health and Human Services ("the Secretary"), Kathleen Sebelius, is charged by Congress with administering the Medicare statute. *Id.* § 1395ff(a)(1).

Part B of the Medicare Act extends coverage to certain types of durable medical equipment (DME) for qualified recipients. 42 U.S.C. § 1395k(a); *id.* § 1395x(s)(6). Not all DME is guaranteed coverage under Medicare Part B, however. The Medicare statute explicitly provides that "no payment may be made under ... Part B of this subchapter for any expenses incurred for items ... [which] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.*§ 1395y(a)(1)(A).

Acting through her operating components, the Secretary can elect to determine the coverage of DME in one of three ways. First, she can make a "national coverage determination" (NCD) binding throughout the Medicare system and not subject to review by administrative law judges. *Id.* § 1395ff(f)(1)(B). Second, one of the private insurance carriers with whom the Secretary contracts to administer claims under Part B, *see id.* § 1395u(a), can issue a "local coverage determination" (LCD) "respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis." *Id.*

[679 F.3d 300]

§ 1395ff(f)(2)(B). Finally, if no NCD or LCD is in place, "contractors may make individual claim determinations," including whether a particular DME meets the statutory requirement of being "reasonable and necessary." 68 Fed.Reg. 63,693.

The Secretary has also developed guidance in the Medicare Program Integrity Manual (MPIM) for Medicare contractors applying the "reasonable and necessary" standard. Rather than create distinct criteria for individual claim determinations and LCDs, the Secretary has directed contractors to apply a uniform set of standards, providing that "[w]hen making individual claim determinations, ... [a] service may be covered by a contractor if it meets all of the conditions listed in [MPIM] § [1]3.5.1, Reasonable and Necessary Provisions in LCDs below." [1] MPIM § 13.3, Individual Claim Determinations. For a device to be considered "reasonable and necessary," contractors must determine that the item is "safe and effective; not experimental or investigational ...; and appropriate" in terms of both "accepted

medical practice" and "the patient's medical need." MPIM § 13.5.1, Reasonable and Necessary Provisions in LCDs.

The Secretary has also instructed contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either "published authoritative evidence" such as "definitive randomized clinical trials" or "general acceptance by the medical community," with the caveat that "[a]cceptance by individual health care providers" and "limited case studies distributed by sponsors with a financial interest in the outcome[ ] are not sufficient evidence of general acceptance by the medical community." MPIM § 13.7.1, Evidence Supporting LCDs.

The Medicare statute and accompanying regulations create a five-step appeals process for claimants dissatisfied with the initial determination of the Medicare contractor. First, the party can seek redetermination from the initial contractor. 42 U.S.C. § 1395ff(b)(1)(A). Second, the claimant can seek "re-consideration" of the contractor's determinations by a "qualified independent contractor" (QIC). *Id.* § 1395ff(c). If no applicable NCD or LCD governs claims for a particular device, the QIC is instructed by statute to "make a decision with respect to the reconsideration based on applicable information, including clinical experience and medical, technical, and scientific evidence." *Id.* § 1395ff(c)(3)(B)(ii)(III). Third, a claimant can request "a hearing on a decision of a qualified independent contractor" before an administrative law judge. *Id.* § 1395ff(d)(1). Fourth, a party's final administrative appeal within the Department of Health and Human Services is to the Medicare Appeals Council (MAC), a part of the Departmental Appeals Board. *Id.* § 1935ff(d)(2). The statute specifically provides that "the Departmental Appeals Board shall review the case de novo." *Id.* § 1395ff(d)(2)(B). Lastly, a party can bring a civil action in federal court to review a final decision of the Secretary (through the Medicare Appeals Council). *Id.* § 1395ff(b)(1)(A); § 405(g). The statute there prescribes that the Secretary's findings, "if supported by substantial evidence, shall be conclusive" in the judicial proceeding. *Id.*§ 405(g).

B.

The DME at issue in this case is the BioniCare Stimulator System, Model 1000

[679 F.3d 301]

(BIO–1000), a medical device used to treat osteoarthritis of the knee by delivering electrical pulses to the joint. The device was originally developed by Murray Electronics, which sought approval from the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act to market the device. The BIO–1000 was originally submitted for "Pre–Market Approval" (PMA), the most stringent review under the Act, which requires sophisticated proof of the safety and effectiveness of the device. *See*21 U.S.C. § 360c *et seq.* In 1997, however, Murray Electronics notified the FDA of its intent to market the BIO–1000 pursuant to a less-rigorous provision of the statute, known as the "510(k) process." *See*21 U.S.C. § 360c(f)(1)(A)(ii).

Section 510(k) allows a device to be marketed based not on independent clinical

trials of the device itself, but instead because the device is "substantially equivalent to another device" that is already on the market. *Id.* FDA regulations require that for a device to receive 510(k) approval, the device must have "the same intended use as the predicate device" and the sponsor must "demonstrate[ ] that the device is as safe and as effective as a legally marketed device." 21 C.F.R. § 807.100(b)(ii)(B). In July 1997, the FDA issued approval under 510(k) for the BIO–1000 to be marketed, finding that it was substantially equivalent to the Transcutaneous Electric Nerve Stimulator (TENS) device that was already on the market.

Since that time, BioniCare has distributed the BIO–1000 to thousands of patients and submitted numerous Medicare claims. While some contractors have provided Medicare coverage for the BIO–1000, others have frequently refused to cover the device. At issue in this appeal are eight groups of claims denying coverage, which were appealed through the entire administrative process to the MAC. In seven of those cases, the Secretary, through the MAC, determined that the BIO–1000 was not "reasonable and necessary" and was therefore excluded from the statutory coverage of Medicare Part B. All seven cases relied on BioniCare's failure to provide evidence in accordance with MPIM § 13.7.1 that demonstrated that the device was "safe and effective." Appellant's Br. at 21–27 (describing the 535, 310, 208, 891, 852, 259, and 781 Decisions). In the eighth case, BioniCare did not appeal the ALJ's determination that the device was "reasonable and necessary," and so the MAC did not address that question. Instead, the MAC merely affirmed a payment calculation based on a local fee schedule that was unfavorable to BioniCare. Appellant's Br. at 27–28 (describing 191 Decision).

Plaintiff Monique D. Almy, the Chapter 7 trustee for the bankruptcy estate of BioniCare, filed this lawsuit in May 2008, seeking a reversal of the MAC decisions. Both Almy and the Secretary moved for summary judgment, and on September 3, 2010, the district court granted the Secretary's motion in full. This appeal followed.

II.

A brief discussion of the standard of review of the Secretary's decision is necessary at the outset.

A.

With respect to factual determinations, the Medicare statute specifies that "the findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g). The Supreme Court has defined substantial evidence as "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."

[679 F.3d 302]

Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 59 S.Ct. 206, 83 L.Ed. 126 (1938). Our review is therefore necessarily a limited one. "[W]e do not undertake to re-weigh conflicting evidence, make credibility determinations, or substitute our judgment for that of the Secretary. Where conflicting evidence allows reasonable minds to differ ..., the responsibility for that decision falls on the Secretary." *Craig v. Chater,* 76 F.3d 585, 589 (4th Cir.1996).

Quite apart from matters of fact, the Secretary's decisions are governed by the Administrative Procedure Act (APA), which requires courts to determine whether the agency's action was "arbitrary, capricious, an abuse of discretion, ... otherwise not in accordance with law, ... [or] without observance of procedure required by law." 5 U.S.C. § 706(2). Our court has been clear that "[r]eview under this standard is highly deferential, with a presumption in favor of finding the agency action valid." *Ohio Vall. Envt'l Coalition v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir.2009). In practice, an action will not be considered arbitrary and capricious so long as "the agency has examined the relevant data and provided an explanation of its decision that includes 'a rational connection between the facts found and the choice made.' " *Id.* at 192–93 (quoting *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)).

B.

In addition to these statutory directives, a variety of judicial doctrines require that courts not casually overturn the Secretary's decisions. First, it is well recognized that the Secretary's interpretation of what is "reasonable and necessary" under the Medicare Act is entitled to judicial deference pursuant to *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). "[B]ecause the Secretary is charged with administering the Medicare Act, we substantially defer to the Secretary's construction of any ambiguous language in the Act, if the Secretary's construction 'is based on a permissible construction of the statute.' " *MacKenzie Medical Supply, Inc. v. Leavitt*, 506 F.3d 341, 346 (4th Cir.2007) (quoting *id.* at 843, 104 S.Ct. 2778).

Second, the Secretary is also entitled to deference under *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 65 S.Ct. 1215, 89 L.Ed. 1700 (1945), for her interpretation of the regulations that implement the Medicare Act's "reasonable and necessary" standard. This principle requires courts to give an agency's view of its own regulations "controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Id.* at 414, 65 S.Ct. 1215. The Supreme Court has emphasized the importance of careful adherence to this standard in the Medicare context, which deals with "a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns." *Th. Jefferson Univ. v. Shalala*, 512 U.S. 504, 512, 114 S.Ct. 2381, 129 L.Ed.2d 405 (1994)

Thus the very nature of the Medicare program suggests that the Secretary's determinations are entitled to deference from this court. The parties agree that Medicare regulation "is technical and complex" and that the Secretary "has longstanding expertise in the area," circumstances under which "principles of deference have particular force." *Alum. Co. of Amer. v. Cent. Lincoln Peoples' Util. Dist.*, 467 U.S. 380, 390, 104 S.Ct. 2472, 81 L.Ed.2d 301 (1984). Because the determination of what is "reasonable and necessary" also requires

[679 F.3d 303]

a significant degree of medical judgment, we must be mindful that "[w]hen examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential." *Balt. Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 103, 103 S.Ct. 2246, 76 L.Ed.2d 437 (1983).

With these limitations in mind, we consider in turn BioniCare's three challenges to the MAC decisions affirmed by the district court. First, BioniCare disputes the Secretary's use of the individual adjudication process at all, arguing that she should instead have issued an NCD or LCD for the BIO–1000. Second, even if adjudication was the correct process, BioniCare asserts that the MAC decisions were not supported by substantial evidence. Finally, BioniCare alleges a variety of procedural errors at the various rungs of the administrative ladder that it claims infect the MAC's ultimate decisions.

III.

BioniCare contends that because the MAC decisions were based on the safety and effectiveness of the BIO–1000 generally, rather than the medical necessity of the device for any particular patient, the Secretary erred by proceeding through individual adjudications, and she should instead have issued an NCD or LCD to implement a prospective coverage policy. But BioniCare ignores directly applicable Supreme Court precedent, which makes clear that the Secretary enjoys full discretion to choose to proceed by adjudication rather than by rulemaking.

One of the earliest principles developed in American administrative law was the idea that "the choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203, 67 S.Ct. 1575, 91 L.Ed. 1995 (1947). The Medicare statute preserves this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process. Indeed, in *Heckler v. Ringer*, 466 U.S. 602, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984), the Supreme Court expressly foreclosed the argument that BioniCare now presses, holding that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Id.* at 617, 104 S.Ct. 2013.

Not only does the Secretary have the discretion to choose which route to take in assessing the Part B coverage for a device, but BioniCare's asserted concern that the Secretary is "improperly implement[ing] a coverage policy," Appellant's Br. at 50, is simply illusory. The Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect. *See, e.g.*,42 C.F.R. § 405.1062 ("If an ALJ or MAC declines to follow a policy in a particular case, ... [the] decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect."). The purported "policy" in this case is nothing more than the accretion of individual decisions finding that

the BIO–1000 does not meet the statutory requirements for coverage.

Our court has previously refused to constrict the "flexibility of the Secretary" in implementing the "reasonable and necessary" standard, *MacKenzie Medical Supply*, 506 F.3d at 348, but that is precisely

[679 F.3d 304]

what BioniCare asks us to do. As the district court correctly recognized, the result of BioniCare's theory would be to "effectively requir[e] the Secretary to issue item-specific coverage rules for each and every item of DME before issuing case adjudications." *Almy v. Sebelius*, 749 F.Supp.2d 315, 324 n. 2 (D.Md.2010). But Congress has clearly left it to the discretion of the Secretary to decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year. The Medicare Act "has produced a complex and highly technical regulatory program," the administration of which turns on "[t]he identification and classification of medical eligibility criteria [that] necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns." *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 697, 111 S.Ct. 2524, 115 L.Ed.2d 604 (1991). These are the hallmarks of agency discretion, and BioniCare points to no statutory text or other legal basis that would allow the courts to inject themselves into the administration of the Part B claims process. Congress has not seen fit to set mandatory conditions for the use of NCDs or LCDs, and we refuse to craft such requirements out of whole cloth.

The Supreme Court has long warned about the unsuitability of precisely the kind of rule BioniCare urges us to adopt: "To hold that the [Secretary] had no alternative in this proceeding but to approve the proposed transaction, while formulating any general rules it might desire for use in future cases of this nature, would be to stultify the administrative process." *Chenery*, 332 U.S. at 202, 67 S.Ct. 1575. And like the Supreme Court, "[t]hat we refuse to do." *Id.*

IV.

BioniCare's next major claim is that the Secretary's decisions were not supported by "substantial evidence" as required by both the Medicare statute and the APA. This allegation comes in three parts. First, BioniCare asserts that the Secretary applied the wrong standard in assessing the relevant evidence. Second, it claims that the Secretary has a heightened burden of proof. BioniCare asserts that it made a prima facie case for coverage, which requires the Secretary to produce affirmative evidence in rebuttal in order for the MAC's denial of coverage to be supported by substantial evidence. Finally, BioniCare claims that it did in fact produce adequate evidence to justify coverage of the BIO–1000, and that the MAC's critique of that proof is inadequate to support a denial of such coverage. We disagree with BioniCare on all three fronts.

A.

BioniCare first contends that the MAC decisions applied the wrong standard for individual claim determinations, arguing that the MAC erroneously relied on standards only applicable to LCDs. The Secretary has, however, made clear that the same criteria that govern LCDs should also govern individual adjudications. MPIM § 13.3, Individual Claim Determinations, specifically

provides that for individual adjudications, contractors should use the standards set out for LCDs in MPIM § 13.5.1. It is that section, entitled "Reasonable and Necessary Provisions in LCDs," that sets out the substantive criteria that a device must meet in order to receive coverage. Specifically, in order to be considered "reasonable and necessary," *see*42 U.S.C. § 1395y(a)(1)(A), a device must be "safe and effective; not experimental or investigational ...; and appropriate," MPIM § 13.5.1, and BioniCare does not dispute that a device must meet

[679 F.3d 305]

those requirements in order to receive Part B coverage.

BioniCare contends, however, that the Secretary erred by using the guidelines of MPFM § 13.7.1, Evidence Supporting LCDs, to evaluate the studies it offered to show that the BIO–1000 was safe and effective. BioniCare argues that these standards apply only to LCDs, and not to individual adjudications. As we have explained, however, the Secretary has adopted a single set of standards that governs both LCDs and individual adjudications. The MPFM section on individual adjudications, § 13.3, indisputably incorporates by reference the substantive criteria applicable to LCDs in § 13.5.1, and MPFM § 13.7.1 does no more than explicate the type of evidence that may demonstrate a device's compliance with the conjunctive standards of § 13.5.1. Specifically, MPIM § 13.7.1 requires a claimant to show that a device is safe and effective through "published authoritative evidence" such as "definitive randomized clinical trials" or "general acceptance by the medical community," with the qualification that "[a]cceptance by individual health care providers" and "limited case studies distributed by sponsors with a financial interest in the outcome[ ] are not sufficient evidence of general acceptance by the medical community." MPIM § 13.7.1, Evidence Supporting LCDs. Far from being "arbitrary [or] capricious," the Secretary has directed contractors to use uniform criteria in assessing Part B coverage, supported by uniform types of evidence, and it was not erroneous or inconsistent for the MAC to have applied the requirements of MPIM § 13.7.1.

B.

Second, BioniCare disputes the appropriate burden of proof that governs a "reasonable and necessary" determination by the MAC. It claims that, having made a prima facie case, the burden shifts to the Secretary to rebut that evidence with her own offer of proof, and that it is insufficient for the MAC to provide merely a critique of BioniCare's showing. But there is no basis in law for this assertion. It is well established that "a claimant ... has the burden of proving entitlement to Medicare benefits," *Friedman v. Sec'y of Dept. of Health and Hum. Servs.*, 819 F.2d 42, 45 (2d Cir.1987).

Even the case BioniCare cites in support of its conclusion, *Dir., Off. of Workers' Comp. Progs. v. Greenwich Collieries,* 512 U.S. 267, 114 S.Ct. 2251, 129 L.Ed.2d 221 (1994), does not point to a different result. While it is doubtful that the standards for formal adjudication at issue in that case even apply to these informal proceedings under the Medicare Act, the most that the *Greenwich Collieries* Court concluded was that "when the

party with the burden of persuasion establishes a prima facie case supported by 'credible and credited evidence,' it must either be rebutted or accepted as true." *Id.* at 280, 114 S.Ct. 2251. Here, the MAC's conclusion was that BioniCare had failed to satisfy the critical first step, because it did not provide "credible and credited evidence," as measured against the standards set out in MPIM § 13.7.1.

C.

Using the appropriate standard of review and burden of proof, the Secretary's determination that BioniCare did not establish that the BIO–1000 was "safe and effective" and "not experimental or investigational" was in fact supported by substantial evidence. It is not our office to tender an independent judgment on the value and validity of the various scientific studies submitted. We ask only whether the Secretary's

[679 F.3d 306]

assessment was a reasonable one, and we are satisfied that it was.

The MAC reviewed the studies submitted by BioniCare in support of the BIO–1000 and identified numerous deficiencies that deprived them of persuasive value. BioniCare submitted twenty-one separate studies. Five of these included no analysis and were merely conclusory. Eight did not discuss the type of electrical stimulation treatment for which the BIO–1000 was ostensibly prescribed. One referred to a device other than the BIO–1000. And three tested electrical stimulation treatments in animals.

The MAC identified additional methodological errors in the four remaining studies that did actually address the BIO–1000's safety and effectiveness in humans and that could potentially offer credible evidence. All four studies failed to isolate the effect of concurrent drug therapy. In other words, they failed to exclude the possibility that other drugs or regimens besides the BIO–1000 accounted for any patient improvement. Two studies had small sample sizes, one of only 58 subjects and another with 78 subjects. Two others had experimental design problems—one study was not randomized or double-blind, and the other lacked a proper control group.

In addition, the MAC discounted these four studies because the authors all had financial ties to either BioniCare or the BIO–1000's original developer Murray Electronics. The regulations pertaining to acceptable evidence in the MPIM explicitly provide that "limited case studies distributed by sponsors with a financial interest in the outcome[ ] are not sufficient evidence of general acceptance by the medical community." MPIM § 13.7.1, Evidence Supporting LCDs.

BioniCare asserts that because its studies were independently published, they were not "distributed by sponsors," and therefore not within this rule. Given the substantial deference that we owe the Secretary's reasonable interpretations of her own regulations, however, we cannot conclude that her actions were unreasonable. *See Seminole Rock,* 325 U.S. at 414, 65 S.Ct. 1215. It is a maxim of evidence that a party's interest in a potential outcome can affect his objectivity, and the MPIM regulation is clearly directed at ensuring that coverage decisions

rest on an objective and disinterested foundation. The financial interest of those conducting studies goes to the credibility of the supporting evidence, and this court has been clear that "absent extraordinary circumstances, we will not disturb an [agency]'s credibility determinations." *N.L.R.B. v. Transpersonnel, Inc.*, 349 F.3d 175, 184 (4th Cir.2003).[2]

While the record is more than sufficient to justify the Secretary's factual conclusion that BioniCare had not carried its burden of showing that the BIO–1000 was safe and effective, our analysis is not scientifically detailed. Nor would such an assessment be permitted. The Supreme Court has warned time and again that a "technical factual dispute simply underscores the appropriateness of deferring" to agency decisions. *Talk America, Inc. v. Mich. Bell Tel. Co.*, — U.S. ——, 131 S.Ct. 2254, 2265 n. 7, 180 L.Ed.2d 96 (2011). Properly

[679 F.3d 307]

mindful of this fact, BioniCare's brief does not explore the substance of the science. For "we as a court are confronted with a problem in administrative law, not in chemistry, biology, medicine, or ecology. It is the administrative agency which has been called upon to hear and evaluate testimony ... relevant to its ultimate question." *Envt'l Def. Fund v. EPA*, 489 F.2d 1247, 1252 (D.C.Cir.1973). The MAC "has greater expertise and stands in a better position than this Court to make the technical and policy judgments necessary to administer the complex regulatory program at issue." *Talk America*, 131 S.Ct. at 2265 n. 7. The court's role is to perform the "narrowly defined duty of holding agencies to certain minimal standards of rationality." *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C.Cir.1976). There can be little doubt that the Secretary's decisions surpass that threshold and are supported by "substantial evidence." [3]

V.

Even though the Secretary exercised her statutory discretion to proceed through adjudication, and her decisions were supported by substantial evidence, BioniCare nevertheless contends that the Secretary committed a variety of procedural errors that fatally undermine the MAC decisions. These claims are rooted in the familiar standards of the APA, 5 U.S.C. § 706(2)(A), which permits a court to "set aside agency actions, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* This is a demanding burden for BioniCare to carry. As this court has noted, "[w]hen the question before the court is whether an agency has properly interpreted and applied its own regulation, the reviewing court must give the agency's interpretation 'substantial deference.' " *Md. Gen. Hosp., Inc. v. Thompson*, 308 F.3d 340, 343 (4th Cir.2002) (quoting *Th. Jefferson Univ.*, 512 U.S. at 512, 114 S.Ct. 2381). BioniCare has failed to demonstrate that the MAC's application of the relevant standards was "plainly erroneous or inconsistent with" the regulations, *Seminole Rock*, 325 U.S. at 414, 65 S.Ct. 1215, and these claims therefore have no merit.

A.

BioniCare contends that the Secretary failed to give adequate consideration to the FDA's clearance of the BIO–1000 for marketing under the 510(k) process. It argues

that FDA clearance per se satisfies the requirement of MPIM § 13.5.1 that, in order to be considered "reasonable and necessary," a supplier must establish that a device is safe and effective and not experimental or investigational. This argument misapprehends, however, both the separate statutory allocations of interpretive authority to the Secretary and to the FDA and the relative import of the FDA's 510(k) clearance.

[679 F.3d 308]

The Medicare statute clearly vests the Secretary with the authority to interpret when a device is "reasonable and necessary," and therefore eligible for coverage under Part B. The statute contemplates no role for the FDA, which is charged with applying the standards of the Federal Food, Drug, and Cosmetic Act, not the Medicare statute. The FDA examines "the labeled use of a device only," concentrating its review on the safety of a device, whereas Medicare review "focus[es] on ... a device under average conditions of use" to determine whether the device meets the broader requirement of the Medicare statute that a device be "reasonable and necessary." 54 Fed.Reg. 4307. The Secretary has underscored this difference, noting that Medicare "contractors make coverage determinations and the FDA conducts premarket review of products under different statutory standards and different delegated authority." 68 Fed.Reg. 55,636. The statement proceeds to make clear that while FDA approval has been adopted as a prerequisite to Medicare coverage, "FDA approval/clearance alone does not generally entitle that device to coverage." *Id.* While FDA approval may thus inform the Secretary's decision as to whether a device is "reasonable and necessary," it cannot tie the Secretary's hands.

This holds especially true for a device such as the BIO–1000, which was only cleared by the FDA under the abbreviated 510(k) process. The Secretary has long noted the significance of the type of clearance a device receives: "FDA approval ... will not necessarily lead to a favorable coverage recommendation, particularly if FDA requirements have been met by means of a notice issued under section 510(k).... This is because a section 510(k) notice generally does not involve clinical data showing safety and effectiveness." 54 Fed.Reg. 4307. Section 510(k) approval requires only that a device be "substantially equivalent" to another device that the FDA has already approved for marketing, and not that the device have been clinically examined for safety and effectiveness. The Supreme Court has emphasized this distinction, noting that a device approved under 510(k) "has never been formally reviewed ... for safety or efficacy." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 493, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). In the face of such consistent statements that FDA approval alone is not enough, and that 510(k) clearance is especially deficient, we cannot say that it was arbitrary or capricious of the Secretary to require additional proof of the BIO–1000's safety and effectiveness.

Not only was the BIO–1000 not subject to the more demanding safety review of the Pre–Market Approval (PMA) process, neither was the TENS device that served as the predicate for the 510(k) clearance. Because the TENS device was marketed prior to the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, its

market approval was "grandfathered" rather than the result of satisfying the requirements of the PMA regime. In short, the FDA's clearance of the BIO–1000 was based on its equivalence to a device that was never itself tested for safety and effectiveness. It was therefore surely reasonable for the Secretary to require evidence in addition to the mere fact of 510(k) approval to demonstrate the BIO–1000's safety and effectiveness.

BioniCare further undercut the already limited significance of the "substantially equivalent" 510(k) clearance in the Medicare administrative proceedings by highlighting differences between the BIO–1000 and the TENS device. The TENS device seeks to mask pain in nerve tissue by sending high voltage electrical impulses that interrupt pain signals to the brain. The BIO–1000, by contrast, operates on

[679 F.3d 309]

cartilage tissue, using smaller impulses intended to actually improve the condition of knee joints rather than merely hide the discomfort of the underlying condition. BioniCare also charges significantly more for the BIO–1000 than Medicare allows providers to charge for the TENS device. It was reasonable of the Secretary to conclude that BioniCare's representations showed that the BIO–1000's "average conditions of use" were quite different from the uses of the TENS device that served as the predicate to the FDA's 510(k) clearance, and that the FDA's clearance was therefore not adequate proof of the device's safety and effectiveness.

BioniCare attempts to claim credit for having initially submitted the BIO–1000 under the PMA process, under which "[t]he FDA evaluates safety and effectiveness under the conditions of use set forth on the label." *Riegel v. Medtronic,* 552 U.S. 312, 318, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008). We need not consider here whether PMA approval would per se satisfy the requirements of MPIM § 13.5.1, because although the BIO–1000 was submitted for PMA approval, it only received approval under section 510(k). It is immaterial that the FDA suggested that BioniCare withdraw its request for PMA review and accept a 510(k) approval "as a result of increasing Congressional pressure to clear out its backlog." Appellant's Br. at 46. BioniCare clearly had the choice to remain in the PMA pipeline. Had it done so, it could at least now argue to us the greater significance of the more rigorous approval process. Instead, it opted for the likely more profitable course of getting the device to market faster. BioniCare chose the speedier and less-demanding route of 510(k) clearance, and it cannot now claim the legal benefit of a more exacting review process it ultimately elected not to undertake.

B.

BioniCare next asserts that the intermediate review by a qualified independent contractor (QIC) failed to comply with regulations requiring input from "a panel of physicians or other appropriate health care professionals." 42 C.F.R. § 405.968(a)(1). BioniCare is correct that such input was required, both because "the initial determination involve[d] a finding on whether an item or service is reasonable and necessary," *id.,* and because the "claim pertains to ... the provision of items or services by a physician," *id.* § 405.968(c)(3). But BioniCare's only evidence that this requirement was not satisfied is its assertion

that the record does not document compliant participation by a physician. As the district court properly found, this allegation does not satisfy BioniCare's burden to substantiate its claim. *See Almy*, 749 F.Supp.2d at 333.

The regulation imposes no obligation on the QIC to document the physician review, and BioniCare does not assert that the decisions failed to adequately explain the scientific or medical basis for the QIC's decision. "The presumption of regularity supports the official acts of public officers, and, in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties." *United States v. Chem. Found.*, 272 U.S. 1, 14–15, 47 S.Ct. 1, 71 L.Ed. 131 (1926). Respect for an administrative agency's implementation of its own regulations requires clear evidence to surmount the hurdle of arbitrary and capricious review. BioniCare provides no affirmative proof of failure to comply with the regulation, and we have no reason to displace the "presumption of regularity [that] attaches to the actions of government agencies." *U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 10, 122 S.Ct. 431, 151 L.Ed.2d 323 (2001).

[679 F.3d 310]

C.

BioniCare last argues that the Secretary's decisions were arbitrary and capricious because the MAC decisions at issue here reach a different result from other decisions at the ALJ and contractor levels of the Medicare review process that allowed coverage for the BIO–1000. Because some ALJs and contractors have covered the device and some have not, BioniCare contends that the Secretary has made inconsistent decisions. As BioniCare admits, however, "some inconsistency related to the patient-specific nature of the determination is, perhaps, inevitable." Appellant's Reply Br. at 2.

Moreover, it is undisputed that these lower-level decisions are not precedential and not binding on the MAC. The Secretary's promulgated regulations make clear that a decision by a contractor or ALJ is only binding on the parties to that particular case, and that a decision is not binding once "a party files a written request for a MAC review that is accepted and processed." 42 C.F.R. § 405.984. Other circuits have considered analogous situations, and they all reach the shared conclusion that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level.... [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C.Cir.2003); *see Almy*, 749 F.Supp.2d at 326–28 (collecting cases).

Moreover, the MAC is explicitly charged with undertaking *de novo* review, *see*42 U.S.C. § 1395ff(d)(2)(B); 42 C.F.R. § 405.1100(d), which is incompatible with BioniCare's proffered notion that the MAC is somehow obligated to defer to the outcomes of prior decisions below. Nowhere does any policy or regulation suggest that the MAC owes any deference at all to—much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties merely because they pertain to the same device.

As the Secretary notes, only MAC decisions constitute the final decision of the Secretary. *See id.* § 405.1130. BioniCare points to no other MAC decision specifically finding that the BIO–1000 was "reasonable and necessary" or "safe and effective." We therefore cannot conclude that "the agency has failed to explain its departure from prior precedent," *Bush–Quayle '92 Primary Comm., Inc. v. FEC*, 104 F.3d 448, 453 (D.C.Cir.1997), such that the MAC decisions are deprived of deference, because there simply was no contrary precedent from which the agency departed. While BioniCare attempts finally to assert that even the MAC decisions are inconsistent with one another, in every instance in which the question of whether the device was "reasonable and necessary" was before the MAC, it applied the same proper standards from the MPFM and reached the same conclusions about the inadequacy of BioniCare's proffered evidence.

In addition, BioniCare's proposed expansion of what constitutes binding agency precedent would severely constrict the undisputed delegated authority of the Secretary to administer the Medicare system. The Medicare statute and its accompanying regulations create a "mammoth bureaucracy with seemingly endless layers of internal review." *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir.1987). BioniCare seeks to impose massive resource costs on the Secretary, requiring her to reverse any decision at a lower level of adjudication either through promulgation of an NCD or through MAC review lest that lower decision become

[679 F.3d 311]

precedent that precludes a different considered result in future cases before the MAC. As the Secretary notes, there were 970 million Medicare Part B claims in 2008 alone, and the Secretary rarely participates in the lower level adjudications of those claim determinations. Appellee's Br. at 55 n. 19. Exercising her acknowledged discretion to allocate agency resources, the Secretary has promulgated regulations limiting *sua sponte* review to cases that either "contain[ ] an error of law material to the outcome of the case or present[ ] a broad policy or procedural issue that may affect the general public interest." 42 C.F.R. § 405.1110(c)(2). The Secretary has simply not seen fit to invoke her final authority in every case in which there is an argument over whether the evidence adequately supports a finding that a device was "reasonable and necessary."

In so complex an area as Medicare Part B administration, the courts should not casually direct the Secretary as to when she must exercise her authority to make final determinations, especially where, as here, the final determinations that she has made have been consistent in denying coverage for the BIO–1000. Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local contractors cannot deprive her of that discretion, any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court. It was therefore not arbitrary and capricious of the MAC to make final determinations that may have been at odds with prior coverage decisions that did

not carry the full imprimatur of the Secretary's authority. [4]

VI.

Our court has previously noted that the Medicare statute is "among the most completely impenetrable texts within human experience." *Rehab. Ass'n of Va., Inc. v. Kozlowski,* 42 F.3d 1444, 1450 (4th Cir.1994). This complexity, however, in no

[679 F.3d 312]

way permits courts to abandon their reviewing role, for the absence of judicial oversight would risk unsupported and unexplained agency decisions. We have thus reviewed the claims herein with care, and we are satisfied that the Secretary has proceeded in accordance with law.

To go further would invite unforeseeable consequences in health care costs, public resource allocation, and coverage of dubious medical devices. At the end of the day, we must respect the fact that Congress has chosen to leave the interpretation of the "reasonable and necessary" requirement of Medicare Part B to the informed discretion of the Secretary and the professional panels who exercise her authority. The Secretary has not taken this responsibility lightly, promulgating voluminous regulations, coverage manuals, and notice documents explaining the standards that will guide her determinations. She has created an exhaustive review process ensuring that claimants will have repeated and extensive opportunities to ensure that compliant claims are properly reimbursed.

Yet BioniCare urges us to wade into this area with very little to keep us afloat. It would have us supplant the Secretary's decisions about whether to adjudicate, how to adjudicate, and even how to decide those adjudications without a shred of guidance from Congress to secure our decisions. It is the Secretary, not the courts, who bears the responsibility for the disbursement of billions of dollars of public money under the Medicare system. Appropriations are not our forte, and we shall not redirect the Secretary without a greater showing in law than BioniCare has made here.

The judgment of the district court is *AFFIRMED.*

Notes:

[1] MPIM § 13.3, Individual Claim Determinations, erroneously lists the chapter number for "Reasonable and Necessary Provisions in LCDs" as "3.5.1." This appears to be a typographical error; the correct heading for that subsection is "13.5.1."

[2] BioniCare seeks to rehabilitate its evidence from this deficiency by claiming that any bias in the studies is outweighed by the fact that the articles are peer-reviewed. The weight to be given peer reviews is again an evidentiary matter best left to the MAC as finder of fact, and not to a reviewing court of appeals. Moreover, it is an argument that courts are particularly ill-equipped to assess. Whether a medical study satisfied the standards of scientific rigor that BioniCare claims is hardly a matter on which the normal judicial deference to the Secretary's determinations can be discarded.

[3] BioniCare also argues that the Secretary's acceptance of the BIO–1000's safety and effectiveness is demonstrated by the fact that the Center for Medicare and Medicaid Services assigned a billing code to the device under the Healthcare Common Procedure Coding System (HCPCS) and created a fee schedule for claims for the device. But the fact that the Secretary may have taken steps to facilitate the administration of the thousands of claims for the BIO–1000 cannot dictate the ultimate determination on those claims. The Medicare statute precludes coverage of items that are "not reasonable and necessary" "[n]otwithstanding any other provision of this subchapter." 42 U.S.C. § 1395y(a)(1)(A). Further, the HCPCS code book contains a disclaimer that "[i]nclusion or exclusion of a procedure, supply, product or service does not imply any health insurance coverage or reimbursement policy." *Almy,* 749 F.Supp.2d at 332.

[4] BioniCare raises two other issues that do not merit extended discussion. First, it disputes the application of a local fee schedule in one of the eight MAC cases under review. The Medicare statute limits reimbursement for DME to 80 percent of the lesser of either the actual charge for the item or the fee schedule amount for the item. 42 U.S.C. § 1395m(a)(1); 42 C.F.R. § 414.210(a). The ALJ and MAC made findings that a fee schedule was properly implemented by a local contractor pursuant to guidance from the Secretary authorizing local "gap-filling" fee arrangements when no national fee schedule exists. *See* Medicare Claims Processing Manual (MCPM) Ch. 23, § 60.3. We agree with the district court's conclusion that the MAC did not act arbitrarily or capriciously in determining that the lower payment authorized by the fee schedule amount was the appropriate reimbursement. *See Almy,* 749 F.Supp.2d at 333–34.

Second, BioniCare argues that the Secretary erred in rejecting certain "Advance Beneficiary Notices" (ABN) that purported to shift liability for device costs to the recipients of the BIO–1000. A supplier can shift the burden to a beneficiary by providing the beneficiary with advance written notice that a device will probably not be covered by Medicare. MCPM Ch. 30, § 40.1.1. If the notice merely does "no more than state that Medicare denial of payment is possible," *id.* § 40.3.6.1, however, then liability remains with the supplier. In two decisions at issue here, the Secretary ruled invalid ABNs that stated that "it is unclear what criteria Medicare will use when

evaluating whether the device was reasonable and medically necessary for you. Medicare will not pay for a device that it does not deem reasonably necessary for you." We similarly affirm the district court's conclusion that the MAC did not act arbitrarily or capriciously in finding that these generic statements failed to offer a "genuine reason that denial by Medicare is expected." *Almy*, 749 F.Supp.2d at 335 (quoting MCPM Ch. 30 § 40.3.6.1)

Module 7:
Medicare Part B – Coding & Physician Services

After this session, you will be able to:

1. Understand the role of the International Classification of Diseases (ICD) code sets, and the correct usage of diagnosis and procedure codes in Medicare claims;
2. Understand the roles of both levels of the Healthcare Common Procedure Coding System (HCPCS);
3. Identify the statutory authority that sets forth the scope of benefits for physician services;
4. Understand the key components of evaluation and management (E/M) codes for physician services;
5. Understand why some claims are denied based on National Correct Coding Initiative (NCCI) edits;
6. Understand the use of modifiers to bypass NCCI edits; and
7. Locate NCCI edits in the MediRegs database.

Required Reading:

- ✓ Social Security Act (Act) § 1832
- ✓ Act § 1861(s)(1)
- ✓ 42 C.F.R. § 410.20
- ✓ CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-2)* ch. 15, § 30

References:

- ✓ CMS, *1995 Documentation Guidelines for Evaluation and Management Services*, available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf.
- ✓ CMS, *1997 Documentation Guidelines for Evaluation and Management Services*, available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/97Docguidelines.pdf.

- ✓ CMS, Medicare Learning Network, *Evaluation and Management Services Guide* (2015), available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf

- ✓ CMS, *National Correct Coding Initiative Policy Manual for Medicare Services (NCCI)* (Jan. 2018), available at https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index.html

- ✓ CMS, *ICD-10 Lookup Tool*, at https://www.cms.gov/medicare-coverage-database/staticpages/icd-10-code-lookup.aspx

Introduction – Background and Rationale

Medicare, like other health insurance programs, uses standardized coding systems to process claims. To understand the Medicare program, it is important to understand how these various coding systems are used to submit claims. This module will provide a basic overview of the codes sets used by Medicare as well as demonstrate how certain codes are used when submitting claims for physician services. Additionally, you will learn how to use NCCI edits to prevent improper payment, and how to identify Medicare claim forms.

Objective 1: Understand the roles of the International Classification of Disease (ICD) code sets and the correct usage of diagnosis and procedure codes in Medicare claims.

Prior to October 1, 2015, the ICD, 9th Revision, Clinical Modification (ICD-9-CM) was the code set all providers used to report medical diagnoses and procedures on Medicare claims.

There are two types of ICD-9-CM codes. The first type of ICD-9-CM code identifies diagnoses utilizing a five digit code. For example, "malignant hypertensive heart disease without heart failure" is represented by ICD-9-CM code 402.00. "Benign hypertensive heart disease with heart failure" is represented by ICD-9-CM code 402.11.

The second type of ICD-9-CM code is used by hospitals to identify procedures furnished to hospital inpatients. ICD-9-CM procedure codes are not used for services furnished on an outpatient basis.

ICD-9-CM procedure codes are four digit codes. For example, a "Total Knee Replacement" is represented by ICD-9-CM procedure code 81.54.

It should be noted that **ICD-9-CM diagnosis codes** are used in all healthcare settings (hospitals, doctors' offices, durable medical equipment suppliers, etc.) to identify a patient's diagnosis. **ICD-9-CM procedure codes** are used only by hospitals and only to report procedures furnished to hospital inpatients.

The World Health Organization (WHO) developed ICD-10 as a better way to keep up with new diagnoses, treatments and technology. ICD-10 has more than 140,000 codes, allowing for more specific coding and the addition of new codes in the future. As of October 1, 2015, health care providers are now required to use ICD-10 diagnosis codes in all health care settings. ICD-10 procedure codes are required to be used by all inpatient hospital providers. CPT and HCPCS codes continue to be used for outpatient, ambulatory and office-based procedure coding.

Table of Proper Codes Sets to Use Post- ICD-10 Implementation

	Inpatient	**Outpatient**
Procedures	ICD-10-PCS	CPT/HCPCS
Diagnoses, LCDs and NCDS	ICD-10-CM	ICD-10-CM

ICD-10-CM is the coding system for **diagnosis coding**. They will be used for all health care settings. Diagnosis coding under this system uses 3-7 alpha and numeric digits:

Structure of ICD-10-CM Coding

ICD-10-PCS is the coding system that **defines procedures**, not diagnostic information. It will only be used for coding inpatient hospital procedures. This new procedure coding system uses seven (7) alpha or numeric digits where the ICD-9-PCS uses three (3) or four (4) numeric digits.

Structure of ICD-10-PCS

Character	1	2	3	4	5	6	7
Definition	Name of section	Body System	Root Operation	Body Part	Approach	Device	Qualifier

HCPCS is a standardized coding system which describes specific services, procedures, and supplies provided in the delivery of healthcare.

There are two levels of HCPCS codes. Level I of HCPCS is the American Medical Association's *Current Procedural Terminology* (CPT). Unlike ICD-9-CM procedure codes and ICD-10-PCS codes, which are used by hospitals in the inpatient setting, CPT codes are used by physicians and other medical professionals to identify procedures and professional services furnished in an ambulatory or outpatient setting, including physician visits to inpatients.

CPT codes are five digit codes. For example, the CPT code for a total knee replacement (also called a total knee arthroplasty) is "27447."

CPT codes are broken down into three categories:

- **Category I** codes are used for most outpatient services. Category I codes are updated annually and are broken down into six sections:
    - Evaluation and Management
    - Anesthesiology
    - Surgery
    - Radiology
    - Pathology and Laboratory
    - Medicine
- **Category II** codes are used for performance measurement.
- **Category III** codes are temporary codes for new and emerging technologies. Services identified with these codes include services that are not be performed by many health care professionals across the country, do not have FDA approval, or do not have a proven clinical efficacy.

Level II of HCPCS is a standardized coding system used primarily to identify products, supplies, and services not included in the CPT. HCPCS Level II codes are five digit alphanumeric codes. For example, the HCPCS Level II code for ambulance services, nonemergency transportation and air travel is "A0140." The HCPCS Level II code for a power operated vehicle is "E1230." The HCPCS Level II code for the drug Epoetin Alfa (for non-End Stage Renal Disease use) is "J0885."

It is important to understand how HCPCS codes are used by providers and suppliers to identify services, procedures, and supplies, and how they differ from ICD codes. Notably, inpatient providers such as hospitals use ICD-9-CM procedure codes or ICD-10-PCS codes to identify procedures furnished to hospital inpatients, whereas physicians and other suppliers use HCPCS Level I (CPT) codes to identify procedures furnished in an ambulatory/outpatient setting.

Objective 3: Identify the statutory authority that sets forth the scope of benefits for physician services.

Section 1832 of the Act entitles Medicare Part B beneficiaries to have payment made to them or on their behalf for medical and other health services. Medical and other health services, by definition, include physician services. Act § 1861(s)(1); 42 C.F.R. § 410.10(a).

Physician services are the professional services performed by a physician or physicians for a patient including diagnosis, therapy, surgery, consultation, care plan oversight, and home, office, and institutional calls. Act § 1861(q); 42 C.F.R. § 410.20; *MBPM*, *supra* ch. 15, § 30(A).

Medicare pays for physician services if they are furnished by one of the following professionals who is legally authorized to practice by the State in which he or she performs the service, and who is acting within the scope of his or her license:

- A doctor of medicine (MD) or osteopathy (DO);
- A doctor of dental surgery or dental medicine;
- A doctor of podiatric medicine;
- A doctor of optometry; or
- A chiropractor who meets certain qualifications.

42 C.F.R. § 410.20(b).

A service may be considered to be a physician's service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgment. *MBPM*, *supra*, ch. 15, § 30(A). Direct visualization would be possible by means of x-rays, electrocardiogram and electroencephalogram tapes, tissue samples, etc. *Id.*

Physician services cases vary widely and can involve issues ranging from application of National Coverage Determinations to billing and coding issues.

Objective 4: Understand the key components of evaluation and management (E/M) codes for physician services.

E/M codes begin with "99" and are used to identify consultations and visits (such as doctor's office visits and hospital visits) furnished by physicians.

E/M codes are comprised of three key components: history, examination, and medical decision making. Depending on the code, some or all of the key components must be documented in the medical record. The criteria for each key component are defined in the CMS 1995 and 1997 E/M Guidelines.[1]

Use the 1995 and 1997 E/M Guidelines to determine whether the medical documentation substantiates medical necessity for the codes billed. According to CMS, both the 1995 and 1997 E/M Guidelines are in effect. CMS, Medicare Learning Network, *Evaluation and Management Services Guide* (2015). However, using both the 1995 and 1997 E/M Guidelines for a patient encounter is prohibited (in other words, one can utilize the 1995 or 1997 E/M Guidelines, but never a combination of both guidelines). *Id.* There is one limited exception—for services performed on or after September 10, 2013, physicians may use the 1997 documentation guidelines for an extended history of present illness along with other elements from the 1995 guidelines to document an E/M service.

There is a minor difference in the description of an extended history of present illness (HPI) between the 1995 and 1997 versions of the documentation guidelines. The 1995 guidelines require documentation of four or more elements of the present HPI or associated comorbidities, whereas the 1997 guidelines require at least four elements of the present HPI or the status of at least three chronic or inactive conditions.

The most substantial differences between the 1995 and 1997 versions of the documentation guidelines occur in the examination section. Unlike the 1995 guidelines, the 1997 guidelines set forth specific criteria for a general multi-system examination and several single organ system examinations. The 1997 guidelines then provide bulleted lists for each type of examination. To satisfy the key components of an E/M code, an examination must document bulleted items from either the general multi-system examination list or one of the single organ system examination lists, as appropriate. The required number of bullets depends on the level of physical examination performed (Problem Focused, Expanded Problem Focused, Detailed, or Comprehensive). There are also several specialty exams designed to contain bullets in shaded and/or unshaded boxes.

[1] *See Evaluation and Management Services Guide,* at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/EMDOC.html; *see also Evaluation and Management Services Codes in the American Medical Association Current Procedural Terminology (CPT) Codebook,* at http://hsrl.mediregs.com/cgi-bin/_tocs/tc?view=crs&c=mre_hcpcscpt&n=9130&a=e&r=2

Using the E/M Guidelines is fairly simple. For example, to receive Medicare reimbursement for the E/M code 99214: Office or Other Outpatient Visit for an Established Patient, at least two of the following key components must be documented in the medical record:

A detailed history;
A detailed examination; and
Medical decision making of moderate complexity.

A "detailed examination" is defined by the 1997 E/M Guidelines as "an extended examination of the affected body area(s) or organ system(s) and any other symptomatic or related body area(s) or organ system(s)."[2] The single organ systems are as follows:

- Cardiovascular
- Ears, Nose, Mouth, and Throat
- Eyes
- Genitourinary (Female)
- Genitourinary (Male)
- Hematologic/Lymphatic/Immunologic
- Musculoskeletal
- Neurological
- Psychiatric
- Respiratory
- Skin

For a general multi-system examination, a detailed examination should include at least six organ systems or body areas. For each system/area selected, performance and documentation of at least two elements identified by a bullet (•) is expected. Alternatively, a detailed examination may include performance and documentation of at least twelve elements identified by a bullet (•) in two or more organ systems or body areas.

For a single organ system examination, a detailed examination should include documentation of at least twelve elements identified by a bullet (•), whether in a box with a shaded or unshaded border, unless the documentation is for an eye and psychiatric examination. For an eye and psychiatric examination, a detailed examination should include documentation of at least nine elements identified by a bullet (•), whether in a box with a shaded or unshaded border.

For example, in the musculoskeletal system, if the office visit note demonstrated the physician examined the patient's gait and station, then 1 element/bullet would have been satisfied for that organ system. Evidence of additional elements/bullets in the office visit note/progress note would need to be present to fulfill the requirements of a detailed examination.

[2] *See 1997 Documentation Guidelines for Evaluation and Management Services*, at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/EMDOC.html*

Note: Should the requirements of the 1997 E/M Guidelines remain unfulfilled, one could use the 1995 E/M Guidelines to determine correct assignment of an E/M code. Remember, one can use either the 1995 or 1997 E/M Guidelines, but never a combination of both. CMS, Medicare Learning Network, *Evaluation and Management Services Guide* (2015), preface.

A sample office visit note can be analyzed independently to determine whether a detailed examination was conducted per the 1995 or 1997 E/M Guidelines.

Exhibit 1: Office Visit Note Example

Name:

DOB:

Date: 03/20/09

CHIEF COMPLAINT: ***My back hurts bad.***

This is an 82 year old female who presents to the office today complaining of pain in her lumbar spine described as a 7 out of 10 dull intermittent pain exacerbated by walking, standing, and bending. She says the pain has decreased slightly since her last visit. She says once the pain starts, it lasts for 20 or 30 minutes and she has to stop moving to get the pain to eventually die down. She is here for physical therapy. She is also here for a followup on her hypertension and insulin-dependent diabetes mellitus.

PAST MEDICAL HISTORY: Hypertension, insulin dependent diabetes, GERD, lumbar DJD, left and right shoulder DJD

PAST SURGICAL HISTORY: None

MEDICATIONS: Reglan 10 mg every 6 hours, Zantac 150 mg twice daily, Starlix 120 mg three times daily, Plavix 75 mg every day, Aricept 10 mg every day, Lopressor 25 mg every day, Coreg 3.125 mg twice daily, OsCal and vitamin D twice daily, Celebrex 400 mg every day, Lantus insulin 18 units in the a.m. and 10 units in the p.m.

REVIEW OF SYSTEMS: Patient reports pain in the lumbar spine and pain in both shoulders. The patient denies fever, cough, or other cold symptoms when experiencing pain.

PHYSICAL EXAMINATION:

VITAL SIGNS: Temperature 97.6, pulse 70, respirations 18, blood pressure 140/82. Weight is 110, height 5'6".

HEENT: Inspection of the conjunctivae and lids was noted to be within normal limits. Pupils equal, round, and reactive to light and accommodation. Extraocular muscle movements intact. Sclera white. Conjunctivae clear. Ophthalmoscopic examination showed no vessel changes, exudates, or hemorrhage. External inspection of the ears and nose was within normal limits. Assessment of hearing within normal limits to whispered voice and tuning fork was within normal limits. Inspection of the nasal mucosa, septum, and turbinates was within normal limits. Inspection of the lips, teeth, and gums was within normal limits. Otoscopic examination of the external auditory canals and tympanic membranes was

within normal limits. Examination of the oral mucosa, hard and soft palates, tongue, tonsils, and posterior pharynx was within normal limits.
NECK: Normal symmetry. Normal tracheal position. No JVD. No bruits.

THYROID: No masses, tenderness, or enlargement.

RESPIRATORY: Normal respiratory effort. Percussion and palpitation of the chest, within normal limits.

LUNGS: Clear to auscultation. No rhonchi, rales, or wheezes.

EXTREMITIES: No edema or varicosities noted. She is having shaking in her left arm, hand, and left upper extremity.

BREASTS: Symmetric. No masses, lumps, or tenderness. No nipple discharge.

CARDIOVASCULAR: Palpitation of the heart is within normal limits. Auscultation of the heart S1, S2, no S3. Examination of the carotid arteries, abdominal aorta, and femoral and pedal pulses is within normal limits.

CHEST: External examination, within normal limits.

EXTERNAL GENITALIA: Normal-appearing female genitalia. Tenderness in the right groin area.

LYMPHATIC SYSTEM: Neck, axillae, and groin showed no lymph nodes.

SKIN: No bites, stings, rashes, blisters, ulcerations, or pruritus noted.

GASTROINTESTINAL: Soft. Nontender. No guarding, rebound, tenderness, rigidity, masses, or megalies noted. Bowel sounds heard in all four quadrants.

MUSCULOSKELETAL: Lumbar spine, notes to have increased paravertebral musculature, L4-L5, with tenderness to palpitation and decreased rotational and side bending motion to both the left and right. She is also noted to have stiffness in both the left and right shoulder with decreased abduction and elevation. She has an abnormal gait due to her chronic low back pain for which she is receiving therapy.

NEUROLOGIC: Cranial nerves II through XII grossly intact. Deep tendon reflexes +2/4 equal in upper and lower extremities. Sensation to touch, pin, and vibration within normal limits.

PSYCHIATRIC: Sad, depressed, and blunted affect.

ASSESSMENT:

1. Exacerbation of COPD/bronchitis.
2. Pneumonia.
3. Dehydration.
4. Diarrhea.

5. Hypertension.
6. Insulin dependent diabetes mellitus.
7. GERD.
8. Lumbar DJD.
9. Left and right shoulder DJD.
10. Insomnia.
11. Weakness.
12. Enlarged right groin lymph node.
13. Shaking in the upper extremity, rule out Parkinson's.

PLAN:

1. Continue present Rx.
2. An 1800 calorie ADA diabetic diet.
3. Chart and labs reviewed.
4. HUMS therapy to the lumbar spine consisting of hot packs, ultrasound, massage, and electrical stimulation times 30 minutes. The patient showed improvement status post last therapy.

Objective 5: Understand why some claims are denied based on National Correct Coding Initiative (NCCI) edits.

The NCCI was developed to promote national correct coding methodologies and to control improper coding leading to inappropriate payment in Part B claims. Per the NCCI, physicians may not bill certain CPT codes together. Generally, Medicare will not reimburse providers or suppliers when these code pairs are furnished during the same date of service, anatomic site, or patient encounter.

In addition to code pair NCCI edits, the NCCI also includes a set of edits known as Medically Unlikely Edits (MUEs). An MUE is a maximum number of units of service allowable under most circumstances for a single HCPCS/CPT code billed by a supplier (e.g., physician, nurse practitioner, etc.) on a date of service for a single beneficiary. *NCCI, supra* intro, pp. 2-3.

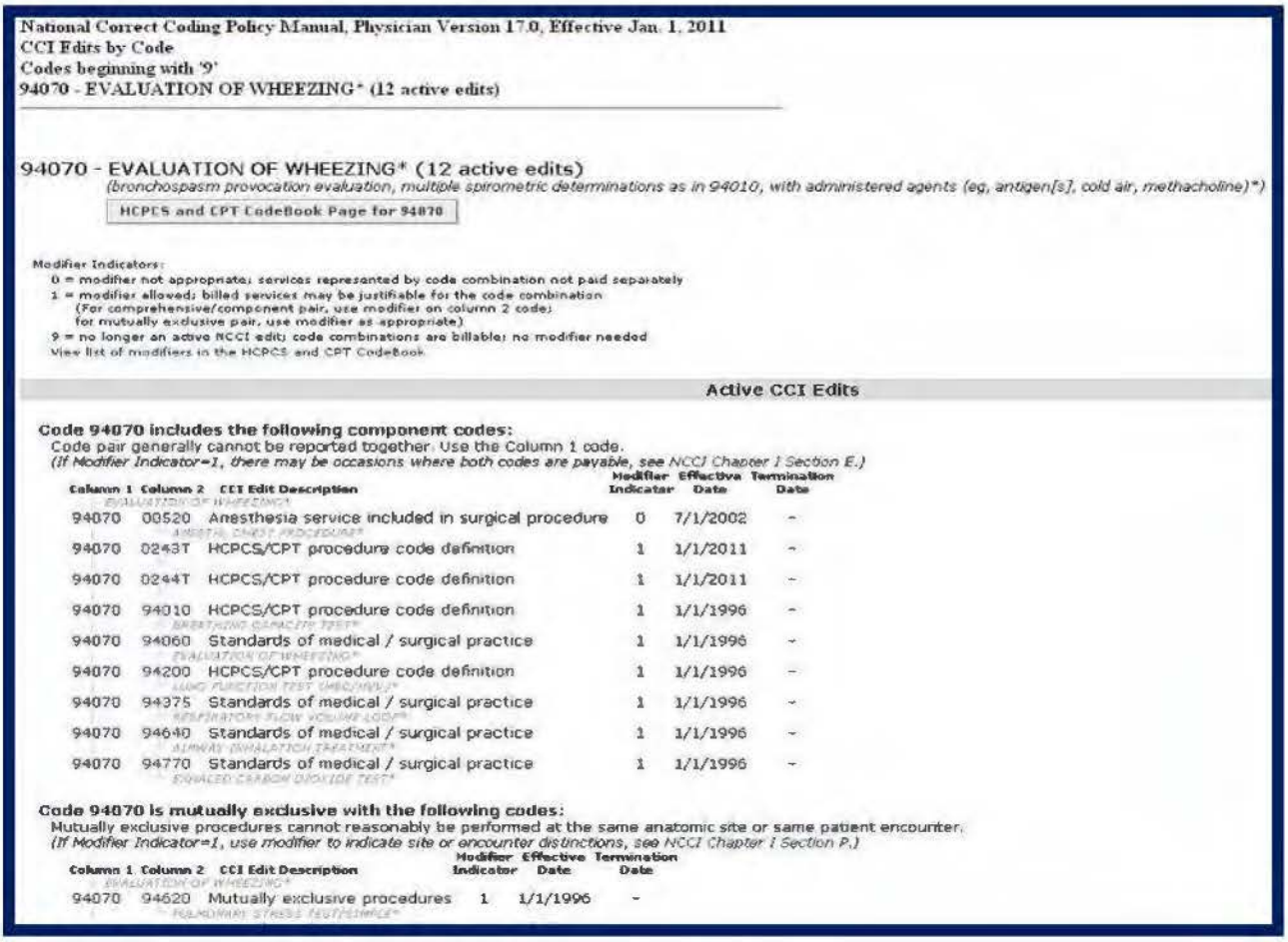
When a service is denied due to an NCCI edit, the beneficiary is never liable for the amount in controversy:

> CPT codes representing services denied based on NCCI edits may not be billed to Medicare beneficiaries. Since these denials are based on incorrect coding rather than medical necessity, the provider cannot utilize an "Advanced Beneficiary Notice" (ABN) form to seek payment from a Medicare beneficiary. Furthermore,

> since the denials are based on incorrect coding rather than a legislated Medicare benefit exclusion, the provider cannot seek payment from the beneficiary with or without a "Notice of Exclusions from Medicare Benefits" (NEMB) form.

NCCI, supra, intro, pp. 4–5.

Exhibit 2: CMS, NCCI Policy Manual, CCI Edits for Evaluation of Wheezing Example



National Correct Coding Policy Manual, Physician Version 17.0, Effective Jan. 1, 2011
CCI Edits by Code
Codes beginning with '9'
94070 - EVALUATION OF WHEEZING* (12 active edits)

94070 - EVALUATION OF WHEEZING* (12 active edits)
(bronchospasm provocation evaluation, multiple spirometric determinations as in 94010, with administered agents (eg, antigen[s], cold air, methacholine)*)

HCPCS and CPT CodeBook Page for 94070

Modifier Indicators:
0 = modifier not appropriate; services represented by code combination not paid separately
1 = modifier allowed; billed services may be justifiable for the code combination
(For comprehensive/component pair, use modifier on column 2 code;
for mutually exclusive pair, use modifier as appropriate)
9 = no longer an active NCCI edit; code combinations are billable; no modifier needed
View list of modifiers in the HCPCS and CPT CodeBook

Active CCI Edits

Code 94070 includes the following component codes:
Code pair generally cannot be reported together. Use the Column 1 code.
(If Modifier Indicator=1, there may be occasions where both codes are payable, see NCCI Chapter I Section E.)

Column 1	Column 2	CCI Edit Description	Modifier Indicator	Effective Date	Termination Date
94070	00520	Anesthesia service included in surgical procedure	0	7/1/2002	-
94070	0243T	HCPCS/CPT procedure code definition	1	1/1/2011	-
94070	0244T	HCPCS/CPT procedure code definition	1	1/1/2011	-
94070	94010	HCPCS/CPT procedure code definition	1	1/1/1996	-
94070	94060	Standards of medical / surgical practice	1	1/1/1996	-
94070	94200	HCPCS/CPT procedure code definition	1	1/1/1996	-
94070	94375	Standards of medical / surgical practice	1	1/1/1996	-
94070	94640	Standards of medical / surgical practice	1	1/1/1996	-
94070	94770	Standards of medical / surgical practice	1	1/1/1996	-

Code 94070 is mutually exclusive with the following codes:
Mutually exclusive procedures cannot reasonably be performed at the same anatomic site or same patient encounter.
(If Modifier Indicator=1, use modifier to indicate site or encounter distinctions, see NCCI Chapter I Section P.)

Column 1	Column 2	CCI Edit Description	Modifier Indicator	Effective Date	Termination Date
94070	94620	Mutually exclusive procedures	1	1/1/1996	-

Objective 6: Understand the use of modifiers to bypass NCCI edits.

Modifiers are used to append CPT codes. The purpose of modifiers is to alert Medicare to special, clinical circumstances which affect reimbursement. With regard to NCCI edits, modifiers are used to bypass an NCCI edit if the clinical circumstances justify the use of a modifier(s). *NCCI, supra* ch. 1, § E.

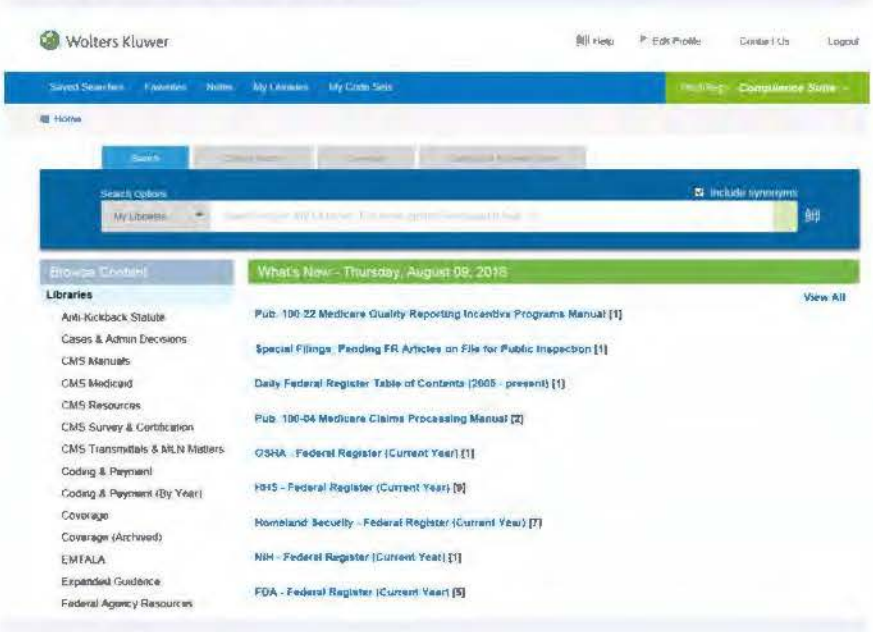
Typically modifiers are two digit codes added at the end of a CPT code. Examples of modifiers which bypass NCCI edits include modifier "25" which indicates a consultation or visit was a significant and separately identifiable E/M service by the same physician on the same day as another procedure or service. *Id.*

Another example of a modifier that bypasses an NCCI edit is the "59" modifier. The "59" modifier indicates a service which was "distinct" from another procedural service. *Id.* The primary purpose of the "59" modifier is to indicate two or more procedures which are performed at different anatomic sites or different patient encounters. *Id.* The "59" modifier should only be used if no other modifier is appropriate for the clinical situation at issue. *Id.*

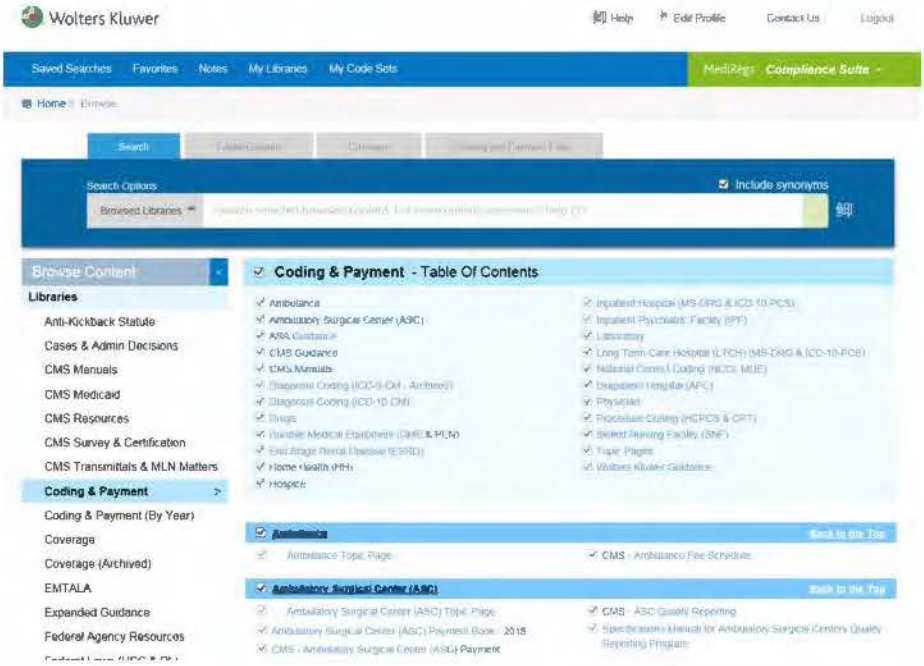
Objective 7: Locate any NCCI edit utilizing the MediRegs Database.

To access Wolters Kluwer MediRegs website for use as a resource on NCCI edits follow the following steps:

1. Access the https://www.wkmediregs.com/ website
2. Login
3. Go to Compliance Suite

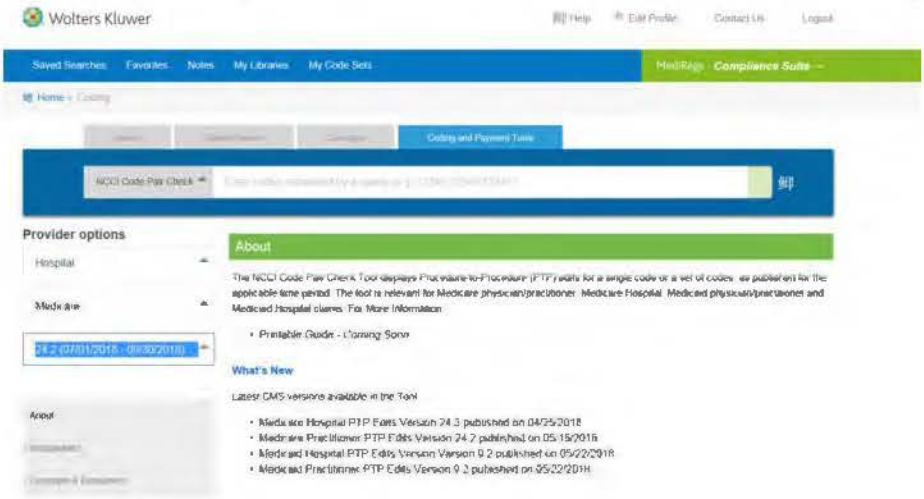


4. On the left menu, click "Coding & Payment" and select "National Correct Coding (NCCI, MUE)"



5. Select "NCCI Code Pair Checking Tool (2006-present)"unde

6. On the left side of the screen under "Provider options" input the provider type, payor, and NCCI Policy Manual Version with the effective dates that are applicable to your case.



Module 8:
Medicare Part B – Diagnostic Tests

After this session, you will be able to:

1. Identify the laws, regulations, and guidelines applicable to diagnostic tests.
2. Explain the scope of benefits for diagnostic tests.
3. Understand the rules for portable x-ray services, emergency room patients, and independent diagnostic testing facilities (IDTFs).
4. Differentiate between the technical and professional components of a diagnostic test.
5. Know the QIC's most common reasons and basis for denial.

Required Reading and References:

- ✓ 42 C.F.R. § 410.32
- ✓ 42 C.F.R. § 410.33
- ✓ Social Security Act (Act) § 1832(a)(1)
- ✓ Act § 1861(s)(2)(C)
- ✓ Act § 1862(a)(7)
- ✓ National Coverage Determination (NCD) 220
- ✓ CMS, *Medicare Claims Processing Manual (MCPM) (Internet-Only Manual Publ'n 100-4)* ch. 13, § 20
- ✓ *MCPM, supra,* ch. 35

Introduction—Background and Rationale

Diagnostic tests include both diagnostic laboratory tests and diagnostic non-laboratory tests.

Diagnostic laboratory tests

Medicare Part B (Medical Insurance) covers medically necessary clinical diagnostic laboratory tests, when ordered by a doctor or practitioner. Clinical diagnostic laboratory services involve biological, microbiological, serological, chemical, immunohematological, hematological, pathological or other examination of materials derived from the human body for the diagnosis, prevention or treatment of a disease or assessment of a medical condition.

Diagnostic non-laboratory tests

Part B covers diagnostic non-laboratory tests when a doctor or other health care provider orders them as part of treating a medical problem. Examples of diagnostic non-laboratory tests include CT scans, MRIs, EKGs, X-rays, and PET scans. These tests are done to help diagnose or rule out a suspected illness or condition.

Objective 1: Identify the laws and regulations applicable to diagnostic tests.

Section 1832(a)(1) of the Act allows Medicare to pay for "medical and other health services."

Section 1861(s)(2)(C) of the Act defines the term "medical and other health services" to include diagnostic services that are furnished to an individual as an outpatient by a hospital, and ordinarily furnished by such hospital to its outpatients for the purpose of diagnostic study.

According to § 1862(a)(7) of the Act, no payment can be made for routine physical checkups.

42 C.F.R. § 410.32 states that all diagnostic tests must be ordered by the physician who is treating the beneficiary and who uses the test results in the management of the beneficiary's specific medical problem.

According to 42 C.F.R. § 410.32(a)(2), nonphysician practitioners (clinical nurse specialists, clinical psychologists, clinical social workers, nurse midwives, nurse practitioners, and physician assistants) may be treated the same as physicians if they are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefits. Thus, nonphysician practitioners may order diagnostic tests in certain jurisdictions.

With the exception of mammograms, all diagnostic tests must be ordered by a physician (or nonphysician practitioner, in certain states) who is treating the beneficiary. NCD 220 contains the Medicare coverage criteria for various radiology services, including computed tomography (CT) scan, magnetic resonance imagining (MRI), ultrasound, etc. Please note that an ALJ is bound by the NCD pursuant to 42 C.F.R. § 405.1060(a)(4).

Chapter 13 of the *MCPM* provides Medicare guidelines for radiology services and other diagnostic procedures. Notably, section 20 of chapter 13 explains the difference between the professional component (PC) and the technical component (TC) of a diagnostic test.

42 C.F.R. § 410.33 and CMS, *MCPM, supra, ch. 35* pertain to diagnostic tests that are furnished in independent diagnostic testing facilities (IDTFs).

Objective 2: Explain the scope of benefits for diagnostic tests.

All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests:

- must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem

  AND

- who uses the results in the management of the beneficiary's specific medical problem.

42 C.F.R. § 410.32(a).

Diagnostic tests are often furnished by hospitals in an outpatient setting, in a physician's office, or in an independent diagnostic testing facility. Diagnostic tests are comprised of a multitude of services, which include x-rays, laboratory blood tests, nerve conduction studies, somatosensory tests, MRI, CT, diagnostic colonoscopy (i.e., biopsy and/or removal of a growth or lesion), and electrocardiography (EKG/ECG).

The diagnostic tests can be furnished (i.e., performed) by physicians and by nonphysician practitioners (i.e., clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants). Nonphysician practitioners may be treated the same as physicians, *if* the nonphysician practitioners are operating within the scope of their authority under State law.

According to 42 C.F.R. § 410.32(b)(3), most diagnostic tests must be furnished under an appropriate level of supervision by a physician. The three levels of physician supervision are as follows:

- **General Supervision:** Most diagnostic tests must be furnished under at least a general level of supervision. General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the physician also has the responsibility of training nonphysician personnel who perform the diagnostic tests. It is also the physician's responsibility to oversee the maintenance and supplies of the diagnostic equipment. 42 C.F.R. § 410.32(b)(3)(i).

- **Direct Supervision:** If the diagnostic tests are furnished in an office setting, the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure; however, the physician does not have to be in the room when the procedure is performed. 42 C.F.R. § 410.32(b)(3)(ii).

- **Personal Supervision:** A physician must be in attendance in the room during the performance of the procedure. 42 C.F.R. § 410.32(b)(3)(iii).

The following diagnostic tests are **exempt** from the physician supervision rules above:

- Diagnostic mammography procedures regulated by the Food and Drug Administration;
- Diagnostic tests personally furnished by a qualified audiologist as defined in § 1861(ll)(3) of the Act;

- Diagnostic psychological and neuropsychological testing services which meet the conditions of 42 C.F.R. § 410.32(b)(2)(iii);
- Diagnostic tests personally performed by a physical therapist and which meet the conditions of 42 C.F.R. § 410.32(b)(2)(iv);
- Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws; and
- Pathology and laboratory procedures listed in the 80000 series of the *Current Procedural Terminology.*

42 C.F.R. § 410.32(b)(2).

Objective 3: Understand the rules for portable x-ray services, emergency room patients, and independent diagnostic testing facilities (IDTFs)

Portable X-ray Services

42 C.F.R. § 410.32(c) pertains to portable x-ray services that are provided in the patient's home.

Portable x-ray services are covered if the following four conditions are met.

1. The services are furnished under the general supervision of a physician;
2. The services are ordered by a physician or, if permitted by State law, by a nonphysician practitioner;
3. The supplier meets the requirements set forth in 42 C.F.R. Part 486, Subpart C; and
4. The services are limited to skeletal films involving the extremities, pelvis, vertebral column, or skull; chest or abdominal films that do not involve the use of contrast media; and diagnostic mammograms.

X-rays & EKGs Furnished to Emergency Room Patients

If an emergency room (ER) patient received an x-ray and both the ER physician and the radiologist interpreted it, Medicare generally pays for the first bill received because it would not know in advance that a second claim would be forthcoming. Medicare will pay for a second interpretation (with use of modifier 77) only under unusual circumstances. The key is whether the second interpretation "directly contributed to the diagnosis and treatment of the individual patient." *MCPM, supra,* ch. 13, § 100.1.

Independent Diagnostic Testing Facilities[1]

- Consistent with 42 C.F.R. § 410.33(a)(1), an IDTF is one that is independent both of an attending or consulting physician's office and of a hospital.
- An IDTF may be a fixed location or a mobile entity.
- The diagnostic test must be ordered by a physician or by a nonphysician practitioner.
- Consistent with 42 C.F.R. § 410.32(a), the supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the supervising physician is the patient's treating physician and is not otherwise prohibited from referring to the IDTF.
- The supervising physician must provide general supervision to no more than three IDTF sites.

42 C.F.R. § 410.33 and *MCPM, supra,* ch. 35.

Objective 4: Differentiate between the technical and professional components of a diagnostic test.

In order to limit double and/or triple billing and questionable business practices (e.g., kickbacks, price mark-ups), Medicare has established payment rules regarding the purchasing and billing of diagnostic tests by physicians, suppliers, and facilities. Depending on the date of service at issue, different rules apply.

With regard to non-laboratory diagnostic tests, the ordering physician may not perform all, or any, aspects of a diagnostic test. For example, a treating physician may prescribe a chest x-ray for her patient; however, the treating physician does not actually have the equipment in her office to perform a chest x-ray. In such instance, the treating physician may have a contract with a radiology facility to perform chest x-rays for the physician's patients. Further, the facility may not have on staff a radiologist to actually interpret the results. Thus, the facility may contract with a radiologist to interpret the chest x-ray film and diagnose the patient's condition. In this situation, Medicare has specific rules regarding which person/entity is eligible to receive Medicare reimbursement.

In order to navigate these payment rules, one must first understand the terms "technical component" and "professional component."

- Technical component is the actual performance of the diagnostic test (e.g., setting up the equipment, placement of the patient, furnishing the x-ray, developing the film, etc.).

[1] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICN909060-IDTF-Fact-Sheet.pdf.

- Professional component means diagnostic test interpretation (e.g., examining the film/results to diagnose the patient's medical condition and completion of a written report).

See CMS, *MCPM, supra,* ch. 13, § 20.

Payment of the Technical Component Prior to June 14, 2010

Prior to June 14, 2010, tests personally performed, or supervised, by a physician were eligible for Medicare reimbursement under the normal fee schedule rate. This eligibility included situations where the test was performed or supervised by a physician with whom the billing physician shared a practice. *MCPM, supra,* ch. 13, § 20.2.4.1 (October 2003).

In the event the physician or medical group actually purchased the technical component from another physician/entity/supplier, the purchasing physician/group may bill Medicare for Part B payment. In order to bill Medicare for a purchased technical component, the purchaser **must perform the interpretation** (i.e., the professional component) and the physician/supplier providing the technical component must be enrolled in the Medicare program. *MCPM, supra,* ch. 13, § 20.2.4.2 (April 2004).

Payment of the Professional Component Prior to June 14, 2010

Physicians, in all settings, who furnish the professional component of radiology services to beneficiaries in an outpatient setting, are entitled to Medicare reimbursement under the fee schedule for physician services. The professional component of a diagnostic test must include a written report. *MCPM, supra,* ch. 13, § 20.1 (October 2003).

A person or entity that provides diagnostic tests may receive Medicare reimbursement for a diagnostic test interpretation (professional component) **purchased** from an independent physician or medical group if all of the following conditions are met:

- The tests are initiated by a physician/medical group which is independent of the person or entity providing the tests;
- The tests are initiated by a physician/medical group which is independent of the physician/medical group providing the interpretation;
- The physician/medical group providing the interpretation does not see the patient;
- The purchaser performs the technical component of the test; and
- The interpreting physician/medical group is enrolled in the Medicare program.

MCPM, supra, ch. 13, § 20.2.4.2 (April 2004).

Payment of the Technical and Professional Component as of June 14, 2010[2]

Tests personally performed, or supervised, by a physician are eligible for Medicare reimbursement under the normal fee schedule rate. This eligibility includes situations where the test was performed or supervised by a physician with whom the billing physician shares a practice. *MCPM, supra,* ch. 13, § 20.3.1 (June 2010).

Physicians, in all settings, who furnish the professional component of radiology services to beneficiaries in an outpatient setting, are entitled to Medicare reimbursement under the fee schedule for physician services. The professional component of a diagnostic test must include a written report. *MCPM, supra,* ch. 13, § 20.1 (June 2010).

A physician or other supplier may bill and receive Part B payment for the technical component or professional component of diagnostic tests which the physician or other supplier contracts a physician, medical group, or other supplier to perform. An "anti-markup limitation" (i.e., possibly reduced reimbursement) will apply in this situation to the technical component or the professional component if the performing physician/supplier does not share a practice with the ordering/billing physician or supplier. *MCPM, supra,* ch. 13, § 20.3.2. (June 2010).

Note: The anti-markup limitation is effective for the professional component starting January 1, 2009.

If the performing physician or other supplier meets the criteria for "sharing a practice" with the billing physician or other supplier, then the anti-markup payment limitation will not apply and the lower of the physician fee schedule amount or billed amount will be paid.

Objective 5: Know the QIC's most common reasons and basis for denial.

- Insufficient documentation (e.g., no physician's order or no medical records from the ordering physician).
- No indication of symptoms or physical findings to support medical necessity of the provided test.
- The documentation did not support a payable condition or diagnosis.
    - The applicable Local Coverage Determination (LCD) may have a list of medical diagnosis codes that support medical necessity for a particular diagnostic test.
- The provided test was a routine screening service, which is non-covered.

[2] The reimbursement policy mentioned in this section for a purchased professional component is effective January 1, 2009.

- According to § 1862(a)(7) of the Act, no payment can be made for routine physical checkups, unless coverage is specifically provided for under 42 C.F.R. § 411.15(a)(1) (e.g., screening mammography, colorectal cancer screening tests, prostate cancer screening tests, etc.).

- No valid physician's signature (e.g., missing or illegible) on the order or written report.
  - Chapter 3, section 3.3.2.4 of the CMS, *Medicare Program Integrity Manual* (*MPIM*) (*Internet-Only Manual Publ'n 100-08*) sets forth the signature requirements for authenticating medical records. Handwritten signatures are acceptable. If a handwritten signature is not legible, then look at the signature log or attestation statement, if any, to determine the identity of the author. Electronic signatures are also acceptable but there is a potential for misuse or abuse. Stamped signatures (rubber stamp) are not acceptable.
  - Effective August 25, 2015, if a signature is illegible, the Medicare Administrative Contractor shall consider evidence in a signature log, attestation statement, or *other documentation* submitted to determine the identity of the author of a medical record entry.

- Excessive number of tests.
  - For example, the performance of 14 diagnostic tests may not be reasonable and necessary for a beneficiary whose chief complaint is joint pain with no trauma or injury.

Module 9:
Partial Hospitalization Program

After this session, you will be able to:

1. Describe the psychiatric partial hospitalization program (PHP) statutes, regulations, and policy; and

2. Identify limitation on liability requirements based on the HCFA Ruling 97-1.

Required Reading/Reference:

- ✓ Social Security Act (Act) § 1861(s)(2)(B)
- ✓ Act §§ 1861(ff)(1)-(2)
- ✓ Act § 1832(a)(2)(J)
- ✓ Act § 1835(a)(2)(F)
- ✓ 42 C.F.R. § 410.43
- ✓ 42 C.F.R. § 424.24(e)
- ✓ CMS, HCFA Ruling 97-1
- ✓ CMS, *Medicare Benefit Policy Manual (MBPM), (Internet-Only Manual Publ'n* 100-2,) ch. 6, § 70

Introduction – Background and Rationale

The Medicare Partial Hospitalization Program (PHP) is a highly structured, short-term program of outpatient psychiatric services provided to patients as an alternative to inpatient psychiatric care. PHPs may be covered under Medicare when they are provided by a hospital outpatient department or a Medicare-certified Community Mental Health Center (CMHC). PHP services are more intense than those provided in outpatient therapy, but less intense than the services provided in an inpatient psychiatric facility. *MBPM, supra* ch. 6, § 70.3.

Objective 1: Describe the Psychiatric Partial Hospitalization Program (PHP) Statutes, Regulations, and Policy

The PHP Benefit

Section 1832 of title XVIII of the Social Security Act ("the Act") establishes the scope of Medicare Part B benefits. In pertinent part, § 1832(a)(1) of the Act entitles Medicare Part B beneficiaries to payment for medical and other health services.

Section 1861(s)(2)(B) of the Act defines "Medical and Other Health Services" to include hospital services incident to physicians' services rendered to outpatients and partial hospitalization services

incident to such services.

Section 1861(ff)(1) of the Act defines "Partial Hospitalization Services."

Section 1835(a)(2)(F) of the Act sets forth pertinent certification requirements applicable to partial hospitalization services.

PHP Eligibility Requirements

- Patient must be admitted to PHP under the care of a physician;
- Physician must certify the need for partial hospitalization;
- Patient requires a minimum of 20 hours per week of therapeutic services (identified in a plan of care) and does not require 24-hour care;
- Patient is likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;
- Patient requires a comprehensive, structured multimodal treatment requiring medical supervision and coordination, provided under an individualized plan of care, because of a mental disorder which severely interferes with multiple areas of daily life, including social, vocational and/or educational functioning. Such dysfunction must be of an acute nature and not a chronic circumstance.
- Patient has a mental health diagnosis and is not judged to be dangerous to self or others;
- Patient must be able to cognitively and emotionally participate in the active treatment process and be capable of tolerating the intensity of a PHP program; and
- The patient's mental illness is generally acute in nature.

42 C.F.R. §§ 410.43, § 424.24(e); *MBPM, supra* ch. 6, § 70.3(B)(1).

Patients eligible for Medicare coverage of a PHP comprise two groups:

- Patients who are discharged from an inpatient hospital treatment program and the PHP is in lieu of continued inpatient treatment OR
- Patients who, in the absence of partial hospitalization, would be of reasonable risk of requiring inpatient hospitalization.

MBPM, supra, ch. 6, § 70.3(B)(1).

It is not enough that a patient qualify under the benefit category requirements in or of

§ 1835(a)(2)(F) of the Act unless he/she also has the need for the active treatment provided by the program of services defined in § 1861(ff) of the Act. It is the need for intensive, active treatment of his/her condition to maintain a functional level and to prevent relapse or hospitalization, which qualifies the patient to receive the services identified in § 1861(ff) of the Act. *Id.* § 70.3(B)(2).

PHP Admission Criteria

Intensity of Service

Patients admitted to a PHP do not require a 24-hour per day level of care as provided in an inpatient setting. A PHP level of care must be necessary to prevent inpatient hospitalization. *See MBPM, supra* ch. 6, §§ 70.1(B), 70.3(B).

The patient's acute psychiatric condition being treated by a PHP must require active treatment, including a combination of services such as intensive nursing and medical intervention, psychotherapy, occupational and activity therapy. Patients must require PHP services at levels of intensity and frequency comparable to patients in an inpatient setting for similar psychiatric illnesses. *Id.* § 70.3.

Severity of Illness

Patients admitted to a PHP must have an acute onset or decompensation of a covered Axis I mental disorder, as defined by the current edition of the Diagnostic and Statistical Manual published by the American Psychiatric Association or listed in Chapter 5, of the version of the International Classification of Diseases (ICD) applicable to the service date, which severely interferes with multiple areas of daily life. *Id.* § 70.3(B)(3).

The degree of impairment will be severe enough to require a multidisciplinary, intensive, structured program, but not so severe that patients are incapable of participating in and benefiting from an active treatment program and able to maintain themselves outside the program. *Id.*

For patients who do not meet this degree of severity of illness, and for whom partial hospitalization services are not necessary for the treatment of a psychiatric condition, professional services of psychiatrists and psychologists may be medically necessary, even though partial hospitalization services are not. Patients admitted for treatment to a PHP will not be in immediate/imminent danger to self, others or property. *Id.;* 42 C.F.R. § 410.43.

Level of Treatment and Reasonable Expectation of Improvement

Active treatment directly addresses the patient's presenting problems requiring admission to the PHP. *MBPM, supra,* ch. 6, § 70.3.

Active treatment consists of clinically recognized therapeutic interventions including individual or group psychotherapy, family counseling services, occupational therapy, and

educational activities that are related to the care and treatment of his/her diagnosed psychiatric condition. *Id.* § 70.3(B).

The patient must have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the partial hospitalization program. *Id.* § 70.3(B)(1); 42 C.F.R. § 410.43(c)(7).

NOTE: A program comprised primarily of diversionary activity, social or recreational therapy does not constitute a PHP. Psychosocial programs that provide only a structured environment, socialization, and/or vocational rehabilitation are not covered by Medicare. *MBPM, supra* ch. 6, § 70.3(A).

PHP services must be for the purpose of diagnostic study or reasonably be expected to improve the patient's condition. The treatment must, at a minimum, be designed to reduce or control the patient's psychiatric symptoms so as to prevent relapse or hospitalization, and improve or maintain the patient's level of functioning. *Id.* § 70.1(A)(3).

"Improvement" in this context is measured by comparing the effect of continuing treatment versus discontinuing it. Where there is a reasonable expectation that if treatment services were withdrawn the patient's condition would deteriorate, relapse further, or require hospitalization, this criterion is met. *Id.*

PHP Discharge Criteria

Patients may be discharged by either stepping up to an inpatient level of care or stepping down to a less-intensive level of outpatient care.

- An inpatient level of care would be required for patients needing 24-hour supervision.
- Stepping down to a less-intensive level of outpatient care when the patient's clinical condition improves or stabilizes and he/she no longer requires structured, intensive, multimodal treatment.

See MBPM, supra, ch. 6, § 70.3(B).

Covered Services

The following may be covered partial hospitalization services:

- Medically necessary diagnostic services related to mental health treatment;
- Individual or group psychotherapy with physicians, psychologists, or other mental health professionals authorized or licensed by the state in which they practice (e.g., licensed clinical social workers, clinical nurse specialists, certified alcohol and drug counselors);

- Occupational therapy requiring the skills of a qualified occupational therapist. Occupational therapy, if required, must be a component of the physician's treatment plan for the individual. While occupational therapy may include prevocational and vocational assessment and training, when the services are related solely to specific employment opportunities, work skills or work settings, they are not covered;

- Services of other staff (social workers, psychiatric nurses, and others) trained to work with psychiatric patients;

- Drugs and biologicals that cannot be self-administered and are furnished for therapeutic purposes (subject to limitations specified in 42 C.F.R. § 410.29);

- Activity therapies but only those that are individualized and essential for the treatment of the patient's condition.

- Family counseling services for which the primary purpose is the treatment of the patient's condition; and

- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment of his/her diagnosed psychiatric condition.

42 C.F.R. § 410.43; *MBPM, supra,* ch. 6, §§ 70.1(C), 70.3(B)(2).

Documentation Requirements

Initial Psychiatric Evaluation/Certification

Upon admission, a certification by the physician must be made that the patient admitted to the PHP would require inpatient psychiatric hospitalization if the partial hospitalization services were not provided, that the services were furnished under a written plan of treatment, and that the services are or were furnished while the patient was under the care of a physician. The certification should also identify the diagnosis and psychiatric need for the partial hospitalization. 42 C.F.R. § 424.24(e); *MBPM, supra,* ch. 6, § 70.3(B)(5).

Physician Recertification Requirements

Signature – The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.
Timing – The first recertification is required as of the 18th calendar day following admission to the PHP. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days.

Content – The recertification must specify that the patient would otherwise require inpatient psychiatric care in the absence of continued stay in the PHP and describe the following:

- The patient's response to the therapeutic interventions provided by the PHP;
- The patient's psychiatric symptoms that continue to place the patient at risk of hospitalization; and
- Treatment goals for coordination of services to facilitate discharge from the PHP.

42 C.F.R. § 424.24(e).

Treatment Plan

The treatment plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth the physician's diagnosis, the type, amount, duration, and frequency of the services, and treatment goals under the plan.

The treatment goals described in the treatment plan should directly address the presenting symptoms and are the basis for evaluating the patient's response to treatment.

The plan should document ongoing efforts to restore the individual patient to a higher level of functioning that would permit discharge from the program, or reflect the continued need for the intensity of the active therapy to maintain the individual's condition and functional level and to prevent relapse or hospitalization.

NOTE: Activities that are primarily recreational and diversionary, or provide only a level of functional support that does not treat the serious presenting psychiatric symptoms placing the patient at risk, do not qualify as partial hospitalization services.

42 C.F.R. § 424.24(e); *MBPM, supra,* ch. 6, § 70.3(B)(5).

Progress Notes

Section 1833(e) of the Social Security Act prevents Medicare from paying for services unless necessary and sufficient information is submitted that shows that services were provided and to determine the amounts due.

The progress note should include a description of the nature of the treatment service, the patient's response to the therapeutic intervention and its relation to the goals indicated in the treatment plan.

MBPM, supra, ch. 6, § 70.3(B)(5).

Objective 2: Identify limitation on liability requirements based on the HCFA Ruling 97-1

Non-Covered Services and Liability

Benefit category denials made under § 1861(ff) or § 1835(a)(2)(F) of the Act are not appealable by the provider and the limitation on liability provision does not apply (HCFA Ruling 97-1). Examples of benefit categories based in § 1861(ff) or § 1835(a)(2)(F) of the Act, for partial hospitalization services generally include the following:

- Day care programs, which provide primarily social, recreational, or diversionary activities, custodial or respite care;
- Programs attempting to maintain psychiatric wellness where there is no risk of relapse or hospitalization, e.g., daycare programs for the chronically mentally ill; and
- Patients who are otherwise psychiatrically stable or require medication management only.

MBPM, supra, ch. 6, § 70.3(B)(4).

The following services are excluded from the scope of partial hospitalization services defined in Section 1861(ff) of the Act. Coverage denials made under § 1861(ff) of the Act are not appealable by the provider and the Limitation on Liability provision does not apply (HCFA Ruling 97-1):

- Services to hospital inpatients;
- Meals, self-administered medications and transportation; and
- Vocational training.

Reasonable and necessary denials based on § 1862(a)(1)(A) of the Act are appealable and the Limitation on Liability provision does apply. The following examples represent reasonable and necessary denials for partial hospitalization services and coverage is excluded under § 1862(a)(1)(A) of the Act:

- Patients who refuse or cannot participate (due to their behavioral, cognitive or emotional status) with active treatment of their mental disorder, or who cannot tolerate the intensity of a PHP; and
- Treatment of chronic conditions without acute exacerbation of symptoms that place the individual at risk of relapse or hospitalization.

Id.

Module 11:
Medicare Drug Benefit: Medicare Part B & Part D

After this session, you will be able to:

1. Understand the scope of benefits recognized as Medicare Part B Drugs and Biologicals;
2. Detail the requirements for coverage of a Part B Drug or Biological;
3. Identify examples of self-administered drugs that are covered/non-covered by Part B;
4. Understand the general scope of benefits recognized as the Medicare Part D Program;
5. Gain familiarity with Medicare Part D law and policy;
6. Recognize common issues that arise in Part D appeals; and,
7. Know how to process expedited Part D appeals.

Required Reading:

- ✓ Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA)
- ✓ Social Security Act (Act) §§ 1832, 1861(s)(1), 1861(s)(2)(A), 1861(s)(2)(B), 1860D-1(a), 1860D-2(e), 1861(t)(2)(B)
- ✓ 42 C.F.R. §§ 410.20, 410.26, 410.29, and 410.30
- ✓ 42 C.F.R. Part 423, Subparts M and U
- ✓ CMS, *Medicare Benefit Policy Manual* (*MBPM*) (*Internet-Only Manual Publ'n 100-2*) ch. 15, § 50
- ✓ CMS, *Medicare Prescription Drug Benefit Manual* (*MPDBM*) (*Internet-Only Manual Publ'n 100-18*)

Overview

This module provides a general overview of the Medicare drug benefits available under Medicare Parts B and D.

Generally, Medicare Part B does not cover most prescription drugs used at home. The Medicare Part B drug benefit does, however, cover a limited number of prescription drugs under certain circumstances. These drugs are typically the type of drugs that cannot be self-administered and are commonly received in a physician's office or an outpatient setting. Such drugs include, but are not limited to, drugs used with durable medical equipment (DME), oral ESRD drugs, shots (ex., flu shots), injectable and infused drugs, and parenteral and enteral nutrition.

What people more commonly identify as "prescription drugs" are drugs covered under Medicare's voluntary prescription drug program—Medicare Part D. Medicare Part D is a voluntary prescription drug benefit program available to individuals who are entitled to benefits under Medicare Part A or enrolled in Medicare benefits under Part B. The regulations governing the Part D program are found at 42 C.F.R. Part 423.

Medicare Part B Drugs and Biologicals

Medicare Part B provides limited benefits with respect to outpatient prescription drugs. Pursuant to sections 1832(a)(1) and 1861(s) of the Act, Medicare Part B covers drugs—not usually self-administered—that are furnished incident to a physician's service.

Generally, Medicare Part B coverage for drugs and biologicals are covered under the foregoing statutory provisions if all of the following requirements are met:

- They meet the definition of drugs or biologicals;
- They are of the type that are not usually self-administered;
- They meet all the general requirements for coverage of items as incident to a physician's services;
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice;
- They are not excluded as non-covered immunizations; and
- They have not been determined by the FDA [Food and Drug Administration] to be less than effective.

MBPM, supra, ch. 15, § 50 (citations omitted).

Definition of Drugs or Biologicals[1]

Section 1861(t)(1) of the Act defines "drugs" and "biologicals," subject to certain exceptions, as agents which are:

> included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

[1] Vaccines, antigens, and blood clotting factors are examples of biologicals. *See* Act §§ 1860D-2(e) and 1861(s). "Whole blood is a biological, which cannot be self-administered and is covered when furnished incident to a physician's services." *MBPM, supra* ch. 15, § 50.3

See MBPM, supra ch. 15, § 50.1.

Not Usually Self-Administered

- ✓ The term "administered" refers only to the physical process by which the drug enters the patient's body. It does not refer to whether the process is supervised by a medical professional. With limited exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, and topical medications are considered to be usually self-administered by the patient. *MBPM, supra* ch. 15, § 50.2.B.

- ✓ The term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and CMS contractors may not make any Medicare payment for it." *MBPM, supra* ch. 15, § 50.2.C.

- ✓ Drugs delivered intravenously and drugs delivered by intramuscular injection (i.e. into the muscle tissue itself) are presumed *not* to be self-administered. On the other hand, drugs administered by subcutaneous injection (i.e. into the tissue layer between the skin and muscle) are presumed to be self-administered. When evaluating whether a drug is self-administered, drugs administered for acute conditions are less likely to be self-administered; drugs administered once or more per week are more likely to be self-administered. *Id.*

- ✓ "By the patient" refers to Medicare beneficiaries as a collective whole, as the determination is made on a drug-by-drug basis and not on a beneficiary-by-beneficiary basis. "By the patient" includes only patients themselves and not other individuals such as spouses, friends, or other caregivers. *Id.* ch. 15, § 50.2.E.

- ✓ In evaluating whether a drug or biological is usually self-administered, CMS contractors must consider peer reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA-approved labeling, and package inserts. Whether an FDA label includes instructions for self-administration is not, by itself, a dispositive factor of whether the drug is excluded from coverage as a drug not usually self-administered. *Id.* ch. 15, § 50.2.F.

Incident to Physician's Services

- ✓ Incident to a physician's services means the services or supplies are furnished as an integral, although incidental, part of the physician's (or other practitioner's) professional services in the course of diagnosis or treatment of an injury or illness. 42 C.F.R. § 410.26(b)(2).

- ✓ In order to meet all the general requirements for coverage under the incident-to provision, an FDA-approved drug or biological must be:

- Of a form that is not usually self-administered;
- Furnished by a physician; and
- Administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

MBPM, supra ch. 15, § 50.3.

Medically Accepted Indication

Medicare Part B also covers drugs or biologicals used in an anticancer chemotherapeutic regimen for a "medically accepted indication," which includes any use which has been approved by the FDA and another use of the drug if—

(i) the drug has been approved by the FDA; and

(ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia:

- American Hospital Formulary Service-Drug Information;
- the American Medical Association Drug Evaluations;
- the United States Pharmacopoeia-Drug Information; and,
- and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia...

Act § 1861(t)(2)(B).

Reasonable and Necessary

- ✓ "Approved Use" of a drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs and biologicals approved for marketing by the FDA are deemed safe and effective when used for indications specified on the labeling. If a drug is administered on or after the date of FDA approval and it is medically reasonable and necessary for the individual patient, the drug and biological may be covered by Medicare Part B. *MBPM, supra* ch. 15, § 50.4.1.

- ✓ Contractors will deny drugs which have not been approved by the FDA, unless they receive contrary instructions from CMS. *Id.*

- ✓ "Unlabeled Use" (also referred to as "off-label use") of a drug or biological means a use that does not appear as an indication on the drug's FDA-approved label. *Id.* ch. 15, § 50.4.2. An unlabeled use, however, may be covered by Medicare if the use is determined "to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice." *Id.* Situations in which use of medications would not be reasonable and necessary according to accepted standards of medical practice include prescribing medications for some

purpose other than to treat a particular condition (e.g., prescribing vitamins for a patient's general well-being), administering medication by injection when standard medical practice recognizes oral administration, and administering medication in amount or frequency that exceeds standard medical practice. *Id.* § 50.4.3.

- ✓ Off-label use of drugs in an anti-cancer chemotherapeutic regimen may be covered for a medically accepted indication that is supported in either one or more approved compendia or peer-reviewed medical literature. Act § 1861(t)(2)(B); *see MBPM, supra* ch. 15, § 50.4.5.

Do not deny coverage based solely on the absence of FDA-approved labeling for the use, if the use is supported by any of the following compendia and the use is **not** listed as unsupported, not indicated, not recommended, or equivalent terms in any of the following compendia, approved by the Secretary:

- American Hospital Formulary Service Drug Information (AHFS-DI);
- National Comprehensive Cancer Network (NCCN) Drugs and Biologicals Compendium;
- Micromedex DRUGDEX;
- Clinical Pharmacology;
- Lexi-Drugs (effective August 12, 2015).

MBPM, supra ch. 15, § 50.4.5.B.

The listed compendia employ various rating and recommendation systems. In general, a use is identified by a compendium as **medically accepted** if the:

1. Indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or

2. Narrative text in AHFS-DI or Clinical Pharmacology is supportive; or

3. Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A."

A use is **not medically accepted** by a compendium if the:

1. Indication is a Category 3 in NCCN or a Class III in DrugDex; or

2. Narrative text in AHFS-DI or Clinical Pharmacology is "not supportive"; or

3. Indication is listed in Lexi-Drugs as "Use: Unsupported."

The complete absence of narrative text on a use is considered neither supportive nor non-supportive.

MBPM, supra ch. 15, § 50.4.5.B.

Note: These compendia are not carbon copies. Sometimes an unlabeled use for a drug can be found in one compendium, but not in others. Thus, when determining whether an unlabeled use is appropriate, the adjudicator should consult all of the applicable compendia.

In addition to these compendia, the Act allows for coverage of an unlabeled use of *anti-cancer* drugs when such use is supported by scientific journals approved by the Secretary. The following journals may be referenced when determining whether an unlabeled use of an anti-cancer drug or biological is for a medically accepted indication:

> *American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association; Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; or Radiation Oncology.*

MBPM, supra ch. 15, § 50.4.5.C.

Self-Administered Drugs Covered By Part B

Some self-administered drugs are expressly covered by Medicare Part B. *See* Act § 1861(s)(2); *MBPM, supra* ch. 15, § 50.5. The following are examples of self-administered drugs which are covered by Medicare Part B:

- Drugs used with durable medical equipment (DME) (like an infusion pump or nebulizer);
- Hemophilia clotting factors;
- Antigens (when prepared by a doctor and given by a properly instructed person);
- Parenteral and enteral nutrition (intravenous and tube feeding);
- Shots (vaccinations):
  - Flu shots;
  - Pneumococcal shots;
  - Hepatitis B shots;
  - Other shots (when directly related to the treatment of an injury or illness);
- Transplant drugs (immunosuppressive drug therapy following a Medicare-covered organ transplant; Part D may cover other transplant drugs not covered by Part B, even if Medicare didn't pay for the transplant);
- Intravenous immunoglobulin (IVIG) provided in the home (for people with a diagnosis of primary immune deficiency disease);
- Erythropoietin (EPO) (for the treatment of anemia for patients with chronic renal failure who are on dialysis);
- Oral anti-nausea drugs (as part of an anti-cancer chemotherapeutic regimen); and

- Oral anti-cancer drugs.

With regard to oral anti-cancer drugs, Medicare policy states these drugs are covered by Medicare Part B when the following conditions are met:

- The drug is prescribed by a physician or other practitioner licensed under State law to prescribe such drugs as anti-cancer chemotherapeutic agents;
- The agent is a drug or biological that has been approved by the FDA;
- The drug has the same active ingredients as a non-self-administrable anti-cancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anti-cancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's "Approved Drug Products" (Orange Book), "Physician's Desk Reference" (PDR), or an authoritative drug compendium;
- The drug is used for the same indications, including unlabeled uses, as the non-self-administrable version of the drug; and
- The drug is reasonable and necessary for the individual patient.

MBPM, *supra* ch. 15, § 50.5.3.

Medicare Part D

Overview/Background/Eligibility[2]

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Voluntary Prescription Drug Benefit Program, which is commonly referred to as Medicare Part D. Part D is an optional prescription drug benefit program for individuals who are entitled to Medicare Part A benefits or who are enrolled in Medicare Part B. Beneficiaries who qualify for both Medicare and Medicaid (dual-eligibles) automatically receive the Medicare Part D drug benefit. The MMA also provides assistance with premiums and cost sharing to eligible low-income beneficiaries.

Generally, Part D coverage is provided through prescription drug plans (PDPs) (which only offer prescription drug coverage) or through Medicare Advantage – Prescription Drug (MA-PD) plans (which offer prescription drug coverage integrated with the health care coverage provided under Part C). PDPs must offer a basic prescription drug benefit; Medicare Advantage organizations (MAOs) must offer either basic benefits or broader coverage at no additional cost. In addition to a basic prescription drug benefit, PDPs and MA-PD plans may offer additional drug coverage for a supplemental premium. Organizations offering drug plans have flexibility in how they design their prescription drug benefit packages, which includes establishing their respective drug formularies.

Because MAOs are required to offer MA-PD plans, Part D adopts much of the same organizational and regulatory structure that exists under Part C. Wherever possible, CMS

[2] *See MPDBM, supra* ch. 1, § 10.1.

modeled the Part D regulations (*viz.*, 42 C.F.R. Part 423) on comparable Part C regulations (*viz.*, 42 C.F.R. Part 422).

A Part D enrollee must live in the PDP service area to be eligible for an available PDP (Act § 1860D-1(a); 42 C.F.R. § 423.30(a)(1)(ii)). Drugs prescribed for Part D enrollees that are eligible for coverage under Medicare Part A or Part B are not covered under Medicare Part D. Act § 1860D-2(e)(2)(B).

Covered Part D Drug

In general, a covered Part D drug must meet all of these conditions:[3]

- The drug is available only by prescription;
- The drug is approved by the FDA;
- The drug is used and sold in the U.S.;
- The drug is used for a medically accepted indication, as defined under the Social Security Act; and
- The drug isn't covered under Part A or Part B.

See Act §§ 1860D-2(e)(1), 1927(k)(2)(A)(i); *see also* 42 C.F.R. § 423.100 ("*Covered Part D* drug means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination...").

In essence, a Part D drug:

- ✓ Is available only by prescription;
- ✓ Is either FDA-approved or "grandfathered" (*see, e.g.*, M-14-2925 (Feb. 18, 2011)), or a biological product, vaccine, insulin or insulin supplies described in section 1927(k) of the Act;
- ✓ Has been prescribed for a medically accepted indication; and,
- ✓ Is not statutorily excluded.

Part D does not cover drugs or classes of drugs, or their medical uses, which are excluded from coverage or otherwise restricted under section 1927(d)(2) of the Act.

Drugs Excluded from Part D coverage:

- Agents when used for anorexia, weight loss, or weight gain (even if used for a non-cosmetic purpose such as morbid obesity).

[3] The term also includes biological products, insulin, and vaccines as more fully described in the statute. *See* Act § 1860D-2(e)(1)(B).

- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Agents when used for the treatment of sexual or erectile dysfunction (ED). ED drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction (such as pulmonary hypertension). **However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act (i.e., AHFS-DI or DRUGDEX).**

Drugs Not Excluded from Part D Coverage:

- Prescription drug products that otherwise satisfy the definition of a Part D drug are Part D drugs when used for AIDS wasting and cachexia due to a chronic disease, if these conditions are medically-accepted indications as defined by section 1927(k)(6) of the Act for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia due to a chronic disease as either agents used for weight gain or agents used for cosmetic purposes.
- Part D drugs indicated for the treatment of psoriasis, acne, rosacea, or vitiligo are not considered cosmetic.
- Vitamin D analogs such as calcitriol, doxercalciferol, and paricalcitol, when used for a medically-accepted indication as defined by section 1927(k)(6) of the Act, are not excluded because CMS interprets the exclusion of prescription vitamin D products as being limited to products consisting of ergocalciferol (vitamin D2) and/or cholecalciferol (vitamin D3).
- Prescription-only smoking cessation products.
- Prescription Niacin products (Niaspan, Niacor).
- Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and/or

colds. For example, when "cough" medications are used to treat a medical condition that causes a cough, such as the use of bronchodilators for the treatment of bronchospasm in asthma, CMS does not consider these "cough" medications as excluded drugs and, therefore, these medications may be covered under Part D. However, antitussives used to treat cough symptoms, and not the underlying medical condition causing the cough, are excluded from basic Part D coverage regardless of the medical condition causing the cough.

- Benzodiazepines.

- Barbiturates.

Medically Accepted Indication

For covered Part D drugs (which are not used as part of an anti-cancer drug regimen), "medically-accepted indication" means any use of a covered Part D drug which is approved under the Federal Food, Drug, and Cosmetic Act, or which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. Act §§ 1860D-2(e)(4) and 1927(k)(6). The only recognized compendia still in publication are:

- AHFS-DI; and
- DRUGDEX.

For covered Part D drugs (which *are* used in an anticancer chemotherapeutic regimen), "medically accepted indication" has the same meaning as that which applies to anti-cancer drugs under Part B. Act § 1861(t)(2)(B).

Part D sponsors will be required to thoroughly understand and apply Part B's definition of an anti-cancer chemotherapeutic regimen, utilize Part B compendia, and consider peer reviewed medical literature when necessary. *MPDBM, supra* ch. 6, § 10.6.

For drugs that are **anti-cancer agents**, the approved compendia are:

- AHFS-DI;
- NCCN;
- DRUGDEX;
- Clinical Pharmacology; and
- Lexi-Drugs (effective August 12, 2015).

Act §§ 1860D-2(e)(4)(A)(i), 1861(t)(2)(B); *MBPM, supra* ch. 15, § 50.4.5.

Part D Definitions and Terms[4]

- *Enrollee* means a Part D eligible individual who has elected or enrolled in a Part D plan.

- *Part D plan or prescription drug plan (PDP)* means a prescription drug plan, an MA-PD plan, or a Programs of All-Inclusive Care for the Elderly (PACE) plan, that offers qualified prescription drug coverage or a cost plan that offers qualified prescription drug coverage.

- *Part D plan sponsor (PDP sponsor or plan sponsor)* means a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

- *Covered Part D drug* means a Part D drug that is included in a PDP's formulary, or treated as being included in a PDP's formulary as a result of a coverage determination or appeal.

- *Formulary* means the entire list of Part D drugs covered by a PDP.

- *Tiered cost-sharing* means a process of grouping Part D drugs into different cost-sharing levels within a formulary; e.g., a three-tiered formulary might be organized as follows:

  - Tier 1 drugs with the lowest copayment (e.g., generic drugs).
  - Tier 2 drugs with higher copayments (e.g., preferred brand name drugs).
  - Tier 3 drugs with the highest copayments (e.g., non-preferred brand name drugs).

- *Brand name drug* means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)).

- *Generic drug* means a drug for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 US.C. § 355(j)).

- *Preferred drug* means a formulary drug for which an enrollee's cost-sharing is lower than that for a non-preferred formulary drug.

- *Appeal* means any of the procedures that deal with reviewing an adverse coverage determination made by a PDP sponsor that concern Part D benefits, including delay in providing or approving drug coverage (when a delay would adversely affect the health of the enrollee), or any amounts the enrollee must pay for drug coverage. These procedures include redetermination by the PDP sponsor, reconsideration by an

[4] Act §§ 1860D-2(e), 1927(g)(1)(B)(i)(III), and 1927(k)(2); 42 C.F.R. §§ 423.4, 423.100, and 423.560; *MBPM, supra* ch. 15, § 50.4.5; *MPDBM, supra* ch. 1, § 20 and ch. 6, § 10.6.

independent review entity (IRE), an ALJ hearing, review by the Medicare Appeals Council, and judicial review.

- *Grievance* means any complaint or dispute, *other than one that involves a coverage determination*, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a PDP sponsor, regardless of whether remedial action is requested.

Medicare Part D Law and Policy

A. Statutes

Act § 1860D-1
Act § 1860D-2
Act § 1927(g) and (k)

B. Regulations

1. 42 C.F.R. Part 423 "Voluntary Medicare Prescription Drug Benefit"

2. The Part D procedural sections are found in:

   a. 42 C.F.R. Part 423, Subpart M "Grievances, Coverage Determinations, Redeterminations, and Reconsiderations" [42 C.F.R. §§ 423.558- 423.638].

   b. 42 C.F.R. Part 423, Subpart U "Reopening, ALJ Hearings and ALJ and Attorney Adjudicator Decisions, Council Review, and Judicial Review" [in particular, 42 C.F.R. §§ 423.1968- 423.2063].

   Practice Tip: When dealing with a Part D appeal, remember that there are procedural (as well as substantive) differences. In addition to slight differences in terminology (e.g., "enrollee" as opposed to "beneficiary," "plan sponsor" as opposed to "Medicare Advantage Organization"), some procedures differ significantly from those which apply in appeals under original Medicare, for example:

   ✓ The enrollee is the only party [42 C.F.R. § 423.2008]; while CMS, the IRE, and PDP sponsor may ask to participate as non-parties [42 C.F.R. § 423.2010], the ALJ or attorney adjudicator has discretion to deny such requests. [42 C.F.R. § 423.2010(c)].

   ✓ In a non-expedited appeal, a *represented* enrollee must submit all additional evidence no later than 10 calendar days after receiving the notice of hearing. If a represented enrollee submits evidence later than 10 calendar days after receipt of the notice of hearing, any applicable adjudication period is extended by the corresponding number of calendar days. No such requirement applies to *unrepresented* enrollees. [42 C.F.R. § 423.2018(b)].

- ✓ In an expedited appeal, an enrollee (whether represented or unrepresented) must submit all additional evidence no later than 2 calendar days after receiving the notice of hearing. If an enrollee submits evidence later than 2 calendar days after receipt of the notice of hearing, any applicable adjudication period is extended by the corresponding number of calendar days. [42 C.F.R. § 423.2018(c)].

- ✓ An ALJ or attorney adjudicator may not consider any evidence submitted regarding a change in the enrollee's medical condition that occurred *after* the PDP sponsor issued its coverage determination; instead, if an enrollee makes such a request, an ALJ or attorney adjudicator MUST remand a Part D proceeding for the IRE to consider the enrollee's evidence of a changed medical condition. [42 C.F.R. §§ 423.2018(a) and 423.2056(e)].

Moreover, simply based on their titles, certain Part D regulations appear to be (but are not) duplicative, for example:

- ✓ 42 C.F.R. §§ 423.1970 and 423.2002 are *both* entitled "Right to an ALJ hearing"

C. Policy Manual

CMS, *MPDBM* (*Internet-Only Manual Publ'n 100-18*).

Practice Tip: When dealing with a Part D case, do not overlook the appendices to Chapter 6 in the *MPDBM*, which include (among other information) some helpful Q & A:

- ✓ Appendix A Common Acute Care Home Infusion Drugs.
- ✓ Appendix B Part D Drugs/Supplemental Drugs Summary Table.
- ✓ Appendix C Medicare Part B versus Part D Coverage Issues.
- ✓ Appendix D the Most Commonly Prescribed Drug Classes for the Medicare Population.
- ✓ Appendix E Sample Transition Supply Scenarios and Eligibility.

Part D Exceptions Process

1. *Formulary Exceptions, 42 C.F.R. § 423.578(b):*

Each PDP must provide an exceptions process for non-formulary Part D drugs that are prescribed for its enrollees. An enrollee, enrollee's appointed representative, or prescribing physician may file the request for an exception. A formulary exception must be granted whenever a non-formulary Part D drug is:

- ✓ Medically necessary;

- ✓ Consistent with the prescriber's oral or written statement that all of the covered Part D drug alternatives on the formulary—
  - ➢ Would not be as effective as the requested drug; and/or
  - ➢ Would have adverse effects for the enrollee; and,
- ✓ The PDP would have covered the drug but for the fact it is a non-formulary drug.

When a formulary exception is approved, the PDP may not require that the enrollee request approval for refills or provide a new prescription so long as the prescriber continues to prescribe the drug, the drug continues to be considered safe for treating the enrollee, and the enrollment period (usually one year) has not expired. 42 C.F.R. § 423.578(c)(4).

2. *Tiering Exceptions, 42 C.F.R. § 423.578(a):*

Each PDP that utilizes a tiered formulary must also provide a tiering exceptions process for its enrollees. An enrollee or prescribing physician may file the request for an exception. A tiering exception must be granted whenever the non-preferred drug is:

- ✓ Medically necessary;
- ✓ Consistent with the prescriber's oral or written statement that the preferred drug—
  - ➢ Would not be as effective as the requested drug; and/or
  - ➢ Would have adverse effects for the enrollee; and,
- ✓ No formulary exception was granted for the requested drug.

When a tiering exception is approved, the PDP must provide coverage for the requested drug at the tiering level that applies for preferred drugs. The PDP may not require that the enrollee request approval for refills or provide a new prescription so long as the prescriber continues to prescribe the drug, the drug continues to be considered safe for treating the enrollee, and the enrollment period (usually one year) has not expired. 42 C.F.R. § 423.578(c)(3).

- ✓ PDP sponsors may not be required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier for generic drugs. 42 C.F.R. § 423.578(a)(6).
- ✓ PDP sponsors may not be required to cover a non-preferred drug at a lower cost-sharing level if there is no preferred drug on a lower tier approved for treating the same condition as the higher tier drug. *See MPDBM, supra* ch. 18, § 30.2.1.

- ✓ If a plan's formulary contains a specialty tier for very high cost and unique items (such as genomic and biotech products), the PDP sponsor may exclude drugs in the specialty tier from eligibility for a tiering exception. 42 C.F.R. § 423.578(a)(7).

- ✓ No tiering exception may be granted for a drug that does not meet the definition of a Part D drug. 42 C.F.R. § 423.578(e).

3. Transitional Supply[5]

A PDP sponsor must provide an appropriate transition process for certain enrollees who are prescribed Part D drugs that represent ongoing therapy with that drug, but that are non-formulary. The purpose of providing a transitional supply is to promote continuity of care and avoid interruptions in drug therapy while a switch to a therapeutically equivalent drug or the completion of an exception request to maintain coverage of the current drug based on medical necessity can be effectuated. *MPDBM, supra* ch. 6, § 30.4.

Medicare Part D allows for a transitional supply when the plan makes a retrospective determination that the drug should not be covered, after it had previously provided coverage for the drug, either as a part of their retrospective review programs required under 42 C.F.R. § 423.153 or incident to another utilization management review. *MPDBM, supra* ch. 6, § 10.6.1.

Common Issues That Arise In Part D Claims[6]

The following are scenarios that OMHA commonly confronts in Part D appeals:

A. Statutory exclusion – *see* M-14-2823 (Jan. 21, 2016) – The ALJ issued an unfavorable decision for Hemax (oral iron supplement) to treat iron deficiency anemia on the basis that prescription vitamins and minerals are excluded from coverage pursuant to § 1927(d)(2) of the Act. The Council adopted the ALJ's decision, explaining that while Hemax may be effective in treating the enrollee's condition and a more cost-effective alternative to blood transfusions, the enrollee's medical need and the cost of the drug were not relevant considerations in this case because prescription vitamins and minerals are statutorily excluded from coverage.

B. Medically accepted indication – *see* M-15-1791 (Nov. 3, 2015) – The Council concluded the plan was not required to cover the drug at issue because it was not prescribed or used for a medically accepted indication as listed on the FDA-approved label or cited in a Medicare-approved compendia.

C. Compounded drug – *see* M-14-2483 (Mar. 12, 2015) – Formulary exception not available

[5] *See* Medicare Appeals Council decision M-15-120 (Jan. 29, 2015).

[6] The citations below identify decisions issued by the Medicare Appeals Council (the Council). Council decisions are not precedential or binding except for the particular action in which the decision was issued or as indicated under 42 C.F.R. §§ 401.109 and 405.1063. The decisions referenced may be accessed through OMHA's MAC-DR. The MAC-DR is an online compilation of Council decisions, available on OMHA's SharePoint portal, which OMHA maintains as an internal, informal research tool.

because the FDA does not approve component bulk pharmaceutical powders used in the compound; in addition, because no component of the compound met the definition of a Part D drug, the compound as a whole was not eligible for Part D coverage.

D. Non-Formulary drug prescribed for off-label use – *see* M-15-1142 (Aug. 13, 2015) – Request for formulary exception denied because prescribing physician did not submit a statement that all other alternatives on the plan's formulary would be less effective and/or would have adverse effects.

E. Formulary exception granted and enrollee requests tiering exception – *see* M-14-1876 (Oct. 16, 2014) – Tiering exception never allowed for a drug that is covered based on a formulary exception.

F. Enrollee requests tiering exception for non-preferred drug at generic level – M-14-3249 (Oct. 7, 2014) – In no case is a PDP sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs. 42 C.F.R. § 423.578(a)(6).

G. Enrollee requests tiering exception for specialty drug – M-14-3559 (Apr. 1, 2015) – Medicare rules allow Part D plans to set up a specialty tier for high cost drugs and design its exception process so that such drugs are not eligible for a tiering exception.

H. Citation to compendia – *see* M-15-1616 (Jan. 6, 2016) – The ALJ granted coverage on the basis the enrollee's use was cited as a "medically accepted indication" in DRUGDEX. The Council found that the ALJ erred as a matter of law in relying on evidence outside of the record because the compendium entry was not admitted into evidence.

Expedited Part D Appeals

Request for Expedited Hearing

After receiving written notice of an unfavorable reconsideration, an enrollee may request an ALJ hearing. The request for an ALJ hearing must be made in writing. If an enrollee is requesting an expedited hearing, the enrollee may make the request either orally or in writing; any oral request must be documented and maintained in the case file. 42 C.F.R. §§ 423.2002 and 2014(b).

The request for hearing consists of:

- Any written or oral[7] request for hearing; and,
- Any additional materials submitted with the request (a letter from the enrollee or physician, medical records, etc.).

[7] Recordings of the oral requests are made available to the ALJ teams for review and incorporation to the record.

The ALJ should determine whether there is enough information with the request for hearing to expedite the appeal.

Only an enrollee (or an enrollee's representative) may request a hearing before an ALJ. 42 C.F.R. § 423.2008. However, it is common for OMHA to receive requests for expedited ALJ Hearings filed by physicians on behalf of their patients. In this instance, an Appointment of Representative Form must be properly executed and submitted by the physician at some point prior to the hearing.

A decision denying or granting expedited status may not be appealed. 42 C.F.R. § 423.2016(b)(4).

Starting at 42 C.F.R. § 423.2000, the pertinent regulations specifically address the requirements for "expedited" status. There are specific caveats and reduced timeframes for notices and decisions related to expedited cases.

Granting Expedited Status

An ALJ must provide an expedited hearing if (1) the appeal involves a coverage determination, (2) the appeal does not solely seek payment for Part D drugs already furnished, and (3) the prescriber indicates, or the ALJ determines, that applying the standard 90-day adjudication period may seriously jeopardize the enrollee's life, health, or ability to regain maximum function (an ALJ or attorney adjudicator may consider this standard met if a lower level adjudicator has granted a request for an expedited hearing). 42 C.F.R. § 423.2016(b)(1).

The ALJ or Attorney Adjudicator must either grant or deny a request for an expedited hearing within 5 calendar days of receipt of the request. 42 C.F.R. § 423.2016(b)(2)(i).

The ALJ or Attorney Adjudicator must give the enrollee prompt <u>oral</u> notice of such ruling, and send timely written notice to the enrollee and PDP sponsor. 42 C.F.R. § 423.2016(b)(2)-(b)(3).

Written Notice of Expedited Hearing is mailed or served at least <u>3 calendar days</u> BEFORE the hearing. 42 C.F.R. § 423. 2022(a)(2).

- For <u>expedited</u> hearings, the ALJ may **<u>orally</u>** provide notice of the hearing to the enrollee and other potential participants but oral notice **<u>must be followed by</u>** an equivalent **<u>written</u>** notice within 1 calendar day of the oral notice. 42 C.F.R. § 423. 2022(a)(2).

If the ALJ grants a request to expedite the hearing, the ALJ must issue a written decision, dismissal, or remand as expeditiously as the enrollee's medical condition requires and no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the entity specified in the reconsideration decision. 42 C.F.R. § 423.2016(b).

Denying Expedited Status

The ALJ must either grant or deny a request for an expedited hearing within 5 calendar days of

receipt of the request. 42 C.F.R. § 423.2016(b)(2)(i).

The ALJ must give the enrollee prompt oral notice of such ruling, and send timely written notice to the enrollee and PDP sponsor. 42 C.F.R. § 423.2016(b)(2)-(b)(3).

If the ALJ DENIES the Expedited Request, the case is handled by the ALJ team as a standard Part D appeal.

Written Notice of the Decision to deny expedited status will be sent within 3 calendar days after the oral notice to the enrollee at his or her last known address and the Part D plan. 42 C.F.R. § 423.2016(b)(3)(iii).

NOTE: Even if DENIED, the case should be prioritized on the ALJ's calendar (providing at least 20 days' notice to the enrollee/representative, Part D IRE, and PDP sponsor).

On The Record Decisions and Withdrawals

An enrollee may waive the right to appear at an expedited hearing either orally or in writing; any oral request must be documented and maintained in the case file. 42 C.F.R. § 423.2036(b)(1).

Pursuant to 42 C.F.R. § 423.2038(a), "If the evidence in the administrative record supports a finding fully in favor of the enrollee(s) on every issue, the ALJ or attorney adjudicator may issue a decision without giving the enrollee(s) prior notice and without an ALJ conducting a hearing." *See also* § 423.2000(g).

Only the enrollee may ask to withdraw the request for a Part D hearing. 42 C.F.R. § 423.2052(c).

Including Compendia in The Case File

If the ALJ decides the beneficiary's use of the drug is supported by one or more citations included or approved for inclusion in any compendia, a copy of the relevant compendia entries must be included in the record. *See* 42 C.F.R. § 423.2042.

Part B and D Compendia Access

Compendium	Authoritative for:
American Dental Association (ADA) Guide to Dental Therapeutics	B
United States Pharmacopoeia National Formulary (USP-NF)	B
American Hospital Formulary Service Drug Information (AHFS-DI)	B chemo D chemo D
National Comprehensive Cancer Network (NCCN) Drugs and Biologicals	B chemo D chemo
DRUGDEX (Truven Health Analytics, formerly Thomson Micromedex)	B chemo D chemo D
Clinical Pharmacology (Gold Standard, Inc. / Elsevier)	B chemo D chemo
Wolters Kluwer Clinical Drug Information Lexi-Drugs	B chemo D chemo

B = Part B non-anticancer chemotherapeutic drugs (§ 1861(t)(1) of the Act; MBPM, Ch. 15, § 50.1)
B chemo = Part B anticancer chemotherapeutic drugs (§ 1861(t)(2); MBPM, Ch. 15, § 50.4.5)
D = Part D non-anticancer chemotherapeutic drugs (§§ 1860D-2(e)(4)(A)(ii), 1927(k)(6) and (g)(1)(B)(i) of the Act)
D chemo = Part D anticancer chemotherapeutic drugs (§§ 1860D-2(e)(4)(A)(i), 1861(t)(2); MBPM, Ch. 15, § 50.4.5)

Module 12:
Part B Durable Medical Equipment

After this session, you will be able to:

1. Identify the laws and regulations applicable to durable medical equipment (DME);
2. Understand the definition of durable medical equipment;
3. Know the documentation requirements for durable medical equipment;
4. Understand the difference between replacement and repair; and
5. Be aware of consolidated billing and prior authorization issues.

Required Reading and References:

- ✓ Social Security Act (Act) § 1862(a)(1)
- ✓ Act § 1862(a)(6)
- ✓ Act § 1861(n)
- ✓ Act § 1861(s)(6)
- ✓ 42 C.F.R. § 410.10(h)
- ✓ 42 C.F.R. § 410.38
- ✓ 42 C.F.R. § 414.202
- ✓ 42 C.F.R. § 424.57(b)(2)
- ✓ CMS, *Medicare National Coverage Determinations Manual (MNCDM) (Internet-Only Manual Publ'n 100-3)* ch. 1, § 280.1 (NCD 280.1)
- ✓ CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-2)* ch. 15, § 110
- ✓ CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-8)* ch. 5, § 5

Introduction – Background and Rationale

Medicare Part A and B cover various types of medical supplies, medical equipment, orthotics and prosthetics.

Generally, Medicare Part A covers these items when an individual is receiving covered Medicare Part A services such as inpatient hospital care, skilled nursing facility services, or home health services. These items would be included in a Part A provider's "consolidated billing".

Individuals are also entitled to coverage for these items under Medicare Part B as long as certain criteria are met. This module provides a broad overview of the coverage and payment requirements for Durable Medical Equipment (DME). DME includes items such as walkers, wheelchairs, and hospital beds—items that are 1) durable, and 2) used for a medical purpose in an individual's home or residence. As there are many types of DME, this benefit is further defined in specific guidance found in Local Coverage Determinations (LCDs).

Objective 1: Identify the Laws and Regulations Applicable to Durable Medical Equipment

A. Applicable Laws and Regulations

- Section 1862(a)(1) of the Act allows Medicare to pay for "medical and other health services."
- Section 1861(s)(6) of the Act defines the term "medical and other health services" to include durable medical equipment.[1]
- Section 1862(a)(6) of the Act states that generally Medicare payment may not be made for personal comfort items.
- According to Section 1861(n) of the Act, the term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, wheelchairs, power-operated vehicles, blood-testing strips, blood glucose monitors, and seat-lift mechanisms.
- 42 C.F.R. § 410.38 describes the scope and conditions of durable medical equipment.
- 42 C.F.R. § 424.57(b)(2) states that suppliers are required to obtain a DMEPOS supplier number conveying billing requirements in order to be eligible to receive payment for Medicare-covered items, and CMS issues only one supplier number for each location.

B. Relevant National Coverage Determinations (NCDs): Sample List

National Coverage Determinations (NCDs) are binding on Administrative Law Judges and attorney adjudicators.[2] There are several NCDs OMHA adjudicators must be aware of when reviewing claims for DME. These include:

- NCD 40.2 – Home Blood Glucose Monitors
- NCD 240.2 – Home Use of Oxygen
- NCD 280.1 – DME Reference List
- NCD 280.3 – Mobility Assistive Equipment
- NCD 280.7 – Hospital Beds

[1] *See* 42 C.F.R. § 410.10(h).
[2] 42 C.F.R. § 405.1060(a)(4).

C. CMS Publications

Chapter 15, section 110 of the Medicare Benefit Policy Manual (MBPM) sets forth detailed coverage guidelines relating to Medicare coverage for DME.

Chapter 5, section 5 of the Medicare Program Integrity Manual (MPIM) provides guidance on items which require special DME review consideration. This section describes the evidence needed to support the medical necessity for wheelchairs and power-operated vehicles, as well as oxygen claims. It also provides detailed guidance related to physician orders for DME, Certificates of Medical Necessity (CMNs), and DME Information Forms (DIFs).

Objective 2: Understand the Definition of Durable Medical Equipment

1862(a)(1) of the Social Security Act allows Medicare to pay for "medical and other health services." "Medical and other health services" is defined to include **durable medical equipment (DME)**(defined at Act § 1861(n); and listed as covered under "medical and other health services" at Act § 1861(s)(6)), **prosthetics, orthotics and medical supplies** (**POS**) (Act §§ 1861(s)(8)-(9)), and other items considered neither DME nor POS (ex., therapeutic shoes for diabetics, Act § 1861(s)(12)).

In general, DME is reusable equipment that primarily serves a medical purpose in the individual's home. Specifically, 42 C.F.R. § 414.202, defines **DME** as equipment that:

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and
- Is appropriate for use in the home.[3]

The scope and conditions for Medicare coverage for DME is set forth in 42 C.F.R. § 410.38. The DME benefit is further defined in chapter 15, section 110 of CMS's MBPM.

DME is a defined benefit that excludes medical items not meeting the above-definition. Of significant note, items covered under the **POS** benefit and the diabetic shoe benefit may seem to satisfy the DME elements, but are categorically distinct benefits. For example, Medicare coverage for **POS**—not discussed in this module—is subject to 42 C.F.R. § 410.36. Prosthetic devices are defined as "devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care)..."[4] Additional guidelines related to the POS benefit are found in chapter 15, sections 120 and 130 of the MBPM.

[3] *See also MBPM, supra,* ch. 15, § 110.1.
[4] Act § 1861(s)(8); *See* 42 C.F.R. § 410.36.

Most Common Types of Durable Medical Equipment:

The DME benefit provides coverage for a wide variety of medical items for home use. Some of these items are specifically addressed in 42 C.F.R. 410.38 (e.g., power mobility devices, equipment to treat ulcers, seat lifts, and TENS units) others are included in the DME Reference List (NCD 280.1). Here are examples of DME items commonly seen at OMHA:

- Power Mobility Devices (PMD), including Manual Wheelchairs, Scooters, Power Wheelchairs - Medicare covers a Power Operated Vehicle (POV) when the patient requires a wheelchair, but cannot maneuver a manual wheelchair. The patient must be able to safely work the controls of a POV, safely get in and out of a POV, and safely sit in a POV without additional support. Medicare covers options and accessories for wheelchairs when a patient has a wheelchair that meets Medicare coverage guidelines, and the options or accessories are necessary for the patient to perform normal daily activities. The patient must have a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home.[5]

- Other Mobility Assistive Equipment (MAE), including Walkers, Canes and Crutches - Medicare covers canes and crutches for patients who have trouble walking, but can walk with support. Medicare does not cover canes for the blind. Medicare covers a walker for patients who can walk, but need additional support that cannot be provided by a cane or crutches.[6]

- Hospital Beds and Related Accessories - Medicare covers a hospital bed when the patient cannot use a normal bed because he/she needs to change body positions in ways not possible with a normal bed, or be in body positions not possible with a normal bed in order to relieve pain, or needs to have the head of the bed higher than 30 degrees most of the time due to illnesses such as congestive heart failure or chronic pulmonary disease, or use traction equipment that must be attached to a hospital bed.[7]

- Oxygen Supplies - Medicare covers oxygen equipment and supplies including oxygen tents, iron lungs, and portable and home oxygen supplies. Medicare covers rental of oxygen equipment, or if you own your own equipment, Medicare will help pay for oxygen contents and supplies for the delivery of oxygen. Documentation indicates that the patient has a severe lung disease or hypoxia-related symptoms and the condition might improve with oxygen therapy, the patients arterial blood gas

[5] *See* 42 C.F.R. § 410.38 and NCD 280.3.
[6] *See* NCD 280.2 and NCD 280.3.
[7] *See* NCD 280.7.

level falls within a certain range, and other alternative measures have been tried and failed, or were not helpful.[8]

- Blood Glucose Monitors and Diabetic Testing Supplies - Medicare covers several different types of blood glucose monitors that measure capillary blood to alert users when glucose values are becoming high (hyperglycemic) and/or low (hypoglycemic). Medicare coverage of these devices and related supplies varies with respect to both the type of device and the medical condition of the patient for whom the device is prescribed.[9]

Note: Continuous Glucose Monitors (CGMs)

CGMs measure glucose in the interstitial fluid, rather than capillary blood. Because they do not measure **blood** glucose, different guidelines and coding (HCPCS/CPT) apply. The primary issue to be considered when reviewing claims for CGMs is whether the device is considered "therapeutic" or "non-therapeutic" -

- "Therapeutic" CGMs: "Therapeutic" CGMs are **CGMs approved by the Food and Drug Administration (FDA) to replace** other blood glucose monitoring testing and to make diabetic treatment decisions.

- "Non-Therapeutic" CGMS: "Non-Therapeutic CGMs are CGMS used in conjunction with blood glucose monitoring testing to make diabetic treatment decisions.

See CMS Ruling 1682-R (CMS-1682-R) (Jan. 12, 2017).

- High Frequency Chest Wall Oscillation Devices (HFCWO) – HFCWO are covered for patients who meet certain criteria as defined in the applicable LCDs.

- Pneumatic Compression Devices - Medicare covers lymphedema pumps or pneumatic compression devices, for patients who have severe swelling due to lack of drainage of lymphatic fluid. These devices are also covered for patients with severe circulation problems or ulcers.[10]

[8] *See* NCD 240.2.
[9] *See* NCD 40.2.
[10] *See* NCD 280.6.

Objective 3: Know the Documentation Requirements for Durable Medical Equipment

I. Certificate of Medical Necessity (CMN) & DME Information Form (DIF)

CMNs and **DIFs** are forms required to document the medical necessity and compliance with coverage criteria for certain types of DME. CMNs are completed by both the supplier and the physician, and include a signed and dated physician's signature, while a DIF is only completed and signed by the supplier. In addition to being a required document, these forms reflect pertinent information such as patient, supplier and prescribing physician names and addresses. They also reflect the underlying treatment diagnosis code(s) and responses to clinical questions, which relate to the coverage criteria for the item.

However, while the information on the CMN or DIF may purport to address elements of the coverage criteria, it is important to note that the CMN entries themselves may not serve as the only supporting evidence, even when the CMN is signed by a physician. A CMN alone is not sufficient documentation to support payment of DME.[11] Medical necessity must be substantiated by the patient's medical record, which includes records from the physician's office, hospital, nursing home, home health agency, or other health care professional.

CMNs may serve the purpose of a physician's detailed written order if it provides a sufficiently detailed narrative description of the DME.[12]

CMN Examples:

- CMS-484 CMN Form is for oxygen equipment.
- CMS-846 CMN Form is for pneumatic compression device.
- CMS-848 CMN Form is for transcutaneous electrical nerve stimulator (TENS).
- CMS-849 CMN Form is for seat lift mechanism.

DIF Examples:

- CMS-10125 DIF Form is for external infusion pumps.
- CMS-10126 DIF Form is for enteral and parenteral nutrition.

II. Physician's Order

All DME requires a physician's order, which must include a description of the item, the beneficiary's name, the physician's name, and the start date of the order.[13]

[11] *See MPIM, supra*, ch. 5, § 5.7.
[12] *Id.* § 5.3.
[13] *See MPIM, supra*, ch. 5, §§ 5.2.1 - 5.2.2.

A supplier must have an order from the treating physician prior to dispensing any DME to a beneficiary. For all DME items, unless otherwise specified, the date of the written order shall be on or before the date of delivery or date shipped if the shipping date is used as the date of service.[14]

All DME items (other than Power Mobility Devices (PMDs)(410.38(c)(4) and "Specified Covered Items" (410.38(g)(2)) require a **Detailed Written Order (DWO)** prior to billing.[15] The supplier may complete portions of the order, e.g. the detailed description of the item; however, the treating physician must review, sign, and date the order. The supplier must have a detailed written order prior to submitting a claim.[16]

If the supplier does not have an order that has been both signed and dated by the treating physician before billing the Medicare program, the claim will be denied as **not reasonable and necessary (i.e. excluded under § 1862(a)(1)(A) of the Act)**.[17]

> **Note: Prescriptions for Therapeutic Shoes for Diabetics**
>
> Therapeutic shoes for diabetes are not part of the DME benefit, but are instead defined by sections 1833(o) and 1861(s)(12). Under the statutory definition of the diabetic shoe benefit, a certification and prescription is required. See Act §1861(s)(12). Therefore, if no order is produced for therapeutic shoes, the item(s) will be denied as not meeting the statutory definition under §§1833(o) and 1861(s)(12). This denial basis will then carry financial implications for the beneficiary.

A Written Order Prior to Delivery (WOPD) is required for PMDs and "Specified Covered Items".[18] For these items, the DME supplier must review a written order, signed and dated by the treating physician, prior to dispensing the ordered equipment.

III. Face-to-Face Evaluation

Medicare requires documentation that a **face-to-face encounter** occurred with a physician or treating practitioner for **Specified Covered Items** and **PMDs**. Evidence of a face-to-face encounter is required to support a conclusion that such items are reasonable and necessary. The face-to-face encounter regulations and guidance for **Specified Covered Items** and **PMDs** are:

[14] *See MPIM, supra*, ch. 5, § 5.2.6 (*effective* June 27, 2017).
[15] *See MPIM, supra*, ch. 5, § 5.2.3.
[16] *Id.*
[17] *Id.*
[18] *See* 42 C.F.R. §§ 410.38(c)(4) and 410.38(g)(2).

Specified Covered Items.[19] Specified Covered Items (e.g., TENS units, hospital beds, oxygen and respiratory equipment) require a face-to-face encounter by a physician, physician assistant, nurse practitioner, or a clinical nurse specialist with the beneficiary within 6 months prior to completing the detailed written order.

Power Mobility Devices.[20] A physician, physician assistant, nurse practitioner, or clinical nurse specialist must conduct a face-to-face examination of the beneficiary to determine medical necessity for the PMD as part of an appropriate overall treatment plan. A face-to-face evaluation and supporting documentation generally requires the following:

- Delineate the history of events that led to the request for the PMD;
- Identify the mobility deficits to be corrected by the PMD;
- Document that other treatments do not obviate the need for the PMD;
- Establish the beneficiary lives in an environment that supports the use of the PMD; and
- Establish the beneficiary or caregiver is capable of operating the PMD.

Objective 4: Know the Difference between Replacement and Repair

DME Replacement

Chapter 15, section 110.2 C of the MBPM provides Medicare guidelines for DME replacement. Per the MBPM, "replacement" is the provision of an identical or nearly identical item. According to the MBPM, DME may be replaced due to:

- **Loss or irreparable damage**. The MBPM defines "irreparable damage" as damage caused by a specific accident (e.g., car accident) or to a natural disaster (e.g., fire, flood). While the MCPM indicates that reimbursement may be made without a physician's order when the DME MAC determines that the equipment still meets the beneficiary's medical needs; the MBPM indicates that a physician's order and/or new CMN, where required, is needed to indicate continued medical necessity and the MPIM indicates that a new order is required when an item is replaced.[21]
- **Irreparable wear**. Replacement due to irreparable wear takes into consideration the reasonable useful lifetime (RUL) of the equipment, which is generally no less than five years.

Replacement of durable medical equipment during the equipment's reasonable useful lifetime may also be covered when the beneficiary has a **change in their medical condition** necessitating a new device.[22] For example, a beneficiary with a degenerative condition may worsen to such an extent that a DME replacement is necessary to address new deficits.

[19] *See* 42 C.F.R. § 410.38(g) and *MPIM, supra,* ch. 5, § 5.2.5.
[20] *See* 42 C.F.R. §§ 410.38(c)(2) and *MPIM, supra,* ch. 5, § 5.9.2.
[21] *Compare* CMS, *Medicare Claims Processing Manual (MCPM) (Internet-Only Manual Publ'n* 100-4) ch. 20, § 50 *with MBPM, supra* ch. 15, § 110.2 *and MPIM, supra* ch. 5, § 5.2.7.
[22] *See MCPM, supra,* ch. 20, § 50.

DME Repair

Section 110.2 A, Chapter 15 of the MBPM provides Medicare guidelines for DME repair. Per the MBPM, "repair" means to fix or mend and to put the equipment back in good condition after damage or wear.

- Repairs to equipment which a beneficiary owns are covered when necessary to make the equipment serviceable.
- During the RUL, Medicare covers repairs up to the cost of replacement for medically necessary equipment owned by the beneficiary.

CMS Contractors are tasked with reviewing repair claims for continued medical necessity and the necessity of the repair.[23] The specific coverage requirements for the original item do not have to be met but there must be evidence that the item continued to be medically necessary, and documentation of the nature of the repair and the work performed.[24]

Objective 5: Be Aware of Consolidated Billing and Prior Authorization Issues

Consolidated billing issues arise when a Part B supplier bills for DMEPOS furnished to a beneficiary who is in a Part A stay in a hospital, skilled nursing facility (SNF), or under a home health agency plan of care.

Payment for medical supplies (e.g., urological, ostomy, or wound care supplies) furnished during a Part A episode of care is generally included in the consolidated billing payment to the Part A provider, and separate payment to a supplier under Part B is prohibited by Sections 1862(a)(14), (18), and (21) of the Act.

- A number of ALJ decisions have been reversed or modified by the Medicare Appeals Council (Council) where an ALJ allowed partial payment for medical supplies furnished to a beneficiary who was in a Part A episode on the date of service, with partial payment made to the Part B supplier on the date that the beneficiary was discharged from the Part A episode. The Council has consistently found that partial payment could not be allowed because an entire 90-day supply was included in the Part A consolidated billing payment, and any additional payment to the Part B supplier would be considered a duplicate payment.

- Thus, partial payment under Part B, beginning on the date of discharge, is not permitted. In other words, any payment under Part B for supplies subject to consolidated billing is considered a duplicate payment, even if the beneficiary was discharged from the hospital, SNF, or home health agency prior to exhausting the entire 90-day supply.

[23] *MPIM, supra,* ch. 5, § 5.8.1.
[24] *Id.*

When a Part B supplier is denied payment, it typically requests a limitation on liability pursuant to Section 1879 of the Act, or a waiver of the overpayment recovery pursuant to Section 1870(b) of the Act.

Part B suppliers may argue that they are not at fault because they relied on third-party electronic systems to confirm that the beneficiary was not receiving Part A services before delivering the supplies at issue.

- The "first avenue" for suppliers to pursue, is to ask the beneficiary (or his/her representative) if he or she is presently receiving home health services.[25]
- The Council has consistently held that suppliers who solely relied upon third-party electronic systems (e.g., HIPAA Eligibility Transaction System (HETS), Common Working File (CWF), and Interactive Voice Response (IVR)), had not taken reasonable steps to determine the beneficiary's status and should not receive payment. The Council has also consistently held that these third-party electronic systems should only be used as a "last resort" and, consequently, the suppliers are not without fault.

Prior Authorization for Certain DMEPOS

On December 30, 2015, new prior authorization requirements were created for certain DMEPOS items that are frequently subject to unnecessary utilization.[26] A prior authorization determination is a condition of payment for items listed on CMS's Required Prior Authorization List.[27] A claim for an item on the Required Prior Authorization List without a provisional affirmation will be denied.[28] However, a contractor's prior authorization determination is not an initial determination.[29]

On December 21, 2016, CMS announced the implementation of the prior authorization program for certain DMEPOS.[30]

Beginning on July 17, 2017, the first two DME items subject to required prior authorization are:

- K0856 HCPCS: Power wheelchair, group 3 std., single power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds.
- K0861 HCPCS: Power wheelchair, group 3 std., multiple power option, sling/solid seat/back, patient weight capacity up to and including 300 pounds.

[25] *MCPM, supra,* ch 10, § 20.1.2.
[26] *See* 42 C.F.R. § 414.234 and 80 Fed. Reg. at 81673.
[27] *See* 42 C.F.R. § 414.234(c)(1).
[28] *See* 42 C.F.R. § 414.234(c)(2).
[29] *See* 42 C.F.R. § 405.926(t).
[30] *See* 81 Fed. Reg. 93636, 93637 (Dec. 21, 2016).

Now that you have completed this lesson, you should now be able to:

1. Identify the laws and regulations applicable to durable medical equipment;
2. Understand the definition of durable medical equipment;
3. Know the documentation requirements for durable medical equipment;
4. Understand the difference between replacement and repair; and
5. Be aware of consolidated billing and prior authorization issues.

Module 13:
Medicare Part B, Outpatient Therapy Services

After this session, you will be able to:

1. Identify the statutes and regulations applicable to outpatient therapy services.
2. Understand Medicare coverage and payment rules for outpatient therapy.
3. Understand the difference between maintenance therapy and rehabilitative therapy.
4. Identify the documentation requirements for outpatient therapy services.
5. Understand how the yearly outpatient therapy cap functions.

Required Reading/Reference:

- ✓ Social Security Act (Act) § 1832(a)(2)(C)
- ✓ Act § 1861(p), (g), (ll), and (s)(2)(D)
- ✓ Act § 1835(a)(1), (a)(2)(C), and (a)(2)(D)
- ✓ 42 C.F.R. §§ 410.59– 410.62
- ✓ 42 C.F.R. §§ 410.100– 410.105
- ✓ 42 C.F.R. § 424.24(c)
- ✓ CMS, *Medicare Benefit Policy Manual* (*MBPM*) (*Internet-Only Manual Publ'n 100-2*), ch. 15, §§ 220–230.6
- ✓ CMS, *Medicare Claims Processing Manual* (MCPM) (*Internet-Only Publ'n 100-4*) ch. 5, §§ 10.2–10.5

Introduction – Background and Rationale

This module provides a general overview of the outpatient therapy benefit provided under Medicare Part B.

Generally, Medicare Part B provides coverage for various outpatient therapy services such as physical therapy, occupational therapy, and speech-language pathology services (also referred to as speech therapy).[1] These services are a benefit defined in sections 1861(p), 1861(g), and 1861(ll) of the Social Security Act (the Act), respectively. Therapy services may also be provided incident to the services of a physician/non-physician practitioner (NPP) under sections 1861(s)(2) and 1862(a)(20) of the Act. Covered therapy services are furnished by providers, by others under arrangements with and under the supervision of providers, or by suppliers (e.g., physicians, NPP, enrolled therapists), who meet the Medicare requirements for therapy services.[2]

[1] Act § 1832(a)(2)(C).

[2] *MBPM*, *supra* ch. 15, § 220.

Comprehensive Outpatient Rehabilitation Facility (CORF) services are also a benefit defined in section 1861(cc) of the Act.[3] CORFs primarily provide outpatient rehabilitation to Medicare beneficiaries who are injured, disabled, or recovering from illness. Generally, CORFs provide three core services consisting of physician services, physical therapy, and social or psychological services. As a separately-defined benefit, separate regulations govern CORF services. These regulations are found at 42 C.F.R. §§ 410.100 through 410.105. When handling claims for outpatient therapy furnished by a CORF, it is important to distinguish the therapy coverage requirements set forth in the CORF regulations from the general outpatient rehabilitation regulations found at 42 C.F.R. §§ 410.59 through 410.62. For instance, CORFs have different certification requirements. Medicare also does not cover maintenance therapy furnished by a CORF.

As noted above, this module is an overview of outpatient therapy as a whole. While outpatient physical therapy, occupational therapy, and speech-language pathology services are benefits that are distinctly defined as separate from therapy provided in a CORF, most of the guidance governing therapy is the same. The modalities used by physical therapists, occupational therapists, and speech-language pathologist are defined by the same LCDs and the coverage requirements for billing these modalities whether furnished by a CORF or in another setting are, in large part, the same. When applicable, the module will identify instances where the coverage requirements are notably different when furnished by a CORF.

I. Laws and Regulations Applicable to Outpatient Therapy Cases

Section 1832(a)(2)(C) of the Act provides that outpatient therapy services are a benefit available under Medicare Part B. Physical therapy, occupational therapy, and speech-language pathology services are defined in sections 1861(p), 1861(g), and 1861(ll) of the Act, respectively. The regulations governing Medicare coverage of therapy services are found at 42 C.F.R. §§ 410.59 through 410.62. Regulations related to Medicare payment for outpatient therapy services are found at 42 C.F.R. § 424.24.

Chapter 15, sections 220 through 230, of the *MBPM* provide additional guidance for outpatient therapy services.

[3] Act § 1832(a)(2)(E).

II. Conditions of Medicare Coverage and Payment

Medicare Coverage

The *MBPM* provides that outpatient therapy services are covered only when furnished in accordance with the following conditions:[4]

- Services are or were required because the individual needed therapy services;[5]
- A plan for furnishing such services has been established by a physician or NPP or by the therapist providing such services and is periodically reviewed by a physician or NPP;[6]
- Services are or were furnished while the individual is or was under the care of a physician;[7]

In certifying an outpatient plan of care for therapy, a physician or NPP is certifying that the above three conditions are met, pursuant to 42 C.F.R. § 424.24(c). Certification is required for coverage and payment of a therapy claim.

- Claims submitted for outpatient (and CORF) physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) services must contain the National Provider Identifier (NPI) of the certifying physician identified for a PT, OT, and SLP plan of care. This requirement is effective for claims with dates of service on or after October 1, 2012.[8]
- Claims submitted for outpatient (and CORF) PT, OT, and SLP services must contain the required functional reporting.[9]
- The patient functional limitation(s) reported on claims, as part of the functional reporting, must be consistent with the functional limitations identified as part of the therapy plan of care and expressed as part of the patient's long term goals.[10]

---

[4] *MBPM, supra,* ch. 15, § 220.1.

[5] 42 C.F.R. § 424.24(c); *MBPM, supra,* ch. 15, § 220.1.3.

[6] 42 C.F.R. § 424.24(c); *MBPM, supra,* ch. 15, § 220.1.2.

[7] 42 C.F.R. § 424.24(c); *MBPM, supra,* ch. 15, § 220.1.1.

[8] CMS, *Medicare Claims Processing Manual (MCPM) (Internet-Only Manual Publ'n 100-4)* ch. 5, § 10.3.

[9] 42 C.F.R. §§ 410.59, 410.60, 410.62, and 410.105; *MCPM, supra,* ch. 5, § 10.6.

[10] 42 C.F.R. §§ 410.61 and 410.105; *MCPM, supra,* ch. 5, § 10.6.

Note: "Functional reporting" is not required for claims with dates of service prior to January 1, 2013. The "functional reporting" requirement was promulgated by section 3005(g) of the Middle Class Tax Relief and Jobs Creation Act, which amended section 1833(g) of the Act to require a claims-based data collection system for outpatient therapy services, including PT, OT and SLP services. This requirement is now implemented by 42 C.F.R. sections 410.59, 410.60, 410.61, 410.62 and 410.105 (CORF).

When are Outpatient Therapy Services Considered Skilled and Necessary?

To meet the reasonable and necessary criteria for Medicare coverage, the following conditions must each be met:

- The services shall be considered under accepted standards of medical practice to be a specific and effective treatment for the patient's condition. Acceptable practices for therapy services are found in:
    - Medicare manuals—such as, the *MBPM*, *Medicare Claims Processing Manual (MCPM)*, and the *Medicare National Coverage Determinations Manual (MNCDM)*;[11]
    - Medicare Administrative Contractors' Local Coverage Determinations; and
    - Guidelines and literature of the professions of physical therapy, occupational therapy, and speech-language pathology.
- The services shall be of such a level of complexity and sophistication, or the condition of the patient shall be such, that the services required can be safely and effectively performed only by a therapist; or, in the case of physical therapy and occupational therapy, by or under the supervision of a therapist. Services that do not require the performance or supervision of a therapist are not skilled and are not considered reasonable or necessary therapy services, even if they are performed or supervised by a qualified professional. Medicare coverage does not turn on the presence or absence of a beneficiary's potential for improvement from therapy, but rather on the beneficiary's need for skilled care.
- If the contractor determines services furnished were of a type that could have been safely and effectively performed only by, or under the supervision of, such a qualified professional, the contractor shall presume that such services were properly supervised when required.

[11] CMS, *Medicare National Coverage Determinations Manual (MNCDM) (Internet-Only Manual Publ'n 100-03)*.

- While a beneficiary's particular medical condition is a valid factor in deciding if skilled therapy services are needed, a beneficiary's diagnosis or prognosis cannot be the sole factor in deciding that a service is or is not skilled. The key issue is whether the skills of a therapist are needed to treat the illness or injury, or whether the services can be carried out by nonskilled personnel.

- The amount, frequency, and duration of the services must be reasonable under accepted standards of practice. The contractor shall consult local professionals, or the state or national therapy associations, in the development of any utilization guidelines.[12]

Medicare Payment

For Medicare payment to be made for outpatient therapy services, a physician must certify that the services are necessary. Specifically, 42 C.F.R. section 424.24(c) requires a **physician's certification** statement that:

> (i) The individual needs, or needed, physical therapy or speech-language pathology services.
> (ii) The services were furnished while the individual was under the care of a physician, nurse practitioner, clinical nurse specialist, or physician assistant.
> (iii) The services were furnished under a plan of treatment that meets the requirements of 42 C.F.R. section 410.61.

Outpatient services are paid pursuant to the **Medicare Physician Fee Schedule (MPFS).** This is the method of payment for outpatient therapy services furnished by:

- CORFs;

- Outpatient physical therapy providers, *also known as outpatient rehabilitation facilities (ORFs)*;

- Hospitals (to outpatients and inpatients who are not in a covered Part A stay);

- Skilled nursing facilities (SNFs) (to residents not in a covered Part A stay and to nonresidents who receive outpatient rehabilitation services from the SNF); and

- Home health agencies (HHAs) (to individuals who are not homebound or otherwise are not receiving services under a home health plan of care (POC)).

NOTE: No provider or supplier other than the SNF will be paid for therapy services during the time the beneficiary is in a covered SNF Part A stay. Similarly, under the home health prospective

[12] *MBPM, supra* ch. 15, § 220.2(B).

payment system, HHAs are responsible for providing, either directly or under arrangements, all outpatient rehabilitation therapy services to beneficiaries receiving services under a home health POC. No other provider or supplier will be paid for these services during the time the beneficiary is in a covered Part A episode.

III. Maintenance v. Rehabilitation Therapy

Rehabilitative Therapy

Rehabilitative therapy includes services designed to address recovery or improvement in function and, when possible, restoration to a previous level of health and well-being. Therefore, evaluation, re-evaluation, and assessment documented in the Progress Report should describe objective measurements which, when compared, show improvements in function, decrease in severity, or rationalization for an optimistic outlook to justify continued treatment. If an individual's expected rehabilitation potential is insignificant in relation to the extent and duration of therapy services required to achieve such potential, rehabilitative therapy is not reasonable and necessary.[13]

Maintenance Therapy

Skilled therapy services that do not meet the criteria for rehabilitative therapy may be covered in certain circumstances as maintenance therapy under a maintenance program. The goal of a maintenance program would be, for example, to maintain functional status or to prevent or slow further deterioration in function. Coverage for skilled therapy services related to a reasonable and necessary maintenance program is available for the establishment or design of maintenance programs. Once a maintenance program is established, coverage of therapy services to carry out a maintenance program turns on the beneficiary's need for skilled care. A maintenance program can generally be performed by the beneficiary alone or with the assistance of a family member, caregiver, or unskilled personnel. In such situations, coverage is not provided. However, skilled therapy services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist are necessary for the performance of safe and effective services in a maintenance program.[14]

Jimmo v. Sebelius[15]

On January 24, 2013, the U. S. District Court for the District of Vermont approved a settlement agreement in the case of *Jimmo v. Sebelius*, involving skilled nursing and skilled therapy services in the SNF, home health, and outpatient therapy settings. The settlement agreement was intended to clarify that, when skilled services are required in order to provide care that is

[13] *MBPM, supra,* ch. 15, § 220.2(C).
[14] *MBPM, supra,* ch. 15, § 220.2(D).
[15] *Jimmo v. Sebelius*, No. 11-cv-17 (D. Vt. 2011).

reasonable and necessary to prevent or slow further deterioration, coverage cannot be denied based on the absence of potential for improvement or restoration. The settlement agreement did not expand coverage, but rather, clarified existing policy.

The following are some significant aspects of the manual clarifications published by CMS following the *Jimmo* settlement:

- No "Improvement Standard" is to be applied in determining Medicare coverage for maintenance claims in which skilled care is required.

  There are situations in which the patient's potential for improvement would be a reasonable criterion to consider, such as when the goal of treatment is to restore function. We note that this would always be the goal of treatment in the inpatient rehabilitation facility (IRF) setting, where skilled therapy must be reasonably expected to improve the patient's functional capacity or adaptation to impairments in order to be covered. However, Medicare has long recognized that there may be situations in the SNF, home health, and outpatient therapy settings where, even though no improvement is expected, skilled nursing and/or therapy services to prevent or slow a decline in condition are necessary because of the particular patient's special medical complications or the complexity of the needed services.

- The manual revisions clarify that a beneficiary's lack of restoration potential cannot, in itself, serve as the basis for denying coverage in this context, without regard to an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care, or services in question. Conversely, such coverage would not be available in a situation where the beneficiary's maintenance care needs can be addressed safely and effectively through the use of nonskilled personnel.

- Medicare has never supported the imposition of an "Improvement Standard" rule-of-thumb in determining whether skilled care is required to prevent or slow deterioration in a patient's condition. Thus, such coverage depends not on the beneficiary's restoration potential, but on whether skilled care is required, along with the underlying reasonableness and necessity of the services themselves. The manual revisions serve to reflect and articulate this basic principle more clearly. Therefore, denial notices for claims involving maintenance care in the SNF, HH, and OPT settings should contain an accurate summary of the reason for the determination, which should always be based on whether the beneficiary has a need for skilled care, rather than on a lack of improvement.[16]

[16] CMS, *Jimmo v. Sebelius Settlement Agreement Program Manual Clarifications Fact Sheet*, at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/snfpps/downloads/jimmo_fact_sheet2_022014_final.pdf.*

> **Note:** The maintenance program provisions outlined in chapter 15 of the *MBPM* do not apply to PT, OT, or SLP services furnished in a CORF because the statute specifies that CORF services are rehabilitative.

PRACTICE NOTE: Reasonable and necessary criteria and documentation criteria for specific outpatient therapy can also be found in the applicable local coverage determination (LCD).

IV. Documentation Requirements

The *MBPM*[17] provides a list of required documentation, which includes:

- **Evaluation and Plan of Care,** including the initial evaluation and any re-evaluations relevant to the episode being reviewed.

An outpatient therapy plan of treatment must be in writing and established by a qualified medical professional (physician, physical therapist, speech-language pathologist, occupational therapist, nurse practitioner, a clinical nurse specialist, or a physician assistant).[18] The plan **must be** established before treatment has begun.[19]

> **Note:** Only a physician may establish a plan of care in a CORF.

The contents of the plan must include, at a minimum:

- The diagnoses;
- The long term treatment goals; and
- The type, amount, duration, and frequency of therapy services.[20]

> **Note:** The functional impairments identified and expressed in the long term treatment goals must be consistent with those used in the claims-based functional reporting, using nonpayable G-codes and severity modifiers, for services furnished on or after January 1, 2013.

The plan may also include these optional elements: short term goals, goals and duration for the current episode of care, specific treatment interventions, procedures, modalities, or techniques and the amount of each.[21]

---

[17] *MBPM, supra,* ch. 15, § 220.3.

[18] Act § 1861(p)(2); 42 C.F.R. § 410.61(b)(2); *MBPM, supra* ch. 15, § 220.1.2.

[19] *MBPM, supra,* ch. 15, § 220.1.2(A).

[20] Act § 1861(p)(2); 42 C.F.R. §§ 424.24, 410.61(c), and 410.105(c) (for CORFs); *MBPM, supra,* ch. 15, § 220.1.2(B).

[21] *MBPM, supra,* ch. 15, § 220.1.2(B).

Changes made to the initial plan of care must be made in writing and signed by a qualified medical professional, including: a physician or NPP; a registered professional nurse or a staff physician, in accordance with oral orders from the physician; or the physical therapist, speech-language pathologist, or occupational therapist who is furnishing the services.[22] Additionally, the changes must be incorporated into the plan immediately.[23]

- **Certifications and Recertification**

Certifications are required for each interval of treatment based on the patient's needs, not to exceed 90 calendar days from the initial therapy treatment. Certifications are timely when the initial certification (or certification of a significantly modified plan of care) is dated within 30 calendar days of the initial treatment under that plan. Recertification is timely when dated during the duration of the initial plan of care or within 90 calendar days of the initial treatment under that plan, whichever is less.[24]

Practice Note: Certification is the physician's or NPP's approval of the plan of care. Certification requires a dated signature on the plan of care or some other document that indicates approval of the plan of care.[25] Signature means a legible identifier of any type acceptable according to policies in the *Medicare Program Integrity Manual* (*MPIM*), chapter 3, section 3.3.2.4[26] concerning signatures.[27] The signature and professional identity (e.g., MD, OTR/L) of the person who established the plan and the date it was established must be recorded with the plan. Establishing the plan is not the same as certifying the plan.[28]

Delayed Certification

It is not intended that needed therapy be stopped or denied when certification is delayed. The delayed certification of otherwise covered services should be accepted unless the contractor has reason to believe that there was no physician involved in the patient's care, or treatment did not meet the patient's need (and therefore, the certification was signed inappropriately).[29]

Lack of Certification

Denial of payment that is based on absence of certification is a **technical denial**, which means a statutory requirement has not been met. Limitation on Liability provisions of section 1879 of the Act do not apply to the technical denial.[30]

---

[22] 42 C.F.R. § 410.61(d)(1).

[23] 42 C.F.R. § 410.61(d)(2).

[24] *MBPM, supra,* ch. 15, § 220.1.3.

[25] *MBPM, supra,* ch. 15, § 220(A).

[26] CMS, *Medicare Program Integrity Manual (MPIM) (Internet-only Manual Publ'n 100-8)* ch. 3, § 3.3.2.4.

[27] *MBPM, supra,* ch. 15, § 220(A).

[28] *Id.* § 220.1.2.

[29] 42 C.F.R. § 424.11(d)(3); MBPM, *supra* ch. 15, § 220.1.3(D).

[30] *MBPM, supra,* ch. 15, § 220.1.3(E).

If the service was provided by a **supplier** (individual practitioners, such as physicians, NPPs, physical therapists, and occupational therapists who have Medicare provider numbers)[31] the beneficiary would be held liable. A **provider** (hospital, rural primary care hospital, SNF, HHA, hospice program, or CORF) is precluded from charging the beneficiary for services denied as a result of missing certification under 42 C.F.R. section 489.21.[32]

- **Progress Reports,** including discharge notes, if applicable.[33] The progress report provides justification for the medical necessity of treatment. The minimum progress report period shall be at least once every 10 treatment days.

Progress reports written by a clinician shall include:

1. Assessment of improvement, extent of progress (or lack thereof) toward each goal;
2. Plans for continuing treatment, reference to additional evaluation results, and/or treatment plan revisions should be documented in the clinician's progress report; and
3. Changes to long or short term goals, discharge or an updated plan of care that is sent to the physician or NPP for certification of the next interval of treatment.
4. Functional documentation is required as part of the progress report at the end of each progress reporting period. It is also required at the time of discharge on the discharge note or summary, as applicable.

- **Treatment notes** for each treatment day (may also serve as progress reports when the required information is included in the notes).[34]

Documentation of each treatment shall include the following required elements:

1. Date of treatment;
2. Identification of each specific intervention/modality provided and billed, for both timed and untimed codes;
3. Total timed code treatment minutes and total treatment time in minutes; and
4. Signature and professional identification of the qualified professional who furnished or supervised the services and a list of each person who contributed to the treatment.

Documentation of each treatment may also include the following optional elements:

1. Patient self-report;

[31] *Id.* § 220(A).
[32] *Id.* § 220.1.3.
[33] *Id.* § 220.3(D).
[34] *Id.* § 220.3(E).

2. Adverse reaction to intervention;
3. Communication/consultation with other providers;
4. Significant, unusual, or unexpected changes in clinical status; or
5. Equipment provided.

- A **separate justification statement** may be included either as a separate document or within the other documents if the provider/supplier wishes to assure the contractor understands their reasoning for services that are more extensive than is typical for the condition treated. A separate justification statement, however, is not required if the record justifies treatment without further explanation. [35]

V. Outpatient Therapy Cap

Medicare imposes a monetary limit (therapy cap) on the amount of covered outpatient therapy a Medicare beneficiary may receive each year. Section 4541(c) of the Balanced Budget Act (BBA) of 1997 required application of these financial limitations. Since the creation of therapy caps, Congress has enacted several moratoria on the limits for 2004 and 2005. Therapy caps were re-implemented on January 1, 2006.[36]

The therapy caps are determined on a calendar year (CY) basis. The outpatient therapy cap for CY 2017 is $1,980 for physical therapy and speech-language pathology services combined. There is another limit of $1,980 for occupational therapy services.[37] Medicare determines whether you reach the therapy cap by adding the amount Medicare has paid plus amounts paid by the beneficiary. Amounts paid by the beneficiary may include the Part B deductible ($183 per year for CY 2017) and coinsurance.

If a beneficiary reaches the yearly outpatient therapy cap and still requires therapy, Medicare will pay under an exception process if the therapy is found to be medically necessary. The therapist will have to provide medical documentation to demonstrate that continued outpatient therapy is required. To indicate this medical necessity, the therapy provider is required to add a KX modifier to the claim for each applicable service to attest that the above-the-cap therapy is medically necessary for the beneficiary.[38]

---

[35] *Id.* § 220.3(B).
[36] *MCPM, supra* ch. 5, §§ 10.2–10.3.
[37] Medicare.gov: The Official U.S. Government Site for Medicare, at http://www.medicare.gov/coverage/pt-and-ot-and-speech-language-pathology.html; *See* CMS: Therapy Services, at https://www.cms.gov/Medicare/Billing/TherapyServices/index.html?redirect=/TherapyServices/05_Annual_Therapy_Update.asp#TopOfPage.
[38] *MCPM, supra,* ch. 5, § 10.3.

As part of the exceptions process, there are additional limits (called "thresholds"). The threshold amounts for calendar year 2017 are $3,700 for physical therapy and speech-language pathology services combined, and $3,700 for occupational therapy.[39]

The above mentioned limitations apply to outpatient services and do not apply to SNF residents in a covered Part A stay, including swing beds. Rehabilitation services are included within the global Part A per diem payment that the SNF receives under the prospective payment system (PPS) for the covered stay.

Also, the limitations do not apply to any therapy services billed under the Home Health PPS, or by inpatient hospitals or the outpatient department of hospitals, including critical access hospitals.[40]

More information on the application of the outpatient therapy cap and exceptions to therapy caps can be found in the *MCPM*, chapter 5, sections 10.2–10.3.

Please note that the recent Bipartisan Budget Act of 2018 **repealed** therapy cap for services provided on or after January 1, 2018. CMS will be providing further guidance on how this provision affects coverage of outpatient therapy services in the future.

Therapy Caps and Liability Provisions

Prior to the implementation of the American Taxpayer Relief Act (ATRA) of 2012, Medicare claims for therapy service at or above therapy caps, that did not qualify for a coverage exception, were denied as a benefit category denial, and the beneficiary was financially liable for the non-covered services. Prior to ATRA, CMS encouraged suppliers and providers to issue a voluntary Advance Beneficiary Notice of Noncoverage (ABN), as a courtesy, to alert beneficiaries to potential financial liability; however, issuance of an ABN was not required for the beneficiary to be held financially liable.[41]

However, ATRA provisions amended section 1833(g)(5) of the Act to apply limitation on liability provisions pursuant to § 1879 of the Act, to beneficiaries receiving outpatient therapy services on or after January 1, 2013, when services are denied and the services provided are in excess of therapy cap amounts, and the services do not qualify for a therapy cap exception. The provider or supplier must issue a valid, mandatory ABN to the beneficiary before providing services above the cap when the therapy coverage exceptions process is not applicable (i.e., when continued therapy services are no longer medically necessary). Providers or suppliers must not issue an ABN to all beneficiaries who receive services that exceed the cap amount. A valid ABN allows the provider or supplier to charge the beneficiary if Medicare does not pay. If the ABN is

[39] CMS: Therapy Services, at https://www.cms.gov/Medicare/Billing/TherapyServices/index.html?redirect=/TherapyServices/05_Annual_Therapy_Update.asp#TopOfPage.
[40] *MCPM, supra*, ch. 5, § 10.3.
[41] *Id.* § 10.5.

not issued and Medicare does not pay the claim, the provider or supplier will be liable for the charges.[42]

Reference Material for *Jimmo v Sebelius*

- **http://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2013-12-19-Jimmo-vs-Sebelius.html**
- **http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R179BP.pdf**
- **http://cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8458.pdf**
- **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Jimmo-FactSheet.pdf**

Summary

Now that you have completed this lesson, you should be able to:

1. Identify the statutes and regulations applicable to outpatient therapy services.
2. Understand Medicare coverage and payment rules for outpatient therapy.
3. Understand the difference between maintenance therapy and rehabilitative therapy.
4. Identify the documentation requirements for outpatient therapy services.
5. Understand how the yearly outpatient therapy cap functions.

[42] *Id.* § 10.5.

Module 14:
Medicare Advantage (Part C)

After this session, you will be able to:

1. Understand the background of Medicare Part C;
2. Identify the types of issues found in Part C cases;
3. Recognize how the Part C appeals process differs from the appeals process for Parts A and B;
4. Understand the difference between an appeal and a grievance; and
5. Identify what a Part C Plan covers and what it does not cover.

Required Reading/Reference:

- ✓ Social Security Act (Act) §§ 1851, 1852
- ✓ 42 C.F.R. Part 422
- ✓ CMS, *Medicare Managed Care Manual (MMCM) (Internet-Only Manual Publ'n 100-16)*

Disclaimer: This module is only a general summary of Medicare's rules and regulations with respect to Medicare Part C. It is not a legal document.

Introduction – Background and Rationale

The Medicare Part C program was established by the Balanced Budget Act of 1997 (BBA). The Medicare Part C program allows public and private organizations to contract with the Centers for Medicare & Medicaid Services (CMS) to provide beneficiaries with Medicare Part A and B benefits. These benefits are furnished by the public and private organizations through a variety of health plan options approved by CMS.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) increased the choice of plans available for beneficiaries under Part C, including regional preferred provider organizations (RPPO) plans and special needs plans (SNPs). The MMA also established the Medicare prescription drug benefit (Part D) program, and amended the Part C program to allow (and, for organizations offering coordinated care plans, require) most Medicare Advantage (MA) plans to offer prescription drug coverage.

The program was again amended in 2010 by the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act; collectively referred to as the Affordable Care Act (ACA). The ACA provisions related to the Part C and Part D programs improved beneficiary protections and reformed MA payments.

Overview

MA plans are policy contracts issued by MA organizations (MAOs) that cover specific sets of health benefits offered at uniform premiums and uniform levels of cost-sharing to all Medicare beneficiaries who reside in plan service areas. MA plans are administered and run by private insurers that contract with Medicare to provide an individual with all of their basic Medicare Part A (excluding hospice care) and Part B benefits.[1] MA plans are offered by private companies that have been approved by Medicare. Individuals enrolled in MA plans are enrolled in the Medicare program and have Medicare rights and protections.

The Secretary of the Department of Health and Human Services (HHS) is required to establish standards, regulations, and rules for Medicare Part C that are consistent with existing standards and regulations governing Health Maintenance Organizations and competitive medical plans (CMPs).[2] The regulations established for Part C are found at 42 C.F.R. Part 422.

MAOs must be authorized by the Secretary. MAOs are public or private entities organized and licensed by a state as a risk-bearing entity (with the exception of provider-sponsor organizations receiving waivers) that are certified by CMS as meeting MA contract requirements.[3]

While MA plans must provide all basic benefits currently available under Medicare Parts A and B,[4] plans may impose different copayments and deductibles than under Parts A and B as long as the monthly premium and cost-sharing are actuarially equivalent to cost-sharing under traditional Medicare.[5] MA plans must also pass on to enrollees a percentage of any cost savings in the form of additional health benefits or reduced premiums.[6] MA plans may offer supplemental benefits for which a separate premium may be charged, but the separate premium may not vary among individuals within the plan and must not exceed certain actuarial and community rating requirements.[7] MA plans must accept eligible beneficiaries who elect that organization's plan during an open enrollment period, without restrictions.[8]

> **Practice Tip:** MA plans are required to clearly communicate to enrollees through the Evidence of Coverage (EOC) and Summary of Benefits the MA plan's service area, the benefits offered under the plan including premiums and cost-sharing, and information related to access of services.[9]
>
> Make sure the administrative record includes a copy of the EOC as described in the OMHA Case Processing Manual. OMHA adjudicators have a duty to create a

[1] 42 C.F.R. §§ 422.100(c)(1), 101(a).
[2] Act § 1856(b)(1)–(2); *see* Act § 1876.
[3] 42 C.F.R. § 422.2.
[4] Act § 1852(a); 42 C.F.R. § 422.101.
[5] Act § 1854(e)(4).
[6] 42 C.F.R. § 422.266(a).
[7] Act § 1852; 42 C.F.R. § 422.102.
[8] Act § 1851(g); 42 C.F.R. § 422.60(a)(1)-(2).
[9] 42 C.F.R. § 422.111.

complete record of the evidence.[10] The Medicare Appeals Council (Council) frequently remands cases to ALJs and attorney adjudicators because the record is missing plan documents such as the EOC.

Different MA plan options are available. MAOs may offer multiple types of plans which include:

- Coordinated Care Plans (HMOs and PPOs)
- Medicare Medical Savings Accounts (MSAs)
- Private Fee-for-Service Plans
- Religious Fraternal Benefit Society Plans
- Local and Regional MA Plans
- Specialized Medicare Advantage Plans for Special Needs Individuals
- Cost Plans

Eligibility

Eligible Persons

To be eligible for a MA plan, an individual must be entitled to benefits under Part A and enrolled in Medicare Part B.[11] To enroll in a MA plan, an individual must complete and sign an election form or complete a CMS-approved election method offered by the MAO.[12]

An individual cannot be denied enrollment in a MA plan due to a pre-existing condition, unless that individual has end-stage renal disease (ESRD).[13] Persons with ESRD are excluded, except an individual who develops ESRD while enrolled in a MA plan may continue to be enrolled in that plan.[14] Such an individual may also enroll in another MA plan if the ESRD beneficiary loses MA plan coverage when his or her plan terminates its contract with CMS or reduces its service area.[15] However, an individual with ESRD may elect an MA special needs plan as long as that plan has opted to enroll ESRD individuals.[16]

Persons Ineligible to Enroll

An individual who is considered Qualified Medicare Beneficiary, a Specified Low-Income Medicare Beneficiary, a Qualified Disabled and Working Individual, or are otherwise eligible for Medicaid and entitled to Medicare cost-sharing under a state Medicaid program, may not enroll in a MA MSA plan.[17] Federal Employee Health Benefit Plan (FEHBP) members must make sure that plan choices under consideration are those that have been certified by the Director of the

[10] 42 C.F.R. § 405.1042.
[11] Act § 18S1(a)(3)(A); 42 C.F.R. § 422.50(a)(1).
[12] 42 C.F.R. § 422.50(a)(S).
[13] Act § 1852(b)(1); 42 C.F.R. § 422.110.
[14] 42 C.F.R. § 422.50(a)(2).
[15] 42 C.F.R. § 422.50(a)(2)(ii).
[16] 42 C.F.R. §§ 422.50(a)(2)(iii), 422.2.
[17] Act § 1851(b)(3).

Office of Management and Budget to the Secretary and that the Office of Personnel Management has adopted policies that ensure the enrollment of FEHBP individuals in such plans will not result in increased expenditures for health benefits under FEHBP.[18] Similar rules may be applied to individuals eligible for health care from either the Veterans Administration or the Department of Defense.[19]

Coordination of Enrollment and Disenrollment

The enrollment and disenrollment of an individual in a MA plan is governed by the election of coverage under MA plans.[20] An individual may elect a different MA plan by filing the appropriate election with the MAO;[21] or submit a request for disenrollment to the MAO in the form and manner prescribed by CMS, or file the appropriate disenrollment form through other mechanisms as determined by CMS.[22] A disenrollment request is considered to have been made on the date the disenrollment request is received by the MAO.[23] The MAO must submit a disenrollment notice to CMS within time frames specified by CMS;[24] provide the enrollee with notice of disenrollment; include in the notice a statement explaining that the enrollee remains enrolled until the effective date of disenrollment and that until that date, neither the MAO nor CMS pays for services not provided or arranged for by the MA plan in which the enrollee is enrolled; and file and retain disenrollment request for the period specified in CMS instructions.[25]

Coverage of Benefits

As noted above, MA Plans must provide the benefits currently available under Medicare Parts A (excluding hospice care) and B.[26] Generally, rules that apply to coverage under Parts A and B also apply to MA plans.[27] However, MA Plans do have some discretion to ease such restrictions (e.g., MA plans may waive the three-day prior inpatient hospitalization eligibility requirement for coverage of SNF services).

MA plans are required to provide in-network Medicare-covered preventative benefits at zero cost-sharing.[28]

MA plans may not deny, limit, or condition the coverage or provision of benefits based on any health-status related factor nor can they design plan benefits in such a way that is likely to substantially discourage enrollment by certain individuals.[29]

---

[18] Act § 1851(b)(2)(A).
[19] Act § 1851(b)(2)(B).
[20] 42 C.F.R. § 422.62.
[21] 42 C.F.R. § 422.66(a)-(b).
[22] 42 C.F.R. § 422.66(b)(ii).
[23] 42 C.F.R. § 422.66(b)(2).
[24] 42 C.F.R. § 422.66(b)(3)(i).
[25] 42 C.F.R. § 422.66(b)(3)(i)-(iv).
[26] 42 C.F.R. § 422.100(c)(1), 101(a).
[27] *See* 42 C.F.R. § 422.101(b).
[28] 42 C.F.R. §§ 417.454(d), 422.100(k).
[29] 42 C.F.R. § 422.100(f)(2).

MA plans are not required to cover **hospice services**, which is a benefit available under Medicare Part A.[30] Medicare fee-for-service contractors are required by federal regulations to maintain payment responsibility for MA enrollees who elect hospice.[31] If an enrollee elects hospice, CMS makes payment directly to the hospice program and makes monthly payments to the MAO for additional benefits not provided by hospice care.[32]

An enrollee's out-of-pocket expenses for healthcare benefits depend on whether the plan charges a monthly premium, whether the plan has a yearly deductible, how much an individual pays for each visit or service (copayment or coinsurance), the type of health care services needed and how often, and whether network providers are used.

Most MA plans impose restrictions on enrollees' access to Medicare-covered services. MA plans generally have a prior-authorization process and may also specify a network of providers from whom enrollees may obtain services from. The MA plans may offer coverage for only those services provided "**in-network**" or impose higher out-of-pocket expenses for services provided "**out-of-network**."[33] While plans may specify the networks of providers from whom the enrollees may obtain services, such networks must be sufficient to provide adequate access to covered services to meet the needs of the population served.[34]

To provide "**adequate access to services,**" MAOs are sometimes required to cover services outside of their defined networks. MAOs must cover the following services, even if the services were not provided "in-network":

- **Specialty care.** MAOs must provide necessary specialty care or arrange for such specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's needs.[35] If an enrollee requires a very specialized covered service that is not provided by the physicians in the network, the plan must arrange for that service to be provided by a qualified non-contracted provider.[36]

- **Ambulance services**. MAOs are financially responsible for ambulance services, including when dispatched through 911, where other means of transportation would endanger the beneficiary's health.[37]

- **Emergency Services**. Emergency services are inpatient or outpatient services needed to evaluate or stabilize an emergency medical condition.[38] An

[30] 42 C.F.R. § 422.100(c)(1).
[31] 42 C.F.R. § 417.585.
[32] Act § 1853(h); 42 C.F.R. § 422.320(c).
[33] 42 C.F.R. § 422.112.
[34] 42 C.F.R. § 422.112(a).
[35] 42 C.F.R. § 422.112(a)(3); *See* 42 C.F.R. § 422.101(a).
[36] *MMCM, supra* ch. 4, § 110.1.1; 42 C.F.R. § 422.112(a)(3).
[37] 42 C.F.R. §§ 422.112(a)(9), 422.113(a).

emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention would result in serious jeopardy to the health of the individual; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part.[39]

- **Urgently needed services**. Urgently needed services are covered services that are not emergency services as defined above, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required as a result of an unforeseen illness, injury or condition; and it was not reasonable given the circumstances to obtain the service through the organization offering the MA plan.[40]

    - **Note:** In 2015, the definition of "urgently needed services" found at 42 C.F.R. § 422.113 was revised to remove the phrase "under extraordinary and unusual circumstances." The revision was made to ensure enrollees have access to out-of-network facilities in non-extraordinary circumstances; such as services furnished outside of the network's normal business hours. The comments in the final rule suggest that this change was made to encourage Part C plans to contract with clinics that operate 24 hours/day, 7 days/week to address the needs of enrollees who need care on weekends or after normal business hours.[41]

- **Post-Stabilization services**. MAOs may be financially liable for post-stabilization services provided outside of its network. Post-stabilization services are defined as covered services, related to an emergency medical condition that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under certain circumstances, required to improve or resolve the enrollee's condition.[42]

[38] 42 C.F.R. §§ 422.112(a)(9), 422.113(b)(1)(ii).
[39] 42 C.F.R. § 422.113(b)(1).
[40] 42 C.F.R. §§ 422.112(a)(9), 422.113(b)(1)(iii).
[41] 80 Fed. Reg. 7912, 7949 (Feb. 12, 2015).
[42] 42 C.F.R. § 422.113(c)(1).

Appeals and Grievances

MA appeal procedures include an internal grievance process and a formal appeal process with external review. The grievance and appeal processes are intended for different kinds of complaints. MAOs must ensure that all enrollees receive written information about the grievance and appeal procedures that are available to them.[43]

Grievances- *General*

Each MAO must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any MA plan it offers.[44] Grievance procedures are separate and distinct from appeals.[45] Appeals address concerns and disagreements with organizational determinations (whether an item, service, or procedure is covered).[46] Grievances go to issues about the quality of services received, time and location of services, and related matters.[47] Grievances are not reviewable by an ALJ or an attorney adjudicator.

In addition, the MA plan's grievance process is separate from the quality of care complaint filed with a Quality Improvement Organization (QIO), which address enrollees' written complaints about the quality of services received under the Medicare program.[48] For quality of care issues, the enrollee may file a written complaint with the MAO or the QIO, or both.[49] Complaints concerning quality of care are not reviewable by an ALJ or an attorney adjudicator.

Further, the MAO must have an established recordkeeping process for tracking records on all grievances received, both orally and in writing.[50] The record is to contain, at a minimum, the date of receipt of the grievance, the final disposition of the grievance, and the date that the MAO notified the enrollee of the disposition.[51]

Grievance Process

CMS defines a grievance as an issue that does not involve organization determinations and is any complaint or dispute, other than one that constitutes an organization determination, expressing dissatisfaction with any aspect of an MAO's or provider's operations, activities, or behavior regardless of whether remedial action is requested.[52]

---

[43] 42 C.F.R. § 422.562(a)(1).
[44] 42 C.F.R. § 422.564(a).
[45] *Compare* 42 C.F.R. § 422.564(b) *with* 42 C.F.R. § 422.566(b).
[46] 42 C.F.R. § 422.566(b).
[47] *See* 42 C.F.R. § 422.564(b).
[48] *See MCMM, supra,* ch. 13, § 30.1.1.
[49] 42 C.F.R. § 422.564(c); *See* Act § 1154 (for the functions of the QIO).
[50] 42 C.F.R. § 422.564(g).
[51] *Id.*
[52] 42 C.F.R. § 422.564(b).

The grievance process is designed to provide a remedy for MA enrollees who have concerns about things other than coverage of benefits. For example, a grievance might be brought concerning rudeness of staff members, inconvenience of facilities, location and hours of service, or receipt of membership materials. Every MAO is required to provide "meaningful procedures for timely resolution of grievances between enrollees and the organization."[53] Grievances also include disputes with "any other entity or individual through which the organization provides health care services."[54]

An enrollee may file a grievance with an MA plan either orally or in writing.[55] The grievance must be filed no later than 60 days after the event or incident that precipitates the grievance.[56] The MA plan must notify the enrollee of its decision as expeditiously as possible, based on health status, but no later than 30 days of receipt of grievance.[57] The MAO may extend the 30-day time frame by up to 14 days if the enrollee requests the extension, or if the MA organization justifies a need for additional information and documents how the delay is in the interest of the enrollee.[58] If the MAO extends the deadline, it must notify the enrollee in writing of the reasons for the delay.[59]

Grievances submitted in writing must be responded to in writing; grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.[60] Grievances related to quality of care, regardless of how filed, must be responded to in writing and must include a description of the enrollee's right to file a written complaint with the QIO.[61] In addition, the MA organization must cooperate with the QIO in resolving the complaint.[62]

Upon receiving a complaint, an MAO must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.[63]

Appeals-*General*

Unlike a grievance, which is a complaint or dispute about a MAO's or provider's operations, activities, or behavior, an appeal involves an organization determination.[64] Under the regulations, and appeal is defined as any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is

[53] 42 C.F.R. § 422.564(a).
[54] *Id.*
[55] 42 C.F.R. § 422.564(d)(1).
[56] 42 C.F.R. § 422.564(d)(2).
[57] 42 C.F.R. § 422.564(e)(1).
[58] 42 C.F.R. § 422.564(e)(2).
[59] *Id.*
[60] 42 C.F.R. § 422.564(e)(3)(i)-(ii).
[61] 42 C.F.R. § 422.564(e)(3)(iii).
[62] *Id.*
[63] 42 C.F.R. § 422.564(b).
[64] *See id.*

entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under 42 C.F.R. § 422.566(b).[65] These procedures include reconsiderations by the MAO, and reconsiderations by the independent review entities.[66]

MAO Determinations

Each MAO must have a procedure for making timely organization determinations regarding the benefits to which the enrollee is entitled under the MA plan, including such things as basic benefits, mandatory and optional supplemental benefits, and the amount, if any, the enrollee is to pay.[67]

An organization determination is any determination made by a MAO with respect to (1) payment for temporary out of the area renal dialysis services, emergency services, post-stabilization care or urgent care; (2) payment for any other health services furnished by a provider other than the MAO that the enrollee believes are covered under Medicare or if not covered under Medicare, should be furnished, arranged for, or reimbursed by the MA organization; (3) the MAO's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MAO; and (4) discontinuation or reduction of a service if the enrollee believes that continuation of the service is medically necessary; (5) the failure of the MAO to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or the provision of timely notice to an enrollee with respect to an adverse determination, such that the delay would adversely affect the health of the enrollee.[68]

Who Can Request an Organization Determination?

Individuals or entities who can request an organization determination are the enrollee (including his or her authorized representative); any provider that furnishes, or intends to furnish, services to the enrollee; or the legal representative of a deceased enrollee's estate).[69] An expedited organization determination, as explained below, can be requested by an enrollee (including his or her authorized representative) or a physician (regardless of whether the physician is affiliated with the MAO).[70]

Parties to an organization determination include the enrollee (including his or her representative) or an assignee of the enrollee (a physician or other service provider who waives any right to payment from the enrollee for that service) and the legal representative of a deceased enrollee's estate, as well as any provider or entity (other than the MAO) determined to

[65] 42 C.F.R. § 422.566.
[66] 42 C.F.R. §§ 422.578 and 422 592.
[67] 42 C.F.R. § 422.566(a).
[68] 42 C.F.R. § 422.566(b).
[69] 42 C.F.R. § 422.566(c)(1)(i)-(iii).
[70] 42 C.F.R. § 422.566 (c)(2)(i)-(ii).

have an appealable interest.[71] The effect of an organization determination is binding on all parties unless it is reconsidered or reopened.[72]

Reconsideration – *General*

Any party to an organization determination may request that the determination be reconsidered under the procedures described in 42 C.F.R. § 422.582 (requests for a standard reconsideration).[73] An enrollee or a physician (acting on behalf of an enrollee) can request an expedited reconsideration.[74]

Parties

The parties to the reconsideration are the parties to the organization determination, and any other provider or entity (other than the MAO) whose rights with respect to the organization determination may be affected by the reconsideration, as determined by the entity that conducts the reconsideration.[75] The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal to the MAO.[76]

Contractor Requirements

Persons not involved in the organization determination may hear an adverse MAO determination; medical necessity determinations must be made by a physician with expertise in the field of medicine that is appropriate for the service at issue, although the physician need not in all cases be of the same specialty or subspecialty as the treating physician.[77]

Review by Part C Independent Review Entity or QIO

When the MAO affirms, in whole or part, its adverse organization determinations, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS; the entity must meet contract deadlines for its decisions; the parties to a reconsideration are the same as those before the MAO's reconsideration, with the addition of the MAO.[78] When an MA Plan terminates pre-authorized coverage of an inpatient hospital admission or skilled nursing facility admission, or services furnished by a Home Health Agency, or a Comprehensive Outpatient Rehabilitation Facility, a special expedited review procedure applies. Expedited review requests filed timely (prior to discharge) bypass the MA Plan's reconsideration process, and the QIO, an Independent Review Entity (IRE), performs the review.

[71] 42 C.F.R. § 422.574.
[72] 42 C.F.R. § 422.576.
[73] 42 C.F.R. § 422.578.
[74] 42 C.F.R. § 422.584.
[75] 42 C.F.R. § 422.582(d).
[76] 42 C.F.R. § 422.582(e).
[77] 42 C.F.R. § 422.590(h).
[78] 42 C.F.R. § 422.592.

If an enrollee receives immediate QIO review (as provided in 42 C.F.R. § 422.622) of a determination of noncoverage of inpatient hospital care, the enrollee is not entitled to review of that issue by the MA organization.[79]

The independent entity is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to CMS.[80] The notice must state the specific reasons for the entity's decision in understandable language; and if the decision is adverse, it must inform the parties of their right to an ALJ hearing, if the amount in controversy is satisfied.[81]

A reconsidered determination is final and binding on all parties unless a party other than the MAO files a request for a hearing under the provisions for request for an ALJ or an attorney adjudicator review, or unless the reconsidered determination is revised.[82] If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MAO) who is dissatisfied with the reconsideration determination has a right to a hearing before an ALJ.[83]

OMHA

If the Part C IRE upholds a plan's adverse determination, the enrollee or enrollee's representative may appeal the IRE's decision by requesting review by an OMHA adjudicator.[84] The amount remaining in controversy, which can include any combination of Parts A and Part B services, is computed in accordance with section 42 C.F.R. § 405.1006.[85] The parties to a hearing are the parties to the reconsideration, the MAO, and any other person or entity whose rights with the respect to the reconsideration may be affected by the hearing, as determined by the ALJ or attorney adjudicator.[86]

If a request for an ALJ hearing clearly shows that the amount in controversy is less than the required jurisdictional amount, the ALJ dismisses the request; if the hearing is initiated, and the ALJ finds the amount in controversy is less than the required jurisdictional amount, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.[87]

Practice Tip: The MAOs are parties to a hearing;[88] MAOs must be sent the notice of hearing.[89]

---

[79] 42 C.F.R. § 422.562(c)(1).
[80] 42 C.F.R. § 422.594(a).
[81] 42 C.F.R. § 422.594(b).
[82] 42 C.F.R. § 422.596; *See* 42 C.F.R. § 422.616.
[83] 42 C.F.R. § 422.600(a).
[84] 42 C.F.R. § 422.600.
[85] 42 C.F.R. § 422.600(b).
[86] 42 C.F.R. § 422.602(c).
[87] 42 C.F.R. § 422.602(d).; *See* Act § 1869(b)(1)(E)(iii); 42 C.F.R. § 405.1006.
[88] 42 C.F.R. § 422.602(c).
[89] 42 C.F.R. § 405.1022(a).

Generally, the provisions of 42 C.F.R. Part 405 apply to MAOs. Unless otherwise stated in the 42 C.F.R. Part 422 Subpart M or § 422.562(d)(2) below, the provisions of 42 C.F.R. Part 405 to Part C appeals:[90]

(2) The following regulations in part 405 of this chapter, and any references thereto, specifically do not apply under this subpart:

(i) Section 405.950 (time frames for making a redetermination).

(ii) Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level).

(iii) Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council).

(iv) The option to request that an appeal be escalated from the OMHA level to the Council as provided in § 405.1100(b), and time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in § 405.1100(c) and (d).

(v) Section 405.1132 (request for escalation to Federal court).

(vi) Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

Attorney Adjudicators

A party, including the MA organization, may request judicial review of an ALJ's or attorney adjudicator's decision.[91]

Reopening and Revising Determinations and Decisions

An organization or reconsidered determination made by an MAO, a reconsidered determination made by the IRE, or the decision of an ALJ or an attorney adjudicator or of the Council may be reopened and revised by the entity that made the determination or decision.[92] The rules

[90] 42 C.F.R. § 422.562(d)(1)-(2).

[91] 42 C.F.R. § 422.612(a).

[92] 42 C.F.R. § 422.616.

governing reopening and revising determinations and decisions under Part C are the same as those for Part A and Part B reopenings.[93]

Liability

The financial liability protection provisions of section 1879 of the Act which apply to individuals enrolled in the Medicare Fee-For-Service (FFS) program (Parts A and B), **never** apply to Medicare Part C appeals.[94]

For cases under Medicare Parts A and B, section 1879 of the Act provides for Medicare payment when the beneficiary and provider did not know, and could not reasonably have been expected to know, that Medicare payment would be denied. However, for Part C cases, Medicare discharges its responsibility for paying for medical services when it makes payment to a MAO. The MAO then assumes responsibility for direct payment to a provider, which insulates the Medicare program from liability. Section 1879 of the Act was not intended to assign liability in cases where a MAO makes payment to a provider.[95]

Similarly, the waiver of overpayment recovery provisions of section 1870 of the Act applies when Medicare makes direct payment to a provider. But they do not apply when Medicare makes payment to the MAO. The MAO assumes responsibility for payment to the provider. The MAO, unlike an original Medicare contractor, is not acting as an agent of the Medicare program for purposes of sections 1870 or 1879 of the Act.

Enrollees of MAOs are entitled to the protections specified in 42 C.F.R. 422.504(g).[96]

[93] *See* 42 C.F.R. §§ 405.980–405.986, 422.616(a).
[94] HCFA Ruling 95-1; CMS, *Medicare Claims Processing Manual (MCPM) (Internet-Only Manual Publ'n 100-4)* ch. 30, § 10 (Feb. 2015).
[95] HCFA Ruling 95-1-13.
[96] 42 C.F.R § 422.132.

Module 15: Liability

After this session, you will be able to:

1. Better understand the issues surrounding liability determinations in Medicare appeals.
2. Better understand the role of notice within liability determinations in Medicare appeals.

Required Reading/Reference:

- ✓ Social Security Act (Act) § 1879
- ✓ Act § 1870
- ✓ HCFA Ruling 95-1
- ✓ CMS, *Medicare Claims Processing Manual* (*MCPM*) (*Internet-Only Manual Publ'n 100-04*), ch. 30

Introduction—Background and Rationale

The financial liability protections (FLP) provisions of the Social Security Act (the Act) protect beneficiaries, providers, physicians and other suppliers under certain circumstances from unexpected liability for charges associated with claims that Medicare does not pay.

The FLP provisions apply to individuals enrolled in the Medicare Fee-For-Service (FFS) program (Parts A and B), but are not applicable to Medicare Advantage (Part C) enrollees or to non-Medicare enrollees. The Advance Beneficiary Notices (ABNs) discussed here solely apply to individuals enrolled in the Medicare FFS program and are not to be used for Medicare Advantage enrollees or for non-Medicare enrollees.

Section 1879 Issues

Section 1879 of the Act provides a mechanism by which to limit a party's liability in certain situations. Section 1879 of the Act applies to Medicare claims that are denied pursuant to section 1862(a)(1)(A) of the Act because the items or services were not medically reasonable and necessary, but does not apply to claims that are denied because the technical requirements for Medicare coverage have not been met.

Section 1879 of the Act does not limit a Medicare provider's or supplier's liability if the provider or supplier knew or should have known that Medicare would not pay for the item or service at issue. Likewise, section 1879 of the Act does not limit a beneficiary's liability for the item or service if he or she knew or should have known that Medicare would not pay for the item or service. Neither the beneficiary, nor the provider or supplier, are liable if they did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service or item.

HCFA Ruling 95-1

The Health Care Financing Authority (HCFA) (CMS's predecessor) Ruling 95-1[1] contains a lengthy discussion of the indicia of knowledge that an item/service would likely not be covered by Medicare. Actual or constructive knowledge includes, but is not limited to:

1. A written notice from a Medicare Administrative Contractor (MAC), Quality Improvement Organization (QIO), or Qualified Independent Contractor (QIC) denying a previous claim for "same or comparably similar services";
2. A notice, manual, bulletin, written guideline, CMS directive, local coverage determination (LCD), or national coverage determination (NCD) discussing the service at issue;
3. A preadmission screening procedure conducted by a QIO.

Coverage Denials to Which the Limitation on Liability Applies

A coverage determination for an item or service must be made before there can be a decision with respect to whether Medicare payment may be made under the limitation on liability provision. Medical review entities, acting for the Secretary, such as Qualified Independent Contractors (QICs), Quality Improvement Organizations (QIOs), and Medicare Administrative Contractors (MACs) (formerly known as Fiscal Intermediaries and Carriers) (collectively Medicare Contractors) are authorized to make coverage determinations. *See MCPM, supra,* ch. 30, § 20.1.1.

Medicare Contractors must act in accordance with the Medicare statutes, regulations, national coverage instructions, accepted standards of medical practice, and CMS Rulings when making coverage determinations. The limitation on liability provisions of §1879 of the Act are applicable only to claims for items or services submitted by providers or suppliers that have taken assignment of a claim, which are not otherwise statutorily excluded, and are denied on the basis of §§ 1862(a)(1), 1862(a)(9) , 1879(e), or 1879(g) of the Act. *Id.*

For example:

- Services and items found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§ 1862(a)(1)(A)) of the Act);
- Pneumococcal vaccine and its administration, influenza vaccine and its administration, and hepatitis B vaccine and its administration, furnished to an individual at high or intermediate risk of contracting hepatitis B, that are not reasonable and necessary for the prevention of illness (§ 1862(a)(1)(B))

[1] HCFA Ruling 95-1 is available online at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads/hcfar951.pdf (last accessed on July 22, 2018).

of the Act);

- Services and items that, in the case of hospice care, are not reasonable and necessary for the palliation or management of terminal illness (§ 1862(a)(1)(C) of the Act);
- Clinical care services and items furnished with the concurrence of the Secretary and, with respect to research and experimentation conducted by, or under contract with, the Prospective Payment Assessment Commission or the Secretary, that are not reasonable and necessary to carry out the purposes of § 1886(e)(6) of the Act (which concerns identification of medically appropriate patterns of health resources use) (§ 1862(a)(1)(D)) of the Act);
- Services and items that, in the case of research conducted pursuant to § 1142 of the Act, are not reasonable and necessary to carry out the purposes of that section (which concerns research on outcomes of health care services and procedures) (§ 1862(a)(1)(E) of the Act);
- Screening mammography that is performed more frequently than is covered under § 1834(c)(2) of the Act or that is not conducted by a facility described in § 1834(c)(1)(B) of the Act and screening pap smears and screening pelvic exams performed more frequently than is provided for under § 1861(nn) of the Act (§ 1862(a)(1)(F) of the Act);
- Screening for glaucoma, which is performed more frequently than is provided under § 1861(uu);
- Prostate cancer screening tests (as defined in § 1861(oo)), which are performed more frequently than is covered under such section;
- Colorectal cancer screening tests, which are performed more frequently than is covered under § 1834(d);
- The frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation;
- Custodial care (§ 1862(a)(9) of the Act);
- Inpatient hospital services or extended care services if payment is denied solely because of an unintentional, inadvertent, or erroneous action that resulted in the beneficiary's transfer from a certified bed (one that does not meet the requirements of § 1861(e) or (j) of the Act) in a skilled nursing facility (SNF) or hospital (§ 1879(e) of the Act);
- Home health services determined to be noncovered because the beneficiary was not "homebound" or did not require "intermittent" skilled

> nursing care (as required by §§ 1814(a)(2)(C) and 1835(a)(2)(A) of the Act) on or after July 1, 1987 . . . (Act §1879(g)(1)) of the Act); and
>
> - Hospice care determined to be noncovered because the beneficiary was not "terminally ill" (as required by § 1861(dd)(3)(A) of the Act), as referenced by § 1879(g)(2) of the Act since BBA 1997.
>
> The limitation on liability protection may also apply if the [Medicare Contractor] reduces the level of payment through § 1862(a)(1) of the Act, when partially denying a more extensive service or item on the basis that it is not reasonable and necessary, even though Medicare pays for a less extensive service or item. A case in which the level of payment is reduced because a component of the service or item is in excess of the beneficiary's medical needs is a medical necessity partial denial of an unnecessary component of the covered item or service. "Excess component" means an item, feature, or service, and/or the extent of, number of, duration of, or expense for an item, feature, or service, which is in addition to, or is more extensive and/or more expensive than, the item or service which is reasonable and necessary under Medicare's coverage requirements.[2]

When Section 1879 Does NOT Apply

Medicare payment under the limitation on liability provision cannot be made when Medicare coverage is denied on any basis other than one of the provisions specified in *MCPM, supra,* ch. 30 § 20.1.1. *See CMS, Medicare Financial Management Manual (Internet-only Manual Publ'n 100-06),* ch. 3, (concerning liability for overpayments arising from other causes).

Section 1879(a) of the Act provides that Medicare payment will be made under the limitation on liability provision "when a determination is made that, by reason of § 1862(a)(1) or (9) or by reason of a coverage denial described in subsection (g) of the Act, payment may not be made under Part A or Part B" and the conditions described in § 1879(a)(2) of the Act are met. Thus, the statute explicitly restricts the application of the limitation on liability provision to cases that are decided on one of the statutory grounds specified in *MCPM, supra,* ch. 30, § 20.1.1. Therefore, the issue of medical necessity of a service or item will not need to be reached if it is determined that the service or item would not otherwise be covered under the statute.

The *MCPM, supra,* ch. 30, § 20.2, provides various examples, including:

> [W]hen a Part B claim is submitted for ambulance services, the first step in processing the claim is to determine whether the services meet the requirements of § 1861(s)(7) of the Act (that is, to ascertain that other methods of transportation

[2] *MCPM, supra* ch. 30, § 20.1.3.

> are contraindicated) and, therefore, may be covered services under the Medicare statute. If other methods of transportation are contraindicated (and all other regulatory criteria met), only then must the Medicare contractor determine if the ambulance services are "reasonable and necessary" under § 1862(a)(1). If other methods of transportation are not contraindicated, there is no reason for the Medicare contractor to make a medical necessity determination under § 1862(a)(1) because the services have already been determined to be not otherwise covered under the Medicare statute.

See MCPM, supra ch. 30, § 20.2.1 for a list of categorical denials and § 20.2.2 for a list of technical denials.

Knowledge

42 C.F.R. § 411.404 A beneficiary is considered to know that services received are not covered by Medicare if a written notice of noncoverage is given to the beneficiary or someone acting on the beneficiary's behalf.

HCFA Ruling 95-1 Interprets 42 C.F.R. § 411.404, in pertinent part, as establishing "a presumption that [the beneficiary] knew, or could reasonably have been expected to know, that Medicare payment for a service or item would be denied if advance written notice has been given either to the beneficiary or to someone acting on his or her behalf that the items or services were not covered." Additionally, HCFA Ruling 95-1 states that "a written notice of Medicare denial of payment must contain sufficient information to enable the beneficiary to understand the basis for the denial."[3]

42 C.F.R. § 411.406 Provides a listing of the criteria for determining if a provider, practitioner, or other supplier knew or should have known that Medicare would not pay for a service or item. Such knowledge may be based on experience, actual notice, or constructive notice, as established by: receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from MACs or QIOs, including notification of QIO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a QIO; *Federal Register* publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service; and, the provider, practitioner, or other supplier's knowledge of what are considered acceptable standards of practice by the local medical community. (42 C.F.R. § 411.406(e)(1)–(3); *See* HCFA Ruling 95-1-18 and 42 C.F.R. §§ 411.404 and 489.2).

***MCPM, supra* ch. 30, § 40.2.1** "Limitation on Liability—§1879(a)(2) of the Act requires that the beneficiary 'did not know, and could not reasonably have been expected to know, that payment would not be made* * *,' for items or services that are excluded from coverage for one of the reasons specified in §20.1, in order for the [limitation on liability] protection to be afforded. This

[3] *See* HCFA Ruling 95-1-16.

includes knowledge based on written notice having been provided to the beneficiary, as well as any other means from which it is determined that the beneficiary knew, or should have known, that payment would not be made."

***MCPM, supra* ch. 30, § 40.2.4** "The failure of any provider, practitioner, or other supplier to furnish to a beneficiary proper advance notice of the likelihood of denial is not sufficient to afford the beneficiary the protection of the limitation on liability provision if the contractor has proof that the beneficiary, nonetheless, had the requisite knowledge that the service would be denied. In any case in which the contractor has such evidence of prior knowledge on the beneficiary's part, the beneficiary must be held liable under the limitation on liability provision."

In many cases, providers and suppliers attempt to meet the "written notice" requirements described above through the use of an Advance Beneficiary Notice of Noncoverage (ABN). To be effective, an ABN must do more than simply state that payment might not be made. As noted in HCFA Ruling 95-1, "in accordance with § 411.404, a written notice of Medicare denial of payment must contain sufficient information to enable the beneficiary to understand the basis for the denial. Such notice constitutes sufficient documentation to show that the beneficiary had prior knowledge of the likelihood of denial of that claim, and of all future claims filed by on or behalf of the beneficiary that involve that same or a similar item or service. In addition, a written notice of Medicare denial of payment from a Medicare contractor for a previous claim for a particular service or item received by the beneficiary serves as prior written notice for all future claims filed by or on behalf of the beneficiary that involve that same or a similar service or item."[4]

The ABN must set out the reasons for probable denial with such specificity as to permit the beneficiary to be able to obtain evidence in rebuttal of the denial, and clearly give the beneficiary the option to elect to receive an item or service (for which they will be financially responsible) or to refuse the item or service and waive their right to appeal its denial.

NOTE: CMS-approved ABN forms are attached to final pages of this Module.

The *MCPM, supra* ch. 30, § 40.3 provides the ABN standards, and states:

> "The purpose of the ABN is to inform a Medicare beneficiary, before he or she receives specified items or services that otherwise might be paid for, that Medicare certainly or probably will not pay for them on that particular occasion. The ABN, also, allows the beneficiary to make an informed consumer decision whether or not to receive the items or services for which he or she may have to pay out of pocket or through other insurance. . . . A provider, practitioner, or supplier (that is, a qualified notifier as defined in §40.3.2), shall notify a beneficiary by means of timely (as defined in §40.3.3) and effective (as defined in §40.3.4) delivery of a proper notice document (as defined in §40.3.1) to a qualified recipient, viz., to the individual beneficiary or to the beneficiary's authorized

[4]HCFA Ruling 95-1-16 to 95-1-16.

representative (as defined in §40.3.5)."

Further, *MCPM, supra* ch. 30, § 40.3 provides that any ABN must meet the notice standards outlined therein in order to be acceptable evidence of the beneficiary's knowledge for the purposes of the FLP provisions, limitation on liability, and refund requirements, except as otherwise explicitly specified. An ABN which does not meet the standards outlined in *MCPM, supra* ch. 30, § 40.3 "may be ruled defective and may not serve to protect the interests of the notifier (provider, practitioner, or supplier). Any requirement to furnish a notice to a beneficiary is not met by delivery of a defective notice."

For example, pursuant to *MCPM, supra* ch. 30, § 40.3.1.2, regarding specificity, delivery, and receipt, "[a]n ABN must:

- Be written in lay language;
- Cite the particular items or services for which payment will be or is likely to be denied;
- Cite the notifier's reasons for believing Medicare payment will be or is likely to be denied. (See §40.3.8);
- Be delivered by a qualified notifier to the beneficiary (or to the beneficiary's authorized representative), before those items or services were furnished; and
- Be received by, and its contents must be comprehended by, the beneficiary (or authorized representative)."

Additionally, pursuant to *MCPM, supra* ch. 30, § 40.3.1.3, regarding defective notice, "[a]n ABN is not acceptable evidence if:

- The notice is unreadable, illegible, or otherwise incomprehensible, or the individual beneficiary (or authorized representative) is incapable of understanding the notice due to the particular circumstances (even if others may understand);
- The notice is given during any emergency, or the beneficiary is under great duress, or the beneficiary (or authorized representative) is, in any way, coerced or misled by the notifier, by the contents of the notice, and/or by the manner of delivery of the notice. (See §40.3.7);
- The notifier routinely gives this notice to all beneficiaries for whom the notifier furnishes items or services. (See §40.3.6);
- The notice is no more than a statement to the effect that there is a possibility that Medicare may not pay for the items or services. (See §40.3.6); or

- The notice was delivered to the beneficiary (or authorized representative) more than one year before the items or services are furnished."

As previously noted, *MCPM, supra* ch. 30, § 40.3 states a defective notice "may not serve to protect the interests of the notifier (provider, practitioner, or supplier). Any requirement to furnish a notice to a beneficiary is not met by delivery of a defective notice." In other words, a defective ABN cannot be used to shift financial liability for denied services/items from a provider/supplier to a beneficiary.

SNFABN vs. Notice of Medicare Noncoverage

A SNF must issue a liability notice to a Medicare beneficiary before the SNF provides an item or service that is usually paid for by Medicare, but may not be paid for in a particular instance because it is not medically reasonable and necessary, or if the service is custodial care. In January 2018, CMS is releasing a newly revised Skilled Nursing Facility Advance Beneficiary Notice of Non-Coverage (SNF ABN) along with newly developed instructions for form completion. CMS will be **discontinuing** the five SNF Denial Letters (attached at the end of this Module) and the Notice of Exclusion from Medicare Benefits – Skilled Nursing Facility (NEMB-SNF). **The revised SNF ABN will be mandatory for use on May 7, 2018**. For **Part A items and services**, SNFs must use the newly revised SNF ABN as the liability notice. For **Part B items and services**, SNFs must use the Advance Beneficiary Notice of Non-Coverage, Form CMS-R-131 (attached at the end of this Module). During the interim, SNFs may continue to use the old version of the SNF ABN, the Denial Letters, or the NEMB-SNF.[5]

SNFs are required to provide a Notice of Medicare Noncoverage (NOMNC) (sometimes referred to as a Generic Notice) to beneficiaries when their Medicare covered services are ending. The NOMNC informs beneficiaries on how to request an expedited determination from their Quality Improvement Organization (QIO) and gives beneficiaries the opportunity to request an expedited determination from a QIO. A Detailed Explanation of Noncoverage (DENC) is given only if a beneficiary requests an expedited determination. The DENC explains the specific reasons for the end of services.[6]

Common Arguments of the Parties

A. **Beneficiary-appellant**: Use of the NOMNC does not constitute adequate notice under section 1879(b) of the Act and, if the services are not covered by Medicare, then the Provider (rather than the beneficiary-appellant) is liable for the non-covered costs.

B. **Provider**: Use of the NOMNC does constitute adequate notice under section 1879(b) of

[5] "Fee for Service SNFABN," available at: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFS-SNF-ABN-.html (last accessed July 22, 2018).
[6] "Fee for Service Expedited Determination Notices," available at: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFS-Expedited-Determination-Notices.html (last accessed July 22, 2018).

the Act, and has been approved for use by CMS.

Beneficiary Knowledge

A. **42 C.F.R. § 411.404** - *See above for full description.*

B. **HCFA Ruling 95-1** - *See above for full description.*

C. ***MCPM, supra* ch. 30, § 40.2.1** - *See above for full description.*

D. ***MCPM, supra* ch. 30, § 40.2.4** - *See above for full description.*

SNFABN

Requirements (*MCPM, supra* ch. 30, § 70.1): There must be a lay language explanation as to why the services will be denied, a specification of the services that Medicare is expected not to pay, and the reason Medicare is unlikely to pay.

Generic Notice of Medicare Noncoverage

Requirements (42 C.F.R. § 405.1200—Notifying beneficiaries of provider service terminations):

1) The date that coverage of service ends;
2) The date that the beneficiary's financial liability for continued service begins;
3) A description of the Beneficiary's right to an expedited determination;
4) A beneficiary's right to receive the detailed information;
5) Any other information required by CMS; and
6) The date and signature of the beneficiary, or its authorized representative.

Sample Language for Liability Analysis for SNF Services:

The absence of two separate and distinct notices is not fatal to the liability analysis as long as the elements required by 42 C.F.R. sections 411.404 and 405.1200 are contained in the notice issued.

In this appeal, the notice contains the date of telephone delivery (_____), the date the beneficiary's financial liability may begin (_____), and a description of the beneficiary's right to an expedited determination. Further, the notice states that the care the beneficiary is receiving is unlikely to be reimbursed by Medicare and will have to be paid by the beneficiary if she continues to receive same. The notice states the reason Medicare will likely not reimburse the beneficiary is because the services the beneficiary requires are no longer skilled.

The beneficiary did not appear at the hearing. The entire record is devoid of any indication that the beneficiary did not know Medicare payment would not be made for services provided after

_____. The ***telephone/personal and written*** notices appear to comply with all of the requirements in 42 C.F.R. sections 411.404 and 405.1200. The provider issued the notice as both a Generic Notice and a SNFABN.

In this case, the provider was terminating skilled nursing services and issued valid notice to the beneficiary's representative that Medicare would no longer cover services after_____date. Thus, the beneficiary knew, or should have known, that payment would not be made, because the skilled services were not reasonable and necessary. The language in the notices and the telephone/personal contact establish sufficient proof that the beneficiary had the requisite knowledge that coverage for the services would be denied. When prior knowledge exists on the beneficiary's part, the beneficiary must be held liable under the limitation on liability provision. Since the beneficiary had prior knowledge that no Medicare payment would be made after _____, under 1879(b) of the Act, the beneficiary is liable for the non-covered charges.

The presence or absence of a SNFABN shifts liability.

ABN vs. Home Health Change of Care Notice

The type of notice given to a beneficiary may vary based on the type of service being provided. The type of notice may also vary based on when it is given. For example, an ABN is generally issued before any service/item is provided, whereas a NOMNC is generally issued when the provider believes services already being provided will no longer qualify for Medicare coverage.

More specifically, the ABN (form CMS-R-131), "is issued by providers (including independent laboratories, home health agencies, and hospices), physicians, practitioners, and suppliers to Original Medicare (fee for service) beneficiaries in situations where Medicare payment is expected to be denied. Guidelines for issuing the ABN are published in the Medicare Claims Processing Manual, Chapter 30, Section 50."[7]

Additionally, home health agencies (HHAs) are responsible for issuing the following beneficiary rights and protections notices to Original Medicare (fee for service) beneficiaries when notice is required:[8]

- Home Health Change of Care Notice (HHCCN)
- Advance Beneficiary Notice of Noncoverage (ABN)
- Notice of Medicare Noncoverage (NOMNC)
- Detailed Explanation of Noncoverage (DENC)

Effective December 9, 2013, the Home Health Advance Beneficiary Notice (HHABN), Form CMS-

[7] "Fee for Service ABN," available at: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html (last accessed July 22, 2018).
[8] "Fee for Service HHCCN," available at: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/HHCCN.html (last accessed July 22, 2018).

R-296, is no longer used and has been replaced with the ABN, Form CMS-R-131 and the HHCCN, Form CMS-10280. The table below gives a brief description of situations requiring notice and lists which notice to use for each situation.

Note: HHABNs that were issued prior to December 9, 2013 for ongoing, repetitive services will remain in effect for the time period indicated on the notice, up to one calendar year from the date of issuance. Please note that, like the HHABN, the ABN is effective for up to one year and must be issued annually for ongoing, repetitive services when notice is required.

HHAs must provide notice:	**Use:**	**Instead of:**
prior to providing an item or service that is usually paid for by Medicare but may not be paid for in this particular case because: • it is not considered medically reasonable and necessary; • the care is custodial; • the individual is not confined to the home; or • the individual does not need intermittent skilled nursing care.	ABN (CMS-R-131)	HHABN Option Box 1
prior to the HHA reducing or discontinuing care listed in the beneficiary's plan of care (POC) for reasons specific to the HHA on that occasion.	HHCCN (CMS-10280)	HHABN Option Box 2
prior to the HHA reducing or discontinuing Medicare covered care listed in the POC because of a physician ordered change in the plan of care or a lack of orders to continue the care.	HHCCN (CMS- 10280)	HHABN Option Box 3

The 1879 Decision Tree

(1) Was the item(s)/service(s) denied as not "reasonable and necessary" and related to one of the following?

- ❑ The diagnosis or treatment of an illness or injury [§1862(a)(1)(A)];
- ❑ Improvement of the function of a malformed body member [§1862(a)(1)(A)];
- ❑ The prevention of illness [§1862(a)(1)(B)];
- ❑ In a hospice, the palliation or management of a terminal illness [§1862(a)(1)(C)];
- ❑ The conduct of a clinical research study [§1862(a)(1)(D)];
- ❑ The conduct of a health service research study [§1862(a)(1)(D)].

YES Go to (7) **NO Go to (2)**

(2) Were the denied services home health care?

YES Was the beneficiary homebound?

- **YES** Were skilled nursing services "intermittent" (or not provided)?
  - **YES Go to (6)**
  - **NO Go to (7)**
- **NO Go to (7)**

NO Go to (3)

(3) Were the services denied as "custodial care"?

YES Were the services hospice care?

- **YES Go to (4)**
- **NO Go to (7)**

NO Go to (4)

(4) Were the denied services hospice care?

YES Was the beneficiary terminally ill?

- **YES Go to (6)**
- **NO Go to (7)**

NO Go to (5)

(5) Did the beneficiary receive any of the following items or services more frequently than indicated, or earlier than they should be provided?

- ❑ Screening mammograms, pap smears, pelvic exams, or glaucoma tests [§1862(a)(1)(F)];
- ❑ Prostate cancer screening exams [§1862(a)(1)(G)];
- ❑ Colorectal cancer screening exams [§1862(a)(1)(H)];
- ❑ Home health services (frequency or duration) [§1862(a)(1)(I)];
- ❑ Drugs/Biologicals purchased under a contract not approved under HHS competitive bidding process [§1862(a)(1)(J)];
- ❑ Initial Part B preventative physical exam [§1862(a)(1)(K)];
- ❑ Cardiovascular screening blood tests [§1862(a)(1)(L)];
- ❑ Diabetes screening blood tests [§1862(a)(1)(M)].

YES Go to (7) **NO Go to (6)**

(6) STOP!!! § 1879 IS NOT A FACTOR IN THE DECISION.

(7) YES, you must consider § 1879 in your decision.

The next step is to determine who knew what. Here is one approach:

Did *either* the beneficiary or the provider know that payment would not be made under either Part A or Part B?

YES Was the provider (or the provider's designee) the only one who knew?

- **YES** Did the provider give the beneficiary an effective ABN which stated payment probably would not be made?
  - **YES** Payment should not be made. The provider has a right to collect from the beneficiary for the cost of the items/services furnished
  - **NO** Payment should not be made, and the provider should reimburse the beneficiary for any advance payment for the items/services
- **NO** This means the beneficiary knew that payment would not be made under Part A or Part B. The beneficiary is not entitled to payment, and the provider is entitled to collect from the beneficiary

NO *Should* either the beneficiary or the provider (or the provider's designee)) *have known* that payment would not be made under either Part A or Part B?

- **YES** Was the provider (or the provider's designee) the only one who should have known?
  - **YES** Did the provider give the beneficiary an effective ABN which stated payment probably would not be made?
    - **YES** Payment should not be made. The provider has a right to collect from the beneficiary.
    - **NO** Payment should not be made, and the provider should reimburse the beneficiary for any advance payment.
  - **NO** This means the beneficiary should have known that payment would not be made under Part A or Part B. The beneficiary is not entitled to payment, and the provider is entitled to collect from the beneficiary.
- **NO** Payment *may* be made
  - ❖ If payment IS made, then it is as if none of the foregoing limitations, exclusions and coverage denials applied to the claim [*see* § 1879(a)(2)].
  - ❖ Where the provider is a physician, it does not matter whether he does or does not "accept assignment;" i.e., agrees to be paid according to the Medicare fee schedule. (42 C.F.R. § 411.408 & § 1842(l)(1)(C) of the Social Security Act).

IMPORTANT! If payment is denied for any item or service NOT considered in this decision tree, § 1879 of the Act DOES NOT APPLY and cannot be used to limit the liability of the parties.

Section 1870 Issues

A. OMHA Template, Sample Language

"Section 1870 of the Social Security Act applies to Medicare claims denied as part of an overpayment and provides, in part, as follows:

(b) Where— (1) more than the correct amount is paid under this title to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider of services or other person, or (B) that such provider of services or other person was without fault with respect to the payment of such excess over the correct amount, . . .

(c) There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1814(e)) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) would defeat the purposes of title II or title XVIII or would be against equity and good conscience. . . ."

B. Context of an Overpayment

1. Generally

- Claim initially submitted to contractor and paid.
- Claim re-opened.
- Claim determined to have been covered in error.

2. OMHA Level

- Adjudicator determines the claim was improperly covered.
- Adjudicator determines the claim is not reimbursable under section 1879 of the Act.
- Adjudicator determines the claim was overpaid.
- Adjudicator determines whether the appellant was "without fault" in creating overpayment under section 1870 of the Act.

Interplay of § 1870 with § 1879

How It Fits Together

There must first be a substantive determination on the merits as to whether the services provided to the beneficiary meet the coverage provisions of the Act and were otherwise medically

reasonable and necessary under section 1862(a)(1) of the Act. If the services at issue are not covered because they did not fall under a benefit category or were otherwise excluded, did not meet technical requirements for coverage, or were not medically reasonable and necessary, the next step of analysis is application of the provisions of section 1879 and/or 1870, as applicable, based on the reason for denying the services at issue.

Sample Decision #1 - **Council Docket No. M-11-318 (Feb. 14, 2011)**

ALJ erred in waiving the overpayment recovery without first determining it existed, using section 1870(c) of the Act instead of section 1870(b) of the Act, and failing to apply section 1879 of the Act, to follow manual guidance, and to apply the three-year period in section 1870(b) of the Act as a rebuttable presumption.

". . . the Council finds that the ALJ erred in applying section 1870 without first having made determinations concerning whether the services at issue were actually covered and, thus, not overpaid at all. In the event that the ALJ found that some or all of the claims were overpaid on the merits, he should have applied the provisions of sections 1879 and 1870, as applicable, to first determine the liability of the appellant and beneficiaries, as applicable, and then determine whether any portion of the overpayment may be waived. This conclusion is compelled not just by the provisions of Medicare manuals, as the appellant suggests, but by the plain language of the Act and regulations. The circumstances that cause an overpayment, if any, including consideration of liability under section 1879, must be determined first before considering waiver of recovery of an overpayment under section 1870(b) of the Act. This consideration is integral to determining whether there is 'evidence to the contrary,' which rebuts the presumption of without fault applied here by the ALJ." (M-11-318 at 6–7).

Section 1870(c) of the Act is only for the beneficiary.

". . . to the extent that the ALJ reached section 1870, the ALJ erred by referring, although implicitly, to section 1870(c) of the Act in support of waiving the overpayment. The appellant in this case was a provider of services, not an individual beneficiary. Thus, only section 1870(b), and not section 1870(c), was applicable to determining the provider's responsibility, if any, for the overpayment." (M-11-318 at 7).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

ORDER OF MEDICARE APPEALS COUNCIL
REMANDING CASE TO ADMINISTRATIVE LAW JUDGE
Docket Number: M-11-318

In the case of	**Claim for**
Charles , O.D. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
Multiple (see attached) (Beneficiary)	Multiple (see attached) (HIC Number)
(Contractor)	1-525 (ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated September 20, 2010, because there is an error of law material to the outcome of the claim. This case arose as a result of an overpayment determination regarding ophthalmology services provided to multiple beneficiaries over multiple dates of service in 2002 (see attached).[1] The ALJ determined that the provider was without fault in causing the overpayment under section 1870 of the Social Security Act (Act). Consequently, the ALJ held that a review of the individual claims in the sample was not necessary to the determination of an overpayment since the appellant's entitlement to a waiver of recovery under section 1870 of the Act was dispositive.

The Council has carefully considered the record before the ALJ as well as the Centers for Medicare & Medicaid Services (CMS) memorandum and the appellant's response, which have been entered into the record as Exhibit (Exh.) MAC-1 and Exh. MAC-2, respectively. For the reasons set forth below, the Council

[1] The Council has attached a copy of the beneficiary list to this decision with the names, HIC numbers, and dates of service for each of the claims at issue.

hereby vacates the hearing decision and remands this case to an ALJ for further proceedings, including a new decision. *See* 42 C.F.R. § 405.1110(d).

BACKGROUND

The appellant submitted claims to Medicare for ophthalmology services (dacryocystorhinostomy (CPT[2] code 68720), ophthalmological services (CPT codes 92004, 92012, 92014), and ophthalmoscopy (CPT codes 92225 and 92226) he provided to nursing home residents in 2002. On April 21, 2003, and July 8, 2003, the CMS program safeguard contractor (PSC), notified the appellant it was conducting a review of these previously paid services. Exh. 1 at 146, 150. On October 23, 2003, the PSC completed its medical review and determined a projected overpayment amount of $289,779. *Id.* at 136-145, 134-135.

By letter dated September 26, 2008, the PSC issued an initial determination of overpayment in which it explained that the PSC's "review of 55 claim[s] found that 55 were fully or partially denied resulting in a 100% error rate. The 55 claims (the 'sample') reviewed were randomly selected from a total of 3,726 (the 'universe')." *Id.* at 130. The letter further stated that the projected overpayment was "based on the lower limit of the one-sided 90% confidence interval." *Id.* According to the October 23, 2003, Post-Pay Medical Review Summary, the audit was initiated "as a result of a review to determine top billing providers with specialty 41. Dr. was number two on the list. An SRS was requested after a cursory review, of limited records, revealed several aberrancies."[3] *Id.* at 136. Among the examples of aberrancies were:

- though Dr. includes a chief complaint on the resident documentation, the services he provides, as reflected in the documentation, cannot be distinguished from a routine eye exam;

[2] The Centers for Medicare and Medicaid Services (CMS) established the Healthcare Common Procedure Coding System (HCPCS) to ensure that Medicare claims are processed in an orderly and consistent manner. The HCPCS is based upon the American Medical Association's (AMA) Physicians' Current Procedural Terminology, Fourth Edition (CPT-4). Medicare Claims Processing Manual (MCPM), (CMS Pub. 100-04), Ch. 23, § 20. In this case, the Council has provided the CPT codes for the services provided unless otherwise specified.

[3] We presume that "SRS" is an abbreviation for a statistically valid random sample.

- the majority of the patients examined did not require treatment of any kind. The medical necessity for billing these high level ophthalmological codes is suspect;

- for established patients, the requirement that a new complication, either a new diagnosis or management problem be identified was never met; and

- all of the beneficiaries were examined in a nursing facility (POS 32), however the claims were submitted with POS 11, indicating physician office.

Id. at 139.

On October 27, 2008, the contractor, , requested a refund of the overpayment. *Id.* at 125. The appellant requested a redetermination on November 20, 2008. *Id.* at 119-122. On July 31, 2009, the contractor upheld the overpayment, finding that the services at issue were not covered by Medicare and that the PSC's assessment of the overpayment was correct. *Id.* at 114. Accompanying the redetermination decision was a document titled, that, despite the title, mostly addresses the appellant's arguments regarding the reopening and waiver under section 1870 of the Act. *Id.* at 114-117.

The appellant requested a reconsideration and on November 3, 2009, the Qualified Independent Contractor (QIC) issued a partially favorable decision, determining that some services were payable, but at a lower level of service. *Id.* at 12-31. The QIC denied some services because the documentation did not meet the local medical review policy (LMRP) requirements or because the appellant had not furnished documentation demonstrating that the services were medically necessary or performed as billed. *Id.* Further, the QIC found that the PSC was authorized to reopen the claims at issue, records from the PSC "contained all the elements to perform a valid statistical overpayment calculation," and the appellant was liable under sections 1879 and 1870 of the Act. *Id.*

In its request for an ALJ hearing, the appellant contended that the reopening of claims by TriCenturion was prohibited and that, because the recoupment occurred more than the third calendar

year after the year of payment, the appellant was deemed to be without fault. *Id.* at 1-11. The appellant also furnished a summary sheet for each patient identifying the dates of service, CPT code billed, the chief complaint, diagnosis, treatment and standard of care for follow-up. *Id.* at 10 (citing Tab 4 in documentation submitted to the ALJ).

The ALJ held a hearing on July 19, 2010, at which the appellant was represented by counsel. Dec. at 1. The ALJ determined that the contractor's decision to reopen is final and not subject to review. *Id.* at 5. The ALJ noted that the audit began on April 21, 2003, when the PSC informed the appellant that it was reviewing claims for services provided in 2002, and that the PSC completed its review on October 23, 2003, but did not notify the appellant of its findings until September 26, 2008. *Id.* The ALJ found this fact "instrumental, and ultimately dispositive, of this appeal because special rules apply when an overpayment is 'discovered' subsequent to the third year following the year in which notice was sent that the amount was paid." *Id.* at 6.

The ALJ found that the QIC incorrectly "entangled the Act's section 1879 standard for fault with the section 1870 standard for fault." Unlike the "presumed knowledge" standard of section 1879, analysis under section 1870 inquires "whether the provider made full disclosure of all material facts and whether . . . it had a reasonable basis for assuming that the payment was correct." The ALJ faulted both the PSC and the QIC for not addressing this issue sufficiently. Regardless, he determined:

> the documentation present in the record on appeal is insufficient to substantiate the conclusion that the provider was at fault in causing the overpayment, nor does it rise to the level of evidence of fault, which is required under a § 1870 analysis. Consequently, even if an individual review of the claims at issue resulted in an overpayment determination, the provisions of § 1870 shield the appellant and the beneficiaries from liability for the overpayment. Therefore, an analysis of the individual claims in the sample is not necessary to the determination since the appellant's entitlement to a waiver of liability under § 1870 of the Social Security Act is dispositive of this appeal.

Id.

CMS referred the ALJ's decision for Council review. 42 C.F.R. § 405.1110(b). CMS' position is that the ALJ erred in waiving recoupment under section 1870 of the Act without making a decision on the merits to determine whether an overpayment exists. Exh. MAC-1 at 7-9. Specifically, CMS asserts that an analysis regarding whether a provider is without fault in causing an overpayment necessarily depends on whether an overpayment exists and the circumstances under which the overpayment occurred. *Id.* at 8-9 (noting that the PSC identified multiple reasons for denial that were not addressed by the ALJ; citing Medicare Financial Management Manual (MFMM), (CMS Pub. 100-06), Ch. 3, §§ 70, 70.3)). Further, CMS contends that the ALJ erred in providing an insufficient notice of hearing to the parties that did not meet the requirements set forth in 42 C.F.R. § 405.1022(b). *Id.* at 9-10. Finally, CMS asserts that the ALJ erred to the extent that he relied upon "concerns of equity and good conscience" as a basis for waiving recoupment because that phrase derives from section 1870(c) of the Act, which is not applicable in this case. *Id.* at 9.

The appellant responded to CMS' referral to the Council. The appellant asserts that the ALJ properly waived recoupment under section 1870 of the Act and that the sections of the MFMM relied upon by CMS are not binding on an ALJ or the Council. Exh. MAC-2 at 1-3 (citing 42 C.F.R. §§ 405.1062(a), 405.1062(b); DAB No. 1824 (2002); (2009)). The appellant also contends that because considerations of "equity and good conscience" were not determinative, there is no express or implied reference to section 1870(c) of the Act. *Id.* at 4. Finally, the appellant contends that the ALJ provided notice of the April 26, 2010, hearing in accordance with 42 C.F.R. § 405.1022(b) because participation by the PSC was not required and the AdQIC had notice of the issues to be presented at the hearing. *Id.*

DISCUSSION

The Council has limited its review of the ALJ's action to those exceptions raised by CMS. 42 C.F.R. § 405.1110(c)(2). The Council has determined that remand is appropriate so that the ALJ can address the merits of the underlying appeal prior to determining whether the appellant was without fault in causing the overpayment. *See* 42 C.F.R. §§ 405.1110(d), 405.1126(a).

The ALJ made no substantive determinations on the merits of the claims at issue, reasoning, incorrectly, that such a determination was obviated by the waiver provisions at section 1870(b) of the Act. *See* Dec. at 5-7. The Council finds, however, that the ALJ should have first determined whether services provided to the beneficiaries in each case met the coverage provisions of the Act and were otherwise medically reasonable and necessary under section 1862(a)(1) of the Act. If the ALJ determined that the services at issue were not covered because they did not fall under a benefit category or were otherwise excluded, did not meet technical requirements for coverage, or were not medically reasonable and necessary, his next step of analysis should have been to apply the provisions of sections 1879, 1870, or both, as applicable, based on the reason for denying the services at issue.

Under section 1879, if applicable to the reason the claim was determined to be overpaid, an adjudicator determines whether payment may be possible, or liability limited, (despite findings of non-coverage) on the grounds that neither the provider nor beneficiary knew or could reasonably have been expected to know that the services would not be covered because they are found not medically reasonable and necessary. Only after these analyses are made concerning those claims that were denied for reasons that invoke section 1879 should the ALJ consider waiver of recovery under section 1870. In this regard, the QIC did not err in applying of section 1879 prior to that of section 1870(b). Exh. 1 at 28-30.

Thus, in summary, the Council finds that the ALJ erred in applying section 1870 without first having made determinations concerning whether the services at issue were actually covered and, thus, not overpaid at all. In the event that the ALJ found that some or all of the claims were overpaid on the merits, he should have applied the provisions of sections 1879 and 1870, as applicable, to first determine the liability of the appellant and beneficiaries, as applicable, and then determine whether any portion of the overpayment may be waived. This conclusion is compelled not just by the provisions of Medicare manuals, as the appellant suggests, but by the plain language of the Act and regulations. The circumstances that cause an overpayment, if any, including consideration of liability under section 1879, must be determined first before considering waiver of recovery of an overpayment under section 1870(b) of the Act. This

consideration is integral to determining whether there is "evidence to the contrary," which rebuts the presumption of without fault applied here by the ALJ.

Moreover, to the extent that the ALJ reached section 1870, the ALJ erred by referring, although implicitly, to section 1870(c) of the Act in support of waiving the overpayment. The appellant in this case was a provider of services, not an individual beneficiary. Thus, only section 1870(b), and not section 1870(c), was applicable to determining the provider's responsibility, if any, for the overpayment.

Finally, the general provisions of section 1870 of the Act and chapter 3 of the MFMM make it clear that the specific provisions of section 1870(b) establish only a *rebuttable presumption* that an appellant is without fault if more than three years since the year of payment on the claim have passed. There is no absolute bar to finding that an appellant is with fault or that recovery of an overpayment is appropriate *solely* on the basis of such passage of time. The guidelines of MFMM contemplate that "different rules apply" after the passage of the three-year period. The MFMM provides guidelines for determining whether fault has, in fact, occurred, regardless of whether fault is assessed within or beyond the three-year period. The ALJ erred in finding that the passage of time was "instrumental and ultimately dispositive" on this issue.

The appellant reasons that the MFMM does not compel either an ALJ or the Council to "conduct a complete step-by-step analysis that mirrors manual instructions to guide Medicare carrier and fiscal intermediary operations." Exh. MAC-2 at 3. *See* Exh. MAC-2 at 2 (citing 42 C.F.R. §§ 405.1062(a), 405.1062(b)). The appellant supports his assertion by referencing a 2002 Departmental Appeals Board (DAB) case, , as well as a 2009 Council decision, . *Id.* at 3. The Council disagrees with the appellant's reliance on these cases.

The Council is not persuaded by the appellant's assertion that the ALJ and the Council should not apply the sequential analysis in the MFMM in this case. First, was not a case decided by the Medicare Appeals Council, did not involve an overpayment determination, and is not dispositive on the issue of whether the Council should decline to give substantial

deference to CMS program guidance in this case.[4] In the language cited by the appellant, the DAB found that an "ALJ should [not] be required to make more findings than is necessary to support the remedies imposed."

The reasoning that an ALJ or the Council following CMS program guidance is akin to "mak[ing] more findings than is necessary to support the remedies imposed" is flawed. The applicable regulation states that an ALJ and the Council, while not bound by CMS program guidance, will "give substantial deference to these policies *if they are applicable to a particular case.*" 42 C.F.R. § 405.1062(a) (emphasis added). Further, if an ALJ or the Council declines to follow a policy in a particular case, the ALJ or Council must explain the reasons why the policy was not followed and the "decision to disregard such policy *applies only to the specific claim being considered and does not have precedential effect.*" 42 C.F.R. § 405.1062(b) (emphasis added). Therefore, if CMS program guidance is applicable in a particular case, which it is in this case, then an ALJ and the Council will give substantial deference to it or provide reasons for not doing so.[5] The fact that the DAB in concluded that an ALJ made unnecessary findings relating to the civil remedies at issue in that case is separate and apart from an ALJ or the Council deciding whether to follow CMS program guidance when it applies. Further, the ALJ in was not subject to Medicare appeals regulations set forth in 42 C.F.R. Part 405, Subpart I.

The Council also disagrees with the appellant's reliance on to support the proposition that the presumption of no fault based on the passage of time can be made once the ALJ determined that three years had passed and did not identify any evidence to rebut the presumption that the provider was not

---

[4] The title Departmental Appeals Board ("DAB") refers both to the Board Members (collectively the "Board") that the Secretary appoints and to the larger staff organization. The DAB provides impartial, independent review of disputed decisions in a wide range of Department programs under more than 60 statutory provisions. The DAB includes the Board itself (supported by the Appellate Division), Administrative Law Judges ("ALJs") (supported by the Civil Remedies Division), and the Medicare Appeals Council (supported by the Medicare Operations Division). Thus, the DAB has three adjudicatory divisions, each with its own set of judges and staff, as well as its own areas of jurisdiction. *See* http://www.hhs.gov/dab.

[5] In fact, the ALJ's decision reflects that the ALJ did consider and apply the MFFM guidelines, in part. *See*, Dec at n. 4-9 and accompanying text.

without fault in such instances. Exh. MAC-2 at 3. The Council determined in that case that the appellant was *not* without fault in causing the overpayment, largely because of factors enumerated in the MFMM. The Council notes that its decisions, like decisions of ALJs, are not precedent. Moreover, each decision is based on case-specific facts, which require an individual determination as to whether the Medicare medical necessity requirements are met.

For the reasons discussed above, it is necessary for the Council to remand the case to an ALJ for further proceedings. The ALJ shall hold a hearing (unless waived by the appellant) and will issue a decision discussing whether the Medicare Part B services provided to each beneficiary were covered and otherwise medically reasonable and necessary.[6] If applicable, the ALJ will then address the liability of the appellant and the beneficiaries[7] under section 1879 of the Act.

If the ALJ determines that some or all of the services are not covered and that payment may also not be made under section 1879 of the Act, the ALJ will then apply section 1870(b) of the Act. The ALJ will determine whether the appellant is without fault for the overpayment with regard to each claim. Additionally, the ALJ will consider the guidelines of the MFMM, chapter 3, sections 90 and 90.1 in determining whether the appellant is without fault for the overpayment.

---

[6] The Council finds that the notice of hearing was sufficient under 42 C.F.R. § 405.1022(b). The notice of hearing set out the specific issues to be addressed and was sent to the QIC. Exh. 2 at 1-5; 42 C.F.R. § 405.1022(c) (noting that

> The notice of hearing should be sent to all parties that filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination, and the QIC that issued the reconsideration, advising them of the proposed time and place of the hearing).

See also Medicare Program: Changes to the Medicare Claims Appeal Procedures; Final Rule, 74 Fed. Reg. 65296, 65322 (December 9, 2009) (to be codified at 42 C.F.R. part 405) (noting that "sending the notice of hearing to the QIC that processed the reconsideration provides adequate notice to CMS and its contractors of the pending ALJ hearing, and thus is not necessary to also send notice of the hearing to the contractor that issued the initial determination").

[7] Beneficiary liability is generally not an issue in multi-beneficiary provider audits. *See generally* 42 C.F.R. §§ 405.956(a)(2), 405.976(a)(2) and 405.1046(a).

The ALJ may take further action not inconsistent with this order.

MEDICARE APPEALS COUNCIL

Administrative Appeals Judge

Departmental Appeals Board

Date: FEB 14 2011

Section 1870(b)—"Without Fault"

Sample Decision #2 **- Council Docket No. M-11-257 (Feb. 4, 2011)**

In a case involving hospital services, the ALJ correctly determined there was an overpayment regarding the services at issue, but erred in waiving the appellant's liability for the overpayment.

Determining Fault

"Section 1870(b) of the Act does not define the meaning of the term 'without fault.' However, program guidance in the [Medicare Financial Management Manual (MFMM)] set forth the standards for determining whether a provider was 'without fault,' e.g., if it exercised reasonable care in billing and accepting Medicare payment. MFMM, ch. 3, § 90. A provider is considered not 'without fault' if, e.g., it did not submit documentation to substantiate that services billed were covered, or billed, or Medicare paid, for services the provider should have known were not covered. *Id.* at § 90.1. A provider should have known about a policy or rule if the policy or rule is in the provider manual or in the regulations. *Id.* Also, a provider's allegation that it was not at fault with respect to payment for noncovered services because it was not aware of coverage requirements is not considered a basis for finding it 'without fault' if one of several conditions is met. One such condition is if the provider billed, or Medicare paid for, services the provider should have known were not covered. *Id.* at § 90." (M-11-257 at 6).

"The ALJ upheld the overpayment determination because 'the circumstances and services provided did not require or rise to the level of an inpatient admission as [the beneficiary] could have been adequately treated on an outpatient level.' Dec. at 8. The ALJ's reason for upholding the overpayment, as quoted herein, is the very reason for which the appellant may be found not 'without fault' for the resulting overpayment. Pursuant to the laws, regulation and program guidance set out above, the appellant is deemed to have had at least constructive knowledge of the program coverage requirements. Knowledge of those requirements precludes a finding that the appellant was not 'without fault in incurring the overpayment.'" (M-11-257 at 6).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-257

In the case of **Claim for**

Hospital Insurance Benefits (Part A)

(Appellant)

(Beneficiary) (HIC Number)

1-55[illegible]

(Contractor) (ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) partially favorable decision dated September 15, 2010, because there is an error of law material to the outcome of the claim. *See* 42 C.F.R. § 405.1110. This case was before the ALJ as a result of an overpayment assessed against the appellant for hospital services provided to the beneficiary on December 1, 2003. The ALJ found that the appellant had received an overpayment, but concluded that Medicare may not recoup the overpayment.

The Council has considered the record that was before the ALJ and the November 8, 2010, memorandum of referral from the Centers for Medicare & Medicaid Services (CMS). The memorandum is entered into the record as Exh. MAC-1. The appellant hospital has not filed exceptions to the referral memorandum.

The Council reverses the ALJ's decision only on the issue of waiver of the appellant's liability for the overpayment under section 1870(b) of the Social Security Act (Act).

BACKGROUND

The appellant submitted a claim for Medicare reimbursement of inpatient hospital services provided to the beneficiary on December 1, 2003. Medicare reimbursed the claim on December 23, 2003. On November 28, 2007, , a Medicare

Recovery Audit Contractor (RAC), notified the appellant that it had been overpaid for this claim. Exh. 1 at 34-36. On redetermination, the Medicare contractor upheld the overpayment determination and found the appellant liable for the overpayment. *See* Exh. 1 at 29. On reconsideration, the Qualified Independent Contractor (QIC), too, upheld the overpayment and found the appellant liable for the overpayment. *Id.* at 7-11. The appellant requested a hearing before an ALJ.

Following a hearing on August 24, 2010, the ALJ determined that the appellant was overpaid for the services provided to the beneficiary. However, the ALJ concluded that both the appellant's and the beneficiary's liability would be waived under section 1870 of the Act. *Id.* at 9. The ALJ reasoned -

> There are special rules that apply when an overpayment is discovered subsequent to the third year following the year in which notice was sent that the amount was paid." *Medicare Financial Management Manual, Pub. 100-06, Chapter 3, Section 80.* In that circumstance, "the provider or beneficiary will be considered without fault unless there is evidence to the contrary," such as a pattern of billing errors. *Id.; See also, Medicare Program Integrity Manual, Pub. 100-08, Chapter 3, Section 3.2.* . . . In the absence of evidence rebutting the presumption that the provider and beneficiary are without fault, the overpayment cannot be recovered. *Medicare Financial Management Manual, Pub. 100-06, Chapter 3, Section 80. See also,* 42 C.F.R. § 405.350(c).
>
> In this case, Medicare paid the claims in 2004. The RAC did not notify appellant of the overpayment until 2008. Since the RAC identified the overpayment more than three calendar years after the 2004 payment was made, a presumption that Appellant is without fault does arise. However, the presumption is rebuttable. In this case, the RAC did not cite, nor did the undersigned find any reason that could be construed as a rebuttal of the presumption.

Dec. at 8-9.[1]

[1] Medicare paid the claim in 2003 and the RAC notified the appellant of the overpayment in 2007. The ALJ's error concerning the years of payment and the overpayment notice does not materially affect the analysis of the issue of waiver of liability in this case. Exh. MAC-1 at 5 n.1 and 7.

CMS's memorandum asks for the Council's own motion review only on the ALJ's conclusion on the waiver of the appellant's liability for the overpayment. 42 C.F.R. § 405.1110(c)(2). CMS argues that -

> The ALJ erred in waiving recovery of the overpayment without analyzing whether the Appellant is without fault based on relevant program criteria. To the extent the Appellant billed for services that it should have known were not covered based on actual or constructive knowledge of coverage requirements, the Appellant did not exercise reasonable care in billing for and accepting payment and therefore is not without fault in regard to the overpayment.

Exh. MAC-1 at 1-2.

AUTHORITIES

Section 1870(b) of the Act provides for waiver of recovery of an overpayment to a provider or supplier of services whenever that provider or supplier is without fault in incurring the overpayment. This section states that, "in the absence of evidence to the contrary," the provider shall "be deemed to be without fault if the Secretary's determination that more than such correct amount was paid was made subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid. . . ."

Chapter 3 of the Medicare Financial Management Manual (MFMM) establishes guidelines for the recovery of overpayments from providers:

> There are special rules that apply when an overpayment is discovered subsequent to the third year following the year in which notice was sent that the amount was paid. Ordinarily, the provider or beneficiary will be considered without fault unless there is evidence to the contrary. In the absence of evidence to the contrary, the [contractor] will not recover the determined overpayment. (One example of evidence to the contrary would be a pattern of billing errors.)

MFMM, Ch. 3 at § 80 (citing Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 3).

4

Section 90 of the MFMM addresses the "fault" provisions and provider liability. It states:

> A provider is liable for overpayments it received unless it is found to be without fault. The FI [fiscal intermediary] or carrier, as applicable, makes this determination.
>
> The FI or carrier considers a provider without fault if it exercised reasonable care in billing for, and accepting, the payment; i.e.,
>
> - It made full disclosure of all material facts; and
> - On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment, it promptly brought the question to the FI or carrier's attention.
>
> Normally, it will be clear from the circumstances whether the provider was without fault in causing the overpayment. Where it is not clear, the FI or carrier shall develop the issue.

MFMM, Ch. 3, § 90. Section 90.1 gives examples of situations in which a provider is liable for an overpayment it received. These include the following:

> **H. The Provider Billed, or Medicare Paid the Provider for Services that the Provider Should Have Known were Noncovered.**
>
> 1. Services Other Than Medically Unnecessary or Custodial Services, e.g., skilled physical therapy services furnished by a nonqualified physical therapist, or services rendered pursuant to an authorization from the VA. (See Medicare Benefit Policy, Chapter 17, Exclusions.)
>
> In general, the provider should have known about a policy or rule, if:

> • The policy or rule is in the provider manual or in Federal regulations,
>
> • The FI or carrier provided general notice to the medical community concerning the policy or rule, or
>
> • The FI or carrier gave written notice of the policy or rule to the particular provider.
>
> Generally, a provider's allegation that it was not at fault with respect to payment for noncovered services because it was not aware of the Medicare coverage provisions is not a basis for finding it without fault if any of the above conditions is met.

Id.

For services that are not medically reasonable and necessary, contractors apply the same criteria used to determine provider knowledge under section 1879 of the Act (which provides for a limitation of a beneficiary's or provider's liability for noncovered items or services based upon whether they had prior knowledge of noncoverage). MFMM, Ch. 3, § 70.3.B.

The Medicare Claims Processing Manual (MCPM), CMS Pub. 100-04, Chapter 30, Section 40.1.2 explains -

> A provider is always considered to have prior knowledge, and no Medicare payment will be made to any provider for any claim, if previous notification was given or if for any other reason the provider clearly should have known that the claim would be denied. Criteria for determining whether a provider had knowledge or should have had knowledge that services or items would be denied are in [the] regulations at 42 CFR 411.406, which cite[] various forms and methods of notification that provide sufficient evidence that the provider knew or should have known that the services or items would be denied . . . In general, notification often is provided by one of the following sources:
>
> * * *
>
> Medicare has issued manuals, bulletins, memoranda, etc., advising providers of the noncoverage of a particular service or category of services. All

> participating providers are issued instructions that discuss and define coverage and noncoverage of specified services under Medicare. For example, instructions in the Medicare Benefit Policy Manual define covered care and provide examples of unskilled services that Medicare does not cover[.]

The regulation in 42 C.F.R. § 411.406(e) explains that a provider has constructive notice of coverage requirements based upon receipt of various CMS notices, bulletins, issuances and other program guidelines.

ANALYSIS

Section 1870(b) of the Act does not define the meaning of the term "without fault." However, program guidance in the MFMM set forth the standards for determining whether a provider was "without fault," e.g., if it exercised reasonable care in billing and accepting Medicare payment. MFMM, Ch. 3, § 90. A provider is considered not "without fault" if, e.g., it did not submit documentation to substantiate that services billed were covered, or billed, or Medicare paid, for services the provider should have known were not covered. *Id.* at § 90.1. A provider should have known about a policy or rule if the policy or rule is in the provider manual or in the regulations. *Id.* Also, a provider's allegation that it was not at fault with respect to payment for noncovered services because it was not aware of coverage requirements is not considered a basis for finding it "without fault" if one of several conditions is met. One such condition is if the provider billed, or Medicare paid for, services the provider should have known were not covered. *Id.* at § 90.

The ALJ upheld the overpayment determination because "the circumstances and services provided did not require or rise to the level of an inpatient admission as [the beneficiary] could have been adequately treated on an outpatient level." Dec. at 8. The ALJ's reason for upholding the overpayment, as quoted herein, is the very reason for which the appellant may be found not "without fault" for the resulting overpayment. Pursuant to the laws, regulation and program guidance set out above, the appellant is deemed to have had at least constructive knowledge of the program coverage requirements. Knowledge of those requirements precludes a finding that the appellant was not "without fault in incurring the overpayment."

The Council reverses the ALJ's decision only on the issue of waiver of recovery of the overpayment. The appellant will remain liable for the resulting overpayment.

MEDICARE APPEALS COUNCIL

Administrative Appeals Judge

Departmental Appeals Board

Date: FEB -4 2011

DMEPOS (Supplies) & Consolidated Billing under Medicare Part A

A supplier's reliance on the Common Working File (CWF) and commercial eligibility verification systems does not constitute reasonable care in billing, as they do not provide a reasonable basis for assuming that the Part B payment was correct.

The Council has been issuing remands and reversals for over three years stating that ALJs were erroneously waiving recoupment of overpayments and liability in consolidated billing cases. *See, e.g.,* M-13-2515 (Sept. 5, 2013); M-13-2562 (Sept. 26, 2013); M-14-1332 (May 14, 2014); M-14-2514 (Sept. 16, 2014); M-15-747 (July 16, 2015); M-16-72 (Dec. 24, 2015).

Sample Decision #3 **– Council Docket Number M-13-2452 (Aug. 13, 2013)**

CMS submitted extensive briefing on this issue and made a six-point argument, as follows:

1) CMS has never instructed suppliers to rely on information in the CWF on the date of service as a basis for determining when the beneficiary was in a Medicare Part A stay. Instead, CMS cautions against relying solely on the CWF since CWF information is based on claims Medicare has received and thus will not provide adequate information if the supplier bills before the HHA or SNF does.

2) CMS has consistently considered a supplier's bill for services subject to consolidated billing to constitute improper billing and does not consider CWF timeliness limitations a basis for waiving recoupment of an overpayment.

3) CMS has not endorsed the third-party eligibility services or the precision, accuracy, thoroughness, reliability and timeliness of the information in the reports. Accordingly, these commercial reports cannot serve as a basis for waiving recoupment of an overpayment owed to Medicare.

4) The supplier shares responsibility for ensuring services subject to consolidated billing are billed correctly; thus, a supplier's failure to ascertain a beneficiary's coverage status does not provide a basis for waiving overpayment liability. *See* MCPM, Chapter 6, § 10.4.2 ("while the SNF itself should take reasonable steps to prevent [problems resulting from duplicate billing] from arising, the supplier in this scenario is also responsible for being aware of and complying with the consolidated billing requirements"); *see also* MCPM, Chapter 10, §20.1.2 ("suppliers of [HH] services must be aware that separate Medicare payment will not be made to them [and therefore must] determine whether or not a home health episode of care exists" before furnishing services to a beneficiary).

5) The supplier's remedy if a duplicate payment is recouped is to obtain payment from the SNF or the HHA.

6) With regard to SNF services, CMS places responsibility and oversight for *all* services furnished to SNF residents with the SNF, instructing "the SNF or the rendering provider or supplier under an arrangement with the SNF" to bill Part B for the covered ancillary services such as surgical dressings. *MCPM, supra* ch. 7, § 10.1. Thus, the appellant would never demonstrate reasonable care in billing Part B services that it independently furnished to a SNF resident.

(*See* M-13-2452 at 4–6).

With respect to the applicable guidance, the Council noted:

> "The Medicare Claims Processing Manual (MCPM) provides instructions for suppliers subject to SNF and HHA consolidated billing and states that to determine if a Part A episode of care exists, the supplier may (1) ask the beneficiary, (2) contact the Medicare contractor, and (3) 'as a last resort,' the supplier may 'request home health eligibility information available on the Common Working File [CWF].' MCPM, ch. 10, § 20.1.2. The MCPM further provides that 'prior to furnishing services to a Medicare beneficiary, the supplier should routinely ascertain whether the beneficiary is currently receiving any comprehensive Medicare benefits (such as SNF or home health benefits) for which Medicare makes a bundled payment that could potentially include the supplier's services.' MCPM, ch. 6, § 10.4.2.
>
> Additionally, the manual strongly cautions suppliers that information on the CWF is supplementary to other sources of information, and 'is only as complete and timely as billing by providers allows it to be.' MCPM, Ch. 10, § 20.1.2. There will always be a lag time between the date a beneficiary is first admitted to a SNF or home health episode of care and the date the CWF is updated to reflect billing for such care. As a result, the manual reminds suppliers that a beneficiary remains the first and best source of information. *Id.*"

(M-13-2452 at 8).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

ORDER OF MEDICARE APPEALS COUNCIL
REMANDING CASE TO ADMINISTRATIVE LAW JUDGE
Docket Number: M-13-2452

In the case of	**Claim for**
Comprehensive Decubitus Therapy, Inc. d/b/a Advanced Tissue (Appellant)	Supplementary Medical Insurance Benefits (Part B)
J.A. and 30 others (see attached) (Beneficiary)	Multiple (see attached) (HIC Number)
DME MAC Jurisdictions A, B, C & D (Contractor)	1-986768522 and 26 others (see attached) (ALJ Appeal Number)

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision, dated April 11, 2013, and issued on the record without a hearing, because there is an error of law material to the outcome of the claims. *See* 42 C.F.R. § 405.1110. The decision addressed overpayments assessed against the appellant-supplier in connection with its claims for Medicare Part B payment for surgical dressings provided to thirty-two (32) beneficiaries who were under Medicare Part A care[1] on multiple dates of service

[1] The ALJ's decision addressed the claims for items furnished to 32 beneficiaries. However, CMS's memorandum addresses thirty-one (31) beneficiaries, indicating that the Administrative Qualified Independent Contractor effectuated the claim for one beneficiary (W.A., ALJ appeal number 1-844429705) because this beneficiary was discharged from home health on the date of service billed. The appellant raises no contention disputing CMS's representation on this point. The Council's action addresses only the remaining 31 beneficiaries.

As CMS's memorandum also points out, a majority of the 31 beneficiaries were in Part A skilled nursing facility (SNF) stays; some were under home health plans of care.

between March 28, 2008, and December 8, 2011.[2] The ALJ determined that the appellant was entitled to a waiver of the overpayments pursuant to section 1870(b) of the Social Security Act (Act).

The Council has considered the record of the ALJ proceedings, the memorandum from the Centers for Medicare & Medicaid Services (CMS), dated June 6, 2013, and the appellant's timely response. The CMS memorandum is entered into the record as Exhibit (Exh.) MAC-1; the appellant's response is admitted as Exhibit MAC-2.

For the reasons explained below, the Council vacates the ALJ's decision and remands this case to an ALJ for further proceedings, including the issuance of a new decision on the 31 beneficiary cases that are the subject of the agency referral. *See* 42 C.F.R. § 405.1110(d). The Council finds that remand is necessary because the appellant asked for an ALJ hearing on the issue of liability for the overpayments assessed against it, and was not given an opportunity for a hearing on that matter.

BACKGROUND

The appellant sought, and initially received, Medicare Part B reimbursement for various surgical dressings furnished to thirty-one beneficiaries on multiple dates of service between March 28, 2008, and December 8, 2011. Exh. 1 (all claim files). The Durable Medical Equipment Medicare Administrative Contractors (DME MACs) subsequently determined that these payments were made in error, assessed overpayments, and sought recovery of the overpayments. *Id.* Upon redetermination, the DME MACs explained that the costs of these supplies could not be reimbursed while the beneficiaries were in Medicare covered Part A skilled nursing facility (SNF) stays or in home health episodes of care because these items were included in the bundled payment received by the home health agency (HHA) or the SNF at the HHA or SNF prospective payment system rate. *Id.* On reconsideration, the Qualified Independent Contractor (QIC) affirmed the overpayment assessments for similar reasons. *Id.* The QIC and DME MACs also found the appellant was not without fault for the overpayment amounts and thus that the appellant was ineligible for waiver of recoupment of the overpayments under section 1870(b) of the Act. *Id.*

---

[2] The dates of service, the ALJ appeal numbers, and the redacted HIC numbers of the 31 beneficiaries are in the attached beneficiary list. The Council refers to the beneficiaries by their initials to protect their privacy.

The appellant filed a request for hearing before an ALJ. The ALJ determined that a hearing was unnecessary because the evidence of record supports a decision in favor of the appellant. Dec. at 1. The ALJ reasoned (quoted verbatim):

> In each of the claims herein, the appellant provided a 30-day quantity of wound care supplies to the beneficiaries on the dates reflected in the Appendix. Evidence consists of the relevant appellant invoices and proofs of delivery. Although there is no proof in the ALJ file, it is not disputed that the beneficiary was later discovered to have been enrolled in a home health episode at the time of shipment, under Medicare Part A.
>
> In its written appeal, the appellant explained that, at the time of shipment, it checked an online database used to confirm Medicare eligibility, and there was no indication the beneficiary was in a home health episode. In fact coverage was allowed and payment was made; it was not until later dates that [the DME MAC] determined an overpayment.
>
> Neither [the DME MAC] nor the QIC specified how long the beneficiaries remained enrolled in home health episodes under Part A. Because the appellant provided a 30-day quantity of wound care supplies, the ALJ finds the appellant entitled to coverage under Part B for any of those days the beneficiary was not covered under Part A.
>
> Further pursuant to §1870 of the Act, the ALJ finds the appellant was without fault in creating the overpayment. It had not been advised by the beneficiaries that they were enrolled in a home health episode, and the appellant diligently checked an online database before shipping, leading it to believe the beneficiary was Part B eligible. The good faith of this belief was reinforced by the initial allowance of coverage. Therefore, the ALJ determines the

The regulations in 42 C.F.R. § 405.1038 permit the ALJ to issue a decision based upon the written record, without holding a hearing, if the evidence of record supports a favorable decision for the appellant on every issue. 42 C.F.R. § 405.1038(a). The ALJ also may do so if all of the parties indicate, in writing, that they do not wish to appear before the ALJ. 42 C.F.R. § 405.1038(b).

> appellant is entitled to waiver of liability for any overpayment.

Id. at 4.

The "Conclusions of Law" section reads as follows:

> Any supplies shipped to the beneficiaries on the dates reflected in the Appendix, covering service dates for thirty days thereafter, were medically reasonable and necessary. For any of those dates the beneficiaries were not under Medicare Part A, the supplies are covered under Medicare Part B. For any of those dates conflicting with Medicare Part B coverage, the appellant is without fault and not liable for the overpayment.

Id.[4]

CMS MEMORANDUM AND APPELLANT'S RESPONSE

CMS urges the Council to review the ALJ's decision because the decision was based on error of law material to the outcome of the claims. Specifically, CMS asserts that the ALJ erred in waiving recoupment of the overpayments under section 1870 of the Act on the basis that the appellant relied on the Common Working File (CWF) via commercial eligibility verification systems to ascertain the beneficiaries' status on the dates of service at issue. Exh. MAC-1 at 2.

CMS maintains that a supplier's reliance on CWF and commercial eligibility verification systems does not constitute reasonable care in billing as they do not provide a reasonable basis for assuming that the Part B payment was correct. *Id.* CMS makes six main points -

> First, CMS has never instructed suppliers to rely on information in the CWF on the date of service as a basis for determining when the beneficiary was in a Medicare Part A stay. Instead, CMS cautions against

[4] Whether the items were medically necessary for the beneficiaries is not the issue. The basic underlying question in these cases concerns entitlement to Medicare Part B reimbursement. Moreover, the ALJ's decision appears to assume that all of the beneficiaries were in home health episodes of care. As CMS's referral notes, 26 of the 31 beneficiaries that are the subject of the referral were in SNF stays; five were under home health care. *See* Exh. MAC-1 at 3, n.3.

relying solely on the CWF since CWF information is based on claims Medicare has received and thus will not provide adequate information if the supplier bills before the HHA or SNF does.

Second, CMS has consistently considered a supplier's bill for services subject to consolidated billing to constitute improper billing and does not consider CWF timeliness limitations a basis for waiving recoupment of an overpayment.

Third, CMS has not endorsed the third-party eligibility services or the precision, accuracy, thoroughness, reliability and timeliness of the information in the reports. Accordingly, these commercial reports cannot serve as a basis for waiving recoupment of an overpayment owed to Medicare.

Fourth, the supplier shares responsibility for ensuring services subject to consolidated billing are billed correctly; thus, a supplier's failure to ascertain a beneficiary's coverage status does not provide a basis for waiving overpayment liability. *See* MCPM, Chapter 6, § 10.4.2 ("while the SNF itself should take reasonable steps to prevent [problems resulting from duplicate billing] from arising, the supplier in this scenario is also responsible for being aware of and complying with the consolidated billing requirements"); *see also* MCPM, Chapter 10, §20.1.2 ("suppliers of [HH] services must be aware that separate Medicare payment will not be made to them [and therefore must] determine whether or not a home health episode of care exists" before furnishing services to a beneficiary).

Fifth, the supplier's remedy if a duplicate payment is recouped is to obtain payment from the SNF or the HHA.

Sixth, with regard to SNF services, CMS places responsibility and oversight for *all* services furnished to SNF residents with the SNF, instructing "the SNF or the rendering provider or supplier under an arrangement with the SNF" to bill Part B for the covered ancillary services such as surgical dressings. MCPM, Chapter 7, § 10.1. Thus, the appellant would never demonstrate reasonable care in billing Part B

> services that it independently furnished to a SNF resident.

See Exh. MAC-1 at 2-3 and 13-19 (emphasis in original).

In opposition to CMS's referral, the appellant argues, *inter alia*, that it is entitled to a waiver of recoupment of the overpayments under section 1870(b) of the Act, citing a prior Council decision favorable to the appellant on the waiver question. The appellant asserts that "the evidence" demonstrates that the appellant exercised reasonable care in billing for and accepting payment for the supplies at issue, but does not specify what evidence supports its position. Exh. MAC-2 at 3, citing Medicare Financial Management Manual (MFMM), Ch. 3, § 90. Moreover, the appellant asserts, the evidence supports the ALJ's decision and thus, there is no basis for own motion review by the Council. The appellant asserts that CMS's referral did not meet the standard for the Council's own motion review of this particular case.

The appellant also asserts that, should the Council find merit in the arguments presented by CMS, the appellant should be afforded the right to a hearing as provided in section 1869(d)(1) of the Act. *Id.* at 4.

STANDARD OF REVIEW

Where CMS (or its contractor(s)) did *not* participate in the ALJ proceedings, CMS (or its contractor(s)) may request the Council's own motion review of an ALJ's decision on two grounds: the ALJ's decision contains error of law material to the outcome of the claim(s), or the case presents a broad policy or procedural issue that may affect the public interest. 42 C.F.R. § 405.1110(c)(2). If, however, CMS (or its contractor(s)) *did* participate in the ALJ proceedings, the regulations permit own motion review on two additional grounds: abuse of discretion by the ALJ, or if the decision is not consistent with the preponderance of the evidence of record. *Id.* at § 405.1110(c)(1); *see also id.* at § 405.1110(b)(1).

The appellant seems to be asserting that CMS is seeking a reversal of the ALJ's determination on the waiver issue based on the "preponderance of the evidence" standard, which is impermissible in this case because CMS (or its contractor(s)) did not participate in the ALJ proceedings. It maintains that, in this case, CMS may seek own motion review only on two

grounds, material legal error or broad policy or procedural issue that may affect the public interest, neither of which is demonstrated in the CMS referral. Exh. MAC-2 at 1-2.

The appellant appears to misunderstand the regulations governing the Council's own motion review. The own motion review regulations in section 405.1110 permit the Council to review the ALJ's decision, *without regard to whether CMS or any of its contractors participated below*, if the Council finds material legal error.

The Council concludes that CMS has articulated material legal error in the ALJ's decision. The error was in misapplying section 1870 of the Act to relieve the appellant from liability for the overpayments on the basis that the appellant's use of commercial eligibility verification systems to verify Part B eligibility was sufficient to show that the appellant exercised reasonable care in billing for and accepting Medicare payment for the supplies at issue in this case. And, in doing so, the ALJ did not consider CMS guidelines relevant to this issue, as summarized herein and discussed in detail in the CMS referral memorandum. Accordingly, the Council has a basis to exercise own motion review authority to address the legal error.

LEGAL AUTHORITIES

Section 1870(b) of the Act provides:

> (b) where -
>
> (1) more than the correct amount is paid under this title to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider of services or other person, or (B) that such provider of services or other person was without fault with respect to the payment of such excess over the correct amount . . .
>
> proper adjustments shall be made, under regulations prescribed . . . by the Secretary . . . .

Section 1870(b) therefore provides for a waiver of recovery for an overpayment in certain circumstances where a provider or supplier is "without fault." The Medicare Financial Management Manual (MFMM) instructs that a provider or supplier is without fault when the provider or supplier exercised reasonable care in billing for, and accepting the payment; i.e. -

- It made full disclosure of all material facts; and
- On the basis of the information available to it, including but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the [contractor's] attention.

MFMM, CMS Pub. 100-06, Ch. 3, § 90.

The Medicare Claims Processing Manual (MCPM) provides instructions for suppliers subject to SNF and HHA consolidated billing and states that to determine if a Part A episode of care exists, the supplier may (1) ask the beneficiary, (2) contact the Medicare contractor, and (3) "as a last resort," the supplier may "request home health eligibility information available on the Common Working File [CWF]." MCPM, Ch. 10, § 20.1.2. The MCPM further provides that "prior to furnishing services to a Medicare beneficiary, the supplier should routinely ascertain whether the beneficiary is currently receiving any comprehensive Medicare benefits (such as SNF or home health benefits) for which Medicare makes a bundled payment that could potentially include the supplier's services." MCPM, Ch. 6, § 10.4.2.

Additionally, the manual strongly cautions suppliers that information on the CWF is supplementary to other sources of information, and "is only as complete and timely as billing by providers allows it to be." MCPM, Ch. 10, § 20.1.2. There will always be a lag time between the date a beneficiary is first admitted to a SNF or home health episode of care and the date the CWF is updated to reflect billing for such care. As a result, the manual reminds suppliers that a beneficiary remains the first and best source of information. *Id.*

DISCUSSION

As stated above, the Council finds that remand is necessary because the appellant asked for a hearing before the ALJ on the issue of liability for the overpayment assessed against the appellant. In its exceptions to the CMS referral, the appellant clearly states that, in the event the Council decides to exercise own motion review authority in this case, it wants to be heard by an ALJ before a new decision is issued on the disputed issue. The Council is therefore remanding this case to the ALJ for further proceedings, to include the opportunity for a hearing.

As discussed earlier, *see* page 7 *supra*, the ALJ's decision does not indicate that the ALJ considered the authorities that are relevant to a determination of whether the appellant exercised reasonable care in billing, as summarized herein and discussed in detail in the CMS referral memorandum. The ALJ must consider those authorities on remand.

The ALJ also must issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record. 42 C.F.R. § 405.1046(a). The ALJ's decision, which we are vacating, does not meet these standards. The ALJ's decision briefly and vaguely stated that the appellant asserted that it accessed an "online database used to confirm Medicare eligibility, and there was no indication the beneficiary was in a home health episode." Dec. at 4. The ALJ then stated that the appellant's "good faith belief was reinforced by the initial allowance of coverage," and thus, the appellant is entitled to waiver of recoupment for any overpayment. *Id.* The Council cannot determine what specific evidence the ALJ relied on to determine that the appellant exercised reasonable care in billing for and accepting Medicare payment for the items at issue, and thus is entitled to waiver of recoupment of the overpayments under section 1870(b). *See id.*

REMAND ORDER

The Council vacates the ALJ's decision and remands this case to an ALJ for further proceedings, including a hearing and a new decision, on the 31 beneficiary cases at issue. *See* 42 C.F.R. § 405.1110(d). On remand, the ALJ shall, at minimum, take the following actions:

1. Offer the appellant an opportunity for a hearing. The ALJ also shall offer the CMS contractor an opportunity to participate in the hearing. Any waiver or declination of the opportunity to participate in an ALJ hearing will be documented, in writing, in the record.

2. Address the issue of the appellant's liability pursuant to section 1870(b) of the Act, as this is the only issue appealed by the appellant in the request for hearing.

3. Make a complete record of the evidence, including the hearing proceedings, if any. The record will include, marked as exhibits, the documents used in making the decision under review, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ admits. In the decision, the ALJ must also discuss any evidence excluded under section 42 C.F.R. § 405.1028 and include a justification for excluding the evidence. 42 C.F.R. § 405.1042(a).

4. Issue a new decision, which includes the factual bases for findings and conclusions.

The ALJ may take further action not inconsistent with this order.

MEDICARE APPEALS COUNCIL

DME from Non-Participating Supplier—Sections 1834(j)(4) and 1834(a)(18) of the Act

Financial liability for non-covered DME due to non-participating supplier is determined pursuant to §§ 1834(j)(4) and 1834(a)(18) of the Act.

Sample Decision #4 **– MAC-DR 101123-D (ALJ # 1-548XXXXX)**

ALJ correctly determined the item was not covered because the supplier did not have a supplier number, but erred in failing to properly consider liability under section 1834(j)(4) of the Act, which provides for the supplier of the DMEPOS to bear responsibility for the costs if Medicare reimbursement is not available in certain defined circumstances (including when the DME supplier does not have a supplier number, in which circumstance the supplier may have to refund the beneficiary per section 1834(a)(18) of the Act). The ALJ also erred in failing to properly notice the supplier of the ALJ hearing, despite the fact that the supplier may be held liable pursuant to sections 1834(j)(4) and 1834(a)(18) of the Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-10-1283

In the case of **Claim for**

Supplementary Medical Insurance Benefits (Part B)

(Appellant)

(Beneficiary) (HIC Number)

(Contractor) 1-54 (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated April 14, 2010, which concerned Medicare coverage for an oral appliance used in treating sleep apnea. The ALJ determined that Medicare does not cover the oral appliance in this case because the supplier, , did not have a Medicare-issued durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier number. The ALJ also determined that the appellant beneficiary is liable for payment for the noncovered appliance. The appellant has asked the Medicare Appeals Council to review this action.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c). The appellant's request for review, including attachments identified as "Appellant/Beneficiary Ref[erence] Documents, ## 1 - 11.3," is made a part of the record as Exhibit (Exh.) MAC-1.

As explained below, Medicare does not cover durable medical equipment unless the supplier has a Medicare-issued DMEPOS supplier number. Although the

hospital and its professionals may participate in Medicare for certain purposes, this does not establish that the practice has specifically enrolled as a DMEPOS supplier. Because the oral appliance is a piece of durable medical equipment, the entity supplying the oral appliance must enroll as a DMEPOS supplier, and receive a DMEPOS supplier identification number as provided in 42 C.F.R. § 424.57. If the supplier has not done this, then financial liability must be determined under the provisions of section 1834(j)(4) of the Social Security Act (Act).

To make an accurate determination of liability upon the remand of this case, the ALJ will need to hold another hearing and find additional facts. The Council therefore vacates the ALJ's April 14, 2010 decision, and remands for further proceedings.

APPELLANT'S CONTENTIONS

The appellant's request for review contends that Medicare should cover the oral appliance for sleep apnea, for a series of reasons. First, she asserts that Medicare has approved the oral appliance for the treatment of sleep apnea. Exh. MAC-1. Second, she points out that the Health System (or hospital) is a Medicare-accepting entity, as is the professional who prescribed her oral appliance for sleep apnea, and they both have Medicare provider numbers. *Id.* Third, the appellant contends that when she obtained the oral appliance from the , she had not been informed previously that she had to obtain the oral appliance from a supplier with a Medicare-issued DMEPOS supplier number. *Id.* Fourth, the appellant contends that after the issues in this case arose she tried contacting a number of DMEPOS suppliers on the Medicare.gov website, but none of these suppliers knew what an oral appliance for obstructive sleep apnea is, or how to obtain one. *Id.* The appellant also states that she paid for the device in advance; it was not furnished on an assigned basis. *Id.*[1]

[1] The appellant also points out that she was 70 years old, when she obtained the device at issue, not 64 as the ALJ stated. Exh. MAC-1 at 4; *see also* Dec. at 2.

FACTUAL AND PROCEDURAL BACKGROUND

The record reflects that the appellant was diagnosed with obstructive sleep apnea in 2003 at the Sleep Center, and referred to the Hospital's Department of Oral & Maxillofacial Surgery for treatment of the condition with an intraoral appliance (a mandibular repositioning device). Exh. 2 at 11-13. This treatment approach was taken in lieu of oral surgery or use of a continuous positive airway pressure (CPAP) machine. Exh. 2 at 131; CD Recording of ALJ Hearing.

The oral appliance was made by a New York-based company, using a mold of the appellant's teeth taken at the . Exh. 4 at 31-32; Exh. 5 at 41-45. Then the oral appliance was shipped to the for a final fitting before she started using it. CD Recording of ALJ Hearing; Exh. 4 at 33. In 2003, when the appellant's first oral appliance for sleep apnea was prescribed, she filed a claim with Medicare and received payment. Exh. 3 at 19-20. The appellant used her first oral appliance for slightly more than five years.

Then, on October 8, 2008, she paid the $1500 for a new, replacement oral appliance, because her previous appliance had worn out. Exh. 1 at 4; Exh. 3 at 14, 15, 18, 22.[2] It appears that the appellant's claim for Medicare coverage for the second oral appliance was initially submitted to the local contractor, which returned it with instructions to submit it to the proper carrier. *See* Exh. 3 at 18; Exh. MAC-1, Reference Document #6 (Medicare Summary Notice (MSN) dated Dec. 5, 2008). Then on May 27, 2009, the appellant filed or re-filed the claim for Medicare payment for the appliance with the DMEPOS contractor. Exh. 3 at 16-18. On June 5, 2009, it appears that the DMEPOS contractor denied the claim, on the ground that it had to be submitted by the provider, and that "Medicare cannot process this claim as you were previously notified that you must use a supplier who has a Medicare supplier identification number." *See* Exh. 1 at 4; Exh. 3 at 23 (same MSN document).

On redetermination, the DMEPOS contractor denied the claim, stating that Medicare "only allow[s] one claim in [a

[2] The bill submitted to Medicare lists UOP OAS as the billing supplier. Exh. 1 at 4. The receipt given the appellant lists CPUP Oral and Maxiofacial Surgery. *See, e.g.*, Exh. 3 at 14. Absent evidence to the contrary we assume this is merely a difference in a "doing business as" name.

beneficiary's] lifetime from a supplier who is not enrolled in the Medicare program," and that "[the appellant] was previously notified that [she] must use a supplier who has a Medicare supplier identification number. [Sic.]" Exh. 3 at 26-29.

On reconsideration, the Qualified Independent Contractor (QIC) denied the claim, stating "You must get your covered equipment or supplies from a supplier enrolled in Medicare," and "The redetermination decision letter indicates that you were notified in 2003 that an approved Medicare supplier must be used when you purchased durable medical equipment (E1399) for the date of service August 28, 2003, from a provider not enrolled in Medicare." Exh. 4 at 36-39.

The ALJ held a hearing on March 16, 2010, in which the appellant and her husband, R.B., participated. They explained the history of and the medical basis for the appellant's use of the oral appliance, and their efforts to get Medicare reimbursement for the 2008 oral appliance. CD Recording of ALJ Hearing. The appellant's husband also explained his efforts to inquire about the fact that the Hospital
supplies other DMEPOS, such as crutches, walkers, and wheelchairs, quite possibly with provisions for Medicare reimbursement (including a DMEPOS supplier number). *Id.* However, he stated, the Hospital does not provide for the oral appliance costs to be reimbursed. *Id.* The ALJ expressed surprise that the did not seem to be a Medicare-approved supplier of DMEPOS, with a supplier identification number. *Id.*

In his subsequent decision, the ALJ denied Medicare coverage for the oral appliance, stating, *inter alia:*

> The supplier number . . . submitted with the claim at issue does not show that the supplier is an approved Medicare supplier. The documentation confirms that the Appellant/ Beneficiary was notified in 2003 that an approved Medicare supplier must be used when purchasing durable medical equipment. [Sic.] . . . Pursuant to the documentation submitted, the ALJ finds that Medicare guidelines have not been met. Accordingly, the item supplied cannot be covered under Medicare Part B. In addition, the ALJ finds that the Appellant/Beneficiary is liable for payment of the non-covered item.

Dec. at 4.

ANALYSIS

A. Medicare does not cover or pay for the oral appliance, unless it is furnished by a Medicare-approved supplier with a DMEPOS supplier identification number.

Medicare is a defined benefits program, providing coverage only for those categories of medical expenses specifically mentioned in the Act, and not otherwise excluded from coverage. No Medicare payment may be made for medical services or equipment unless all of the Medicare requirements are met.

The oral appliance at issue here (HCPCS code E0486) has been classified by Medicare as an item of routinely purchased durable medical equipment. *See* MLN Matters, No. MM4194 (effective Jan. 1, 2006).[3] The fact that the oral appliance is medically reasonable and necessary to treat the appellant's sleep apnea is not in dispute. *See* Ex. 2 at 11-13.

However, there is no indication in the record that the device was supplied by a supplier with a Medicare-issued DMEPOS supplier number, as required by section 1834(j) of the Act. Section 1834(j)(1) of the Act provides:

> (1) ISSUANCE AND RENEWAL OF SUPPLIER NUMBER.---
> (A) PAYMENT.---Except as provided in subparagraph (C) [exception for items furnished "incident to a physician's service"], "no payment may be made under this part after the date of the enactment of the Social Security Act Amendments of 1994 for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

Id. (emphasis added).[4] Pursuant to the Act, the implementing

---

[3] The Health Care Procedure Coding System (HCPCS) was developed by the Centers for Medicare & Medicaid Services (CMS) for processing, screening, identifying and paying Medicare claims. *See* 42 C.F.R. § 414.2.

[4] The oral appliance in this case was not furnished "incident to a physician's service." To be considered as furnished "incident to a physician's service" (and therefore not subject to the requirement that a supplier have a DMEPOS supplier number), the item must be, *inter alia*, furnished as an incidental part of the physician's professional services in the course of diagnosis or treatment, commonly rendered without charge or

(footnote continued on next page)

regulations specify standards for a supplier to obtain a DMEPOS supplier number. *See* section 1834(j)(1)(B); 42 C.F.R. § 424.57.[5]

The purposes of the requirement for a Medicare-issued DMEPOS supplier number are multiple, and include protecting beneficiaries from abusive practices by some suppliers, and protecting the Medicare program against fraud and abuse. *See* Medicare Program; Additional Supplier Standards, 60 Fed. Reg. 63,440; 63,442 (Dec. 11, 1995); Medicare Program; Additional Supplier Standards, 63 Fed. Reg. 2926, 2927 (Jan. 20, 1998); Medicare Program; Additional Supplier Standards, 65 Fed. Reg. 60,366 (Oct. 11, 2000).

The ALJ's conclusion that the oral appliance is not covered because it is not medically reasonable and necessary under section 1862(a)(2) of the Act is erroneous. Instead, coverage is denied because there is no evidence in the record that which supplied the oral appliance to the appellant has obtained a Medicare-issued DMEPOS supplier number. Therefore, Medicare cannot cover or pay for the oral appliance, because it was supplied by a supplier without a Medicare-issued DMEPOS supplier number. *See* section 1834(j) of the Act.

The appellant asserts that she did not know of this requirement. However, knowledge is not material to coverage of the oral appliance by Medicare.

---

included in the physician's bill, and not a service or item having its own benefit category. Pub. 100-2, Medicare Benefit Policy Manual (MBPM), Chapter 15, §§ 60, 60.1. The record in this case is limited; however, it does not document that the oral appliance is an incidental part of the physician's services, or that it is commonly rendered without charge or included in the physician's bill. *Cf.* Exh. 1 at 4, Exh. 3 at 14 (billed separately). *Compare* MBPM, Chapter 15, § 60.1A (supplies such as gauze, ointments, and bandages are typically considered as incident to a physician's service). The oral appliance is also covered under the durable medical equipment benefit category.

[5] In its application for Medicare billing privileges and a supplier number, a DMEPOS supplier must certify that it: meets requirements for compliance with Federal and State licensure and regulatory provisions; advises beneficiaries of their right to rent or purchase equipment; honors all warranties; maintains an appropriate physical facility; permits CMS to conduct on-site inspections; has the requisite insurance; takes responsibility for delivery of Medicare covered items; maintains and replaces at no charge, or repairs directly, the Medicare-covered items; complies with certain disclosure and complaint resolution requirements; and is accredited by a CMS-approved accreditation organization for the specific products and services it supplies, *inter alia*. 42 C.F.R. § 424.57.

B. Financial liability for the noncovered oral appliance on remand, is determined pursuant to sections 1834(j)(4) and 1834(a)(18) of the Act.

The ALJ found that the appellant was liable for the noncovered costs of the oral appliance, without citing any authority for this conclusion. The ALJ did not consider section 1834(j)(4) of the Act, which provides for the supplier of the DMEPOS to bear responsibility for the costs, if Medicare reimbursement is not available, in certain defined circumstances. That section reads, in pertinent part:

> (4) LIMITATION ON PATIENT LIABILITY.---If a supplier of medical equipment and supplies (as defined in paragraph (5))---
>
> (A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1) [which requires a DME supplier number]
>
> * * *
>
> any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

Section 1834(j)(4).

The provisions of subsection 1834(a)(18) of the Act (referenced in section 1834(j)) provide, in part:

> (18) REFUND OF AMOUNTS COLLECTED FOR CERTAIN DISALLOWED ITEMS
>
> (A) IN GENERAL.--- If a nonparticipating supplier furnishes to an individual enrolled under this part a covered item for which no payment may be made under this part by reason of paragraph 17(B)[prohibiting payment for items furnished by suppliers subsequent to unsolicited contacts], the supplier shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless---

> (i) the supplier establishes that the supplier did not know and could not reasonably have been expected to know that payment may not be made for the item by reason of paragraph (17)(B), or
> (ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient agreed to pay for that item.

Id.; see also subsections 1834(a)(1)(B) through (D) (providing for sanctions, time limits, and notice).

The Council determines that is the supplier of the oral appliance, since it charged the appellant for the appliance, issued a receipt for payment, and filed a claim for Medicare coverage. Exh. 1 at 4, Exh. 3 at 14, 18; *see also* 42 C.F.R. § 400.202 (defining "supplier"). However, there is no indication in the record that the supplier received notice of the previous ALJ hearing (*see* Exh. 5 at 112–16), or received a copy of the ALJ's decision (*see* Notice of Decision at 3). Remand is therefore necessary to afford the supplier the opportunity for a hearing, consistent with the foregoing.

Remand Insructions

The ALJ shall offer both parties, the appellant and the , the opportunity for a hearing. 42 C.F.R. § 405.1020(c)(1). The ALJ shall determine liability for the noncovered oral appliance consistent with subsections 1834(j)(1), (j)(4), and (a)(18) of the Act. The ALJ shall issue a new decision, and may take further action not inconsistent with this order.

MEDICARE APPEALS COUNCIL

Administrative Appeals Judge

Departmental Appeals Board

Date:

A. Notifier: **ABNs**

B. Patient Name: **C. Identification Number:**

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for **D.** _____ below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D.** _____ below.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D.** _____ listed above.

  Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the **D.** _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the **D.** _____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

☐ **OPTION 3.** I don't want the **D.** _____ listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY:** 1-877-486-2048). Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:	J. Date:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Form CMS-R-131 (03/11) Form Approved OMB No. 0938-0566

Insert contact information here

Detailed Explanation of Non-coverage

Date:

Patient name: Patient number:

This notice gives a detailed explanation of why your Medicare provider and/or health plan has determined Medicare coverage for your current services should end. ***This notice is not the decision on your appeal.*** The decision on your appeal will come from your Quality Improvement Organization (QIO).

We have reviewed your case and decided that Medicare coverage of your current {insert type} services should end.

• The facts used to make this decision:

• Detailed explanation of why your current services are no longer covered, and the specific Medicare coverage rules and policy used to make this decision:

• Plan policy, provision, or rationale used in making the decision (health plans only):

If you would like a copy of the policy or coverage guidelines used to make this decision, or a copy of the documents sent to the QIO, please call us at: {insert provider/plan toll-free telephone number}

Form CMS-10124-DENC (Approved 12/31/2011) OMB Approval No. 0938–0953

{Insert provider contact information here}
Notice of Medicare Non-Coverage

Patient name: **Patient number:**

The Effective Date Coverage of Your Current **{insert type}** Services Will End: **{insert effective date}**

- Your Medicare provider and/or health plan have determined that Medicare probably will not pay for your current {insert type} services after the effective date indicated above.
- You may have to pay for any services you receive after the above date.

Your Right to Appeal This Decision

- You have the right to an immediate, independent medical review (appeal) of the decision to end Medicare coverage of these services. Your services will continue during the appeal.
- If you choose to appeal, the independent reviewer will ask for your opinion. The reviewer also will look at your medical records and/or other relevant information. You do not have to prepare anything in writing, but you have the right to do so if you wish.
- If you choose to appeal, you and the independent reviewer will each receive a copy of the detailed explanation about why your coverage for servicas should not continue. You will receive this detailed notice only after you request an appeal.
- If you choose to appeal, and the independent reviewer agrees services should no longer be covered after the effective date indicated above;
  - Neither Medicare nor your plan will pay for these services after that date.
- If you stop services no later than the effective date indicated above, you will avoid financial liability.

How to Ask For an Immediate Appeal

- You must make your request to your Quality Improvement Organization (also known as a QIO). A QIO is the independent reviewer authorized by Medicare to review the decision to end these services.
- Your request for an immediate appeal should be made as soon as possible, but no later than noon of the day before the effective date indicated above.
- The QIO will notify you of its decision as soon as possible, generally no later than two days after the effective date of this notice if you are in Original Medicare. If you are in a Medicare health plan, the QIO generally will notify you of its decision by the effective date of this notice.
- Call your QIO at: {insert QIO name and toll-free number of QIO} to appeal, or if you have questions.

See page 2 of this notice for more information.

Form CMS 10123-NOMNC (Approved 12/31/2011) OMB approval 0938-0953

If You Miss The Deadline to Request An Immediate Appeal, You May Have Other Appeal Rights:

- If you have Original Medicare: Call the QIO listed on page 1.
- If you belong to a Medicare health plan: Call your plan at the number given below.

Plan contact information _____

_____

Additional Information (Optional):

Please sign below to indicate you received and understood this notice.

I have been notified that coverage of my services will end on the effective date indicated on this notice and that I may appeal this decision by contacting my QIO.

_____ _____

Signature of Patient or Representative Date

Form CMS 10123-NOMNC (Approved 12/31/2011) OMB approval 0938-0953

Home Health Agency: **Patient Name:**

Address: **Patient Identification:**

Phone:

Home Health Change of Care Notice (HHCCN)

Your home health care is going to change. Starting on ___*[date]*___, your home health agency will change the following items and/or services for the reasons listed below.

Items/services:	Reason for change:

Read the information next to the checked box below. Your home health agency is giving you this information because:

☐ **Your doctor's orders for your home care have changed.**
The home health agency must follow physician orders to give you care.
The home health agency can't give you home care without a physician's order.
If you don't agree with this change, discuss it with your home health agency or the doctor who orders your home care.

☐ **Your home health agency has decided to stop giving you the home care listed above.**
You can look for care from a different home health agency if you have a valid order for home care and still think you need home care.
If you need help finding a different home health agency to give you this care, contact the doctor who ordered your home care.
If you get care from a different home health agency, you can ask it to bill Medicare.

If you have questions about these changes, you can contact your home health agency and/or the doctor who orders your home care.

You cannot appeal to Medicare about payment for the items/services listed above unless you both receive them and a Medicare claim is filed.

Additional Information:

Please sign and date below to show that you received and understand this notice. Return this signed notice to your home health agency in person or by mailing it to them at the address listed at the top of this notice.

Signature of the Patient or of the Authorized Representative*	Date

*If a representative signs for the beneficiary, write "(rep)" or "(representative)" next to the signature. If the representative's signature is not clearly legible, the representative's name must be printed.

Form CMS-10280 (Approved 06/2013) OMB Approval No. 0938-1196

Home Health Advance Beneficiary Notice (HHABN)

[Option Box 1 Sample]

We, _____ , your home health agency, are letting you know that we _____ with the following items and/or services: _____

Because: _____

If you have questions about these changes, you can call us at ( ) _____.

TTY users should call ( ) _____.

The estimated cost of the items and/or services listed above is $ _____

_____

If you have other insurance, please see number 3 below.

You have three options available to you. You must choose only one of these options by checking the box next to the option and then signing below:

- □ 1. I don't want the items and/or services listed above. I understand that I won't be billed and that I have no appeal rights since I will not receive those items and/or services.
- □ 2. I want the items and/or services listed above, and I agree to pay myself since I don't want a claim submitted to Medicare or any other insurance I have. I understand that I have no appeal rights since a claim won't be submitted to Medicare.
- □ 3. I want the items and/or services listed above, and I agree to pay for the items and/or services myself if Medicare or my other insurance doesn't pay. Send the claim to (**Please check one or both boxes**):
  - □ Medicare
  - □ My other insurance: _____

Please note: If you select option 3 and a claim is submitted to Medicare, you will get a Medicare Summary Notice (MSN) showing Medicare's official payment decision. If the MSN indicates that Medicare won't pay all or part of your claim, you may appeal Medicare's decision by following the appeal procedures in the MSN. If you don't receive a MSN for your claim, you can call Medicare at: 1-800-633-4227. TTY: 1-877-486-2048. You may have to pay the full cost at the time you get the items and/or services. If Medicare or your other insurance decides to pay for all or part of the items and/or services that you have already paid for, you should receive a refund for the appropriate amount.

By signing below, I understand that I received this notice because this Home Health Agency believes Medicare will not pay for the items/services listed, and so I chose the option checked above.

Patient's Name	Patient Identification
Signature of the Patient or of the Authorized Representative	Date

Please read and sign this notice. Return it to us or mail it to our address listed above.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0781. The time required to complete this information collection is estimated to average 18 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Form No. CMS-R-296 (10/31/2012) OMB Approval No. 0938-0781

Notice of Exclusions from Medicare Benefits
Skilled Nursing Facility (NEMB-SNF)

Date of Notice: _____

NOTE: You need to make a choice about receiving these health care items or services.

It is not Medicare's opinion but our opinion that Medicare will not pay for the item(s) or service(s) described below. Medicare does not pay for all of your health care costs Medicare only pays for covered items and services when Medicare rules are met The fact that Medicare will not pay for a particular item or service does not mean that you should not receive it. There may be a good reason to receive it Right now in your case **Medicare will not pay for** –

Items or Services:

We believe that Medicare will not pay for the following reason. (See the reason checked off below.)

- ☐ No qualifying 3-day inpatient hospital stay.
- ☐ No days left in this benefit period.
- ☐ Care not ordered or certified by a physician
- ☐ Daily skilled care not needed
- ☐ SNF transfer requirement not met
- ☐ Facility/Bed not certified by Medicare
- ☐ Care not given by nor supervised by, skilled nursing or rehabilitation staff
- ☐ Items or services not furnished under arrangements by the skilled nursing facility
- ☐ **Other** _____

The purpose of this notice is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you will have to pay for them yourself or through other insurance that you may have Before you make a decision about your options, you should **read this entire notice carefully.**

- Ask us to explain if you don't understand why Medicare won t pay.
- Ask us how much these items or services will cost you (**Estimated Cost $**_____.)

Your other insurance is: _____

Please choose one option. Check on box. Sign and date this notice.

☐ **Option 1 YES** I want to receive these items or services and get an official Medicare decision about coverage Please submit a claim, with any evidence supporting my need for these items or services, to Medicare for its official decision. I understand you will notify me when my claim is submitted and that you will not bill me for these items or services until Medicare makes its decision If Medicare denies payment. I agree to be personally and fully responsible for payment. That is. I will pay personally, either out of pocket or through any other insurance that I have

I understand that I can appeal if Medicare decides not to pay. Medicare will send me notice of its official decision not to pay that explains its decision in my case That notice will explain how I can appeal Medicare s decision not to pay If I de not hear from Medicare abeut its official coverage decision within 90 days, I can telephone Medicare at ( ) _____ TTY/TDD ( ) _____

☐ **Option 2. YES** I want to receive these items or services Do NOT submit a claim to Medicare I agree to be fully and personally responsible for payment of any amount for which my other insurance will not pay I realize I cannot appeal to Medicare.

☐ **Option 3. NO** I will not receive these items or services I understand that you will not be able to submit a claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay

Patient's name	Identification Number
Signature of the patient or the authorized representative	Date

Form CMS 20014 OMB Exempt

Skilled Nursing Facility's Name and Address
Telephone number and TTY/TDD number

Skilled Nursing Facility Advance Beneficiary Notice (SNFABN)

Date of Notice: _____

NOTE: You need to make a choice about receiving these health care items or services.

It is not Medicare's opinion, but our opinion, that Medicare will not pay for the items or services described below. Medicare does not pay for all of your health care costs. Medicare only pays for covered items and services when Medicare rules are met. The fact that Medicare may not pay for a particular item or service does not mean that you should not receive it. There may be a good reason to receive it. Right now, in your case, **Medicare probably will not pay for –**

Items or Services:

Because:

The purpose of this form is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you might have to pay for them yourself. Before you make a decision about your options, you should **read this entire notice carefully**.

- Ask us to explain, if you don't understand why Medicare probably won't pay.
- Ask us how much these items or services will cost you (**Estimated Cost: $** _____), in case you have to pay for them yourself or through other insurance you may have.
  Your other insurance is: _____
- If in 90 days you have not gotten a decision on your claim, contact the Medicare contractor at: Address: _____
  or at: Telephone: _____ TTY/TDD: _____
- If you receive these items or services, we will submit your claim for them to Medicare.

PLEASE CHOOSE **ONE** OPTION. CHECK **ONE** BOX. **DATE & SIGN** THIS NOTICE.

☐ **Option 1. YES. I want to receive these items or services.** I understand that Medicare will not decide whether to pay unless I receive these items or services. I understand you will notify me when my claim is submitted and that you will not bill me for these items or services until Medicare makes its decision. If Medicare denies payment, I agree to be personally and fully responsible for payment. That is, I will pay personally, either out of pocket or through any other insurance that I have. I understand that I can appeal Medicare's decision.

☐ **Option 2. NO. I will not receive these items or services.** I understand that you will not be able to submit a claim to Medicare and that I will not be able to appeal your opinion that Medicare won't pay. I understand that, in the case of any physician-ordered items or services, should notify my doctor who ordered them that I did not receive them.

Patient's Name: _____ **Patient Identification #:** _____

_____ _____

Date **Signature of the patient or of the authorized representative**

Form CMS-10055

INTERMEDIARY DETERMINATION OF NONCOVERAGE

NAME OF SNF
ADDRESS
DATE

TO: NAME
ADDRESS

RE: NAME OF BENEFICIARY
HICN
DATE OF ADMISSION

On (Date), the Medicare intermediary advised us that the services you receive will no longer qualify as covered under Medicare beginning (Date).

The Medicare intermediary will send you a formal determination as to the noncoverage of your stay after (Date). If you wish to appeal, the formal notice will contain information about how this can be done. The intermediary will inform you of the reason for denial and your appeal rights.

We regret that this may be your first notice of the noncoverage of services under Medicare. Our efforts to contact you earlier, in person or by telephone, were unsuccessful.

Please verify receipt of this notice by signing below.

Sincerely yours,

_____
Signature of Administrative Officer

VERIFICATION OF RECEIPT OF NOTICE

A. This acknowledges that I received this attached notice of noncoverage of services under Medicare on (date of receipt).

_____
(Signature of Beneficiary or Person
acting on Beneficiary's behalf

B. This is to confirm that you were advised of the noncoverage of the services under Medicare by telephone on (date of telephone contact).

_____
(Name of Beneficiary or
Representative contacted)

_____
(Signature of Administrative Officer)

KEEP A COPY OF THIS FOR YOUR RECORDS

UR COMMITTEE DETERMINATION OF ADMISSION

NAME OF SNF
ADDRESS
DATE

TO: NAME
ADDRESS

RE: NAME OF BENEFICIARY
HICN
DATE OF ADMISSION

On (Date), our Utilization Review Committee reviewed your medical information available at the time of, or prior to your admission, and advised us that the services (you or beneficiary's name) needed do not meet the requirements for coverage under Medicare. The reason is:

(Insert specific reason the services were determined to be noncovered.)

This decision has not been made by Medicare. It represents the Utilization Review Committee's judgment that the services you needed did not meet Medicare payment requirements. Normally, under this situation, a bill is not submitted to Medicare. A bill will only be submitted to Medicare if you request us to submit one. Furthermore, if you want to appeal this decision you must request that a bill be submitted. If you request a bill be submitted, the Medicare intermediary will notify you of its determination. If you disagree with that determination you may file an appeal.

You must also request that a bill be submitted to Medicare if you have questions concerning your liability for payment for the services you received.

Under a provision of the Medicare law, you do not have to pay for noncovered services determined to be custodial care or not reasonable or necessary unless you had reason to know the services were noncovered. You are considered to know that these services were noncovered effective with the date of this notice.

We regret that this may be your first notice of the noncoverage of services under Medicare. Our efforts to contact you earlier in person or by telephone were unsuccessful.

Please check one of the boxes below to indicate whether or not you want your bill submitted to Medicare and sign the notice to verify receipt.

Sincerely yours,

_____
Signature of Administrative Officer

REQUEST FOR MEDICARE INTERMEDIARY REVIEW

/ / A. I want my bill submitted to the intermediary for a Medicare decision. You will be informed when the bill is submitted.

If you do not receive a formal Notice of Medicare Determination within 90 days of this request you should contact: (Name and address of intermediary).

/ / B. I do not want my bill submitted to the intermediary for a Medicare decision.

I understand that I do not have Medicare appeal rights if a bill is not submitted.

NOTE: You are not required to pay for services until a Medicare decision has been made.

VERIFICATION OF RECEIPT OF NOTICE

C. This acknowledges that I received the notice of noncoverage of services under Medicare on (date of receipt).

_____
(Signature of Beneficiary or Person acting on Beneficiary's behalf)

D. This is to confirm that you were advised of the noncoverage of the services under Medicare by telephone on (date of telephone contact).

_____
(Name of Beneficiary or Representative contacted)

_____
(Signature of Administrative Officer)

KEEP A COPY OF THIS FOR YOUR RECORDS

UR COMMITTEE DETERMINATION ON CONTINUED STAY

NAME OF SNF
ADDRESS
DATE

TO: NAME
ADDRESS

RE: NAME OF BENEFICIARY
HICN
DATE OF ADMISSION

On (Date) our Utilization Review Committee reviewed your medical information and found that the services furnished (you or beneficiary's name) no longer qualified for payment by Medicare beginning (Date).

The reason for this is: (Insert specific reason services were determined to be noncovered).

This decision has not been made by Medicare. It represents the Utilization Review Committee's judgment that the services you needed no longer met Medicare payment requirements. A bill will be sent to Medicare for the covered services you received before (Date). Normally, the bill submitted to Medicare does not include services provided after this date. If you want to appeal this decision you must request that the bill submitted to Medicare include the services our URC determined to be noncovered. Medicare will notify you of its determination. If you disagree with that determination you may file an appeal.

Under a provision of the Medicare law, you do not have to pay for noncovered services determined to be custodial or not reasonable or necessary unless you had reason to know the services were noncovered. You are considered to know that these services were noncovered effective with the date of this notice.

We regret that this may be your first notice of the noncoverage of services under Medicare. Our efforts to contact you earlier in person or by telephone were unsuccessful.

Please check one of the boxes below to indicate whether or not you want the bill for services after (date) submitted to Medicare and sign the notice to verify receipt.

Sincerely yours,

_____
Signature of Administrative Officer

SNF DETERMINATION ON ADMISSION

NAME OF SNF
ADDRESS
DATE

TO: NAME
ADDRESS

RE: NAME OF BENEFICIARY
HICN
DATE OF ADMISSION

On (Date), we reviewed your medical information available at the time of, or prior to your admission, and we believe that the services (you or beneficiary's name) needed did not meet the requirements for coverage under Medicare. The reason is:

(Insert specific reason services are determined to be noncovered.)

This decision has not been made by Medicare. It represents our judgment that the services you needed did not meet Medicare payment requirements. Normally, under this situation, a bill is not submitted to Medicare. A bill will only be submitted to Medicare if you request that a bill be submitted. Furthermore, if you want to appeal this decision, you must request that a bill be submitted. If you request that a bill be submitted, the Medicare intermediary will notify you of its determination. If you disagree with that determination, you may file an appeal.

Under a provision of the Medicare law, you do not have to pay for noncovered services determined to be custodial care or not reasonable or necessary unless you had reason to know the services were noncovered. You are considered to know that these services were noncovered effective with the date of this notice.

If you have questions concerning your liability for payment for services you received prior to the date of this notice, you must request that a bill be submitted to Medicare.

We regret that this may be your first notice of the noncoverage of services under Medicare. Our efforts to contact you earlier in person or by telephone were unsuccessful.

Please check one of the boxes below to indicate whether or not you want your bill submitted to Medicare and sign the notice to verify receipt.

Sincerely yours,

_____
Signature of Administrative Officer

SNF DETERMINATION ON CONTINUED STAY

NAME OF SNF
ADDRESS
DATE

TO: NAME
ADDRESS

RE: NAME OF BENEFICIARY
HICN
DATE OF ADMISSION

On (Date), we reviewed your medical information and found that the services furnished (you or beneficiary's name) no longer qualified as covered under Medicare beginning (Date).

The reason is: (Insert specific reason services are considered noncovered.)

This decision has not been made by Medicare. It represents our judgment that the services you needed no longer met Medicare payment requirements. A bill will be sent to Medicare for the services you received before (Date). Normally, the bill submitted to Medicare does not include services provided after this date. If you want to appeal this decision, you must request that the bill submitted to Medicare include the services we determined to be noncovered. Medicare will notify you of its determination. If you disagree with that determination you may file an appeal.

Under a provision of the Medicare law, you do not have to pay for noncovered services determined to be custodial care or not reasonable or necessary unless you had reason to know the services were noncovered. You are considered to know that these services were noncovered effective with the date of this notice.

We regret that this may be your first notice of the noncoverage of services under Medicare. Our efforts to contact you earlier in person or by telephone were unsuccessful.

Please check one of the boxes below to indicate whether or not you want your bill submitted to Medicare and sign the notice to verify receipt.

Sincerely yours,

_____
Signature of Administrative Officer

Important: This notice explains your right to appeal our decision. Read this notice carefully. If you need help, you can call one of the numbers listed on the last page under "Get help & more information."

Notice of Denial of Medical Coverage

{Replace *Denial of Medical Coverage* with *Denial of Payment*, if applicable}

Date: **Member number:**

Name:

[Insert other identifying information, as necessary (e.g., provider name, enrollee's Medicaid number, service subject to notice, date of service)]

Your request was denied

We've {Insert appropriate term: *denied, stopped, reduced, suspended*} the {*payment of*} medical services/items listed below requested by you or your doctor [*provider*]:

Why did we deny your request?

We {Insert appropriate term: *denied, stopped, reduced, suspended*} the {*payment of*} medical services/items listed above because {Provide specific rationale for decision and include State or Federal law and/or Evidence of Coverage provisions to support decision}:

You have the right to appeal our decision

You have the right to ask {health plan name} to review our decision by asking us for an appeal [Insert Medicaid information, if applicable: *and or you can request a State Fair Hearing. You can ask for both types of review at the same time, as long as you meet the deadlines. If you ask us for an appeal first, you may miss the deadline for requesting a State Fair Hearing.*]:

Appeal: Ask {health plan name} for an appeal within **60 days** [Insert State Medicaid timeframe, if different] of the date of this notice. We can give you more time if you have a good reason for missing the deadline.

State Fair Hearing: *Ask for a State Fair Hearing within ( ) days of the date of this notice. You have up to ( ) days if you have a good reason for being late.*

If we're stopping or reducing a service, you can keep getting the service while your case is being reviewed. ***If you want the service to continue, you must ask for an appeal*** (Insert, if applicable: ***or a State Fair Hearing***) ***within 10 days*** *of the date of this notice or before the service is stopped or reduced, whichever is later. Your provider must agree that you should continue getting the service. If you lose your State Fair Hearing appeal, you may have to pay for these services.*

Form CMS 10003-NDMCP (Iss. 06/2013) OMB Approval 0938-0829

If you want someone else to act for you

You can name a relative, friend, attorney, doctor, or someone else to act as your representative. If you want someone else to act for you, call us at: {number(s)} to learn how to name your representative. TTY users call {number}. Both you and the person you want to act for you must sign and date a statement confirming this is what you want. You'll need to mail or fax this statement to us.

Important Information About Your Appeal Rights

There are 2 kinds of appeals

Standard Appeal – We'll give you a written decision on a standard appeal within **30 days** [Insert timeframe for standard Medicaid appeals, if different] after we get your appeal. Our decision might take longer if you ask for an extension, or if we need more information about your case. We'll tell you if we're taking extra time and will explain why more time is needed. If your appeal is for payment of a service you've already received, we'll give you a written decision within **60 days**.

Fast Appeal – We'll give you a decision on a fast appeal within **72 hours** after we get your appeal. You can ask for a fast appeal if you or your doctor believe your health could be seriously harmed by waiting up to 30 days for a decision.

We'll automatically give you a fast appeal if a doctor asks for one for you or supports your request. If you ask for a fast appeal without support from a doctor, we'll decide if your request requires a fast appeal. If we don't give you a fast appeal, we'll give you a decision within 30 days.

How to ask for an appeal with {health plan name}

Step 1: You, your representative, or your doctor [*provider*] must ask us for an appeal [*or State Fair Hearing*]. Your {*written*} request must include:

- Your name
- Address
- Member number
- Reasons for appealing
- Any evidence you want us to review, such as medical records, doctors' letters, or other information that explains why you need the item or service. Call your doctor if you need this information.

[Insert, if applicable: *You can ask to see the medical records and other documents we used to make our decision before or during the appeal. At no cost to you, you can also ask for a copy of the guidelines we used to make our decision.*]

Step 2: Mail, fax, or deliver your appeal {*or call us*}.

For a Standard Appeal: Address:
{Phone:} Fax:

{Insert, if applicable: *If you ask for a standard appeal by phone, we will send you a letter confirming what you told us.*}

For a Fast Appeal: Phone: Fax:

Form CMS 10003-NDMCP (Iss. 06/2013) OMB Approval 0938-0829

What happens next?

If you ask for an appeal and we continue to deny your request for {*payment of*} a service, we'll send you a written decision and automatically send your case to an independent reviewer. **If the independent reviewer denies your request, the written decision will explain if you have additional appeal rights.**

[Insert additional State-specific Medicaid rules, as applicable.]

How to ask for a Medicaid State Fair Hearing

[You have the right to ask for a State Fair Hearing without asking us (health plan) to review our decision first.]

Step 1: *You or your representative must ask for a State Fair Hearing (in writing) within ( ) days of the date of this notice. You have up to ( ) days if you have a good reason for your request being late.*

Your {written} request must include:

- Your name
- Address
- Member number
- Reasons for appealing
- Any evidence you want us to review, such as medical records, doctors' letters, or other information that explains why you need the item or service. Call your doctor if you need this information.

Step 2: *Send your request to:* Address:
Phone: Fax:

What happens next?

The State will hold a hearing. You may attend the hearing in person or by phone. You'll be asked to tell the State why you disagree with our decision. You can ask a friend, relative, advocate, provider, or lawyer to help you. You'll get a written decision within ( ) days. The written decision will explain if you have additional appeal rights.

[A copy of this notice has been sent to:]

Get help & more information

- {Health Plan Name} Toll Free: TTY users call:
  {Insert plan hours of operation}
- 1-800-MEDICARE (1-800-633-4227), 24 hours, 7 days a week. TTY users call: 1-877-486-2048
- Medicare Rights Center: 1-888-HMO-9050
- Elder Care Locator: 1-800-677-1116
- [Medicaid/State contact information]

Form CMS 10003-NDMCP (Iss. 06/2013) OMB Approval 0938-0829