The Medicare (and other) Appeals Process

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Contractor/Auditor Overview

- **Medicare**
  - Medicare Administrative Contractors (MACs)
    - Targeted Probe and Education (TPE)
  - Qualified Improvement Organizations (QIOs)
  - Comprehensive Error Rate Testing (CERT)
  - Unified Program Integrity Contractors (UPICs)
    - Combined duties previously performed by Zone Program Integrity Contractor (ZPIC), Program Safeguard Contractor (PSC) and Medicaid Integrity Contractor (MIC) contracts
  - Recovery Audit Contractors (RACs)
  - Supplemental Medical Review Contractor (SMRC)
  - Office of Inspector General (OIG) audits
- **Commercial Payors**
  - Typically Special Investigation Units/Fraud Investigation Units

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Medicare Overpayment Determination – Prior to Appeal

- **Medical Records Request Letter**
  - Providers/leadership may not recognize the importance of responding to these request letters.
- **Notice of Payment Suspension and/or Pre-Payment Review**
  - This letter may follow an unfavorable determination by the contractor. Providers have an opportunity to respond.

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Shared Burden to Provide Documentation?

- The burden rests with the "provider, supplier, or beneficiary, as appropriate, [to] furnish to the [contractor] sufficient information to determine whether payment is due and the amount of payment." 42 CFR § 424.5(a)(6); see also Social Security Act § 1833(e).
- Our initial request for information is made to the entity submitting the claim. That entity should submit whatever documentation it has in support of the claim. If the documentation provided by the entity submitting the claim does not demonstrate that the service is reasonable and necessary, we will take the following action: (1) Provide the ordering physician information sufficient to identify the claim being reviewed; (2) request from the ordering physician those part of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed; and (3) if the ordering physician does not supply the documentation requested, inform the entity submitting the claim(s) that the documentation has not been supplied and deny the claim.
  - Source: Medicare Program; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services, Final Rule, 66 Fed. Reg. 58788, 58800 (Nov. 23, 2001)
- Federal regulations (42 CFR Part 2) and state law may preclude access to medical records.
  - Part 2's restrictions are even more stringent than HIPAA

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Targeted Probe and Educate (TPE)

- New Audit Strategy
  - Initially launched as a pilot program
  - In 2017, TPE expanded to all MACs
- Focus of TPE audits:
  - Providers and suppliers with a history of high claim error rates or unusual billing practices
  - Items and services that have a high national error rate

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Targeted Probe and Educate (TPE)

- TPE Process – "Three strikes and you're out"
  - Provider receives an initial notification letter – "Notice of Review"
    - Letter explains the reason the provider or supplier was selected for TPE audit
  - The MAC will request to review the records of 20 to 40 claims
    - If the documentation is compliant, the provider or supplier will be removed from the TPE process and the MAC will not review the provider or supplier on the selected topic for at least one year (except if there are significant billing changes)
    - If the MAC detects claim errors, it will offer the provider or supplier a one-on-one education session with the MAC's provider outreach and education staff.
      - After one-on-one, the provider or supplier will be given at least 45 days to improve their billing and documentation.
      - After 45 day period, the MAC will initiate a second record review.
      - If the provider or supplier continues to have a certain error rate after three reviews, the MAC will refer the provider or supplier to CMS for additional action (e.g., prepayment review, extrapolation of overpayment, referral to a RAC, revocation, etc.)

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Targeted Probe and Educate (TPE)

- CGS (J15 HH, JB DME, J15 Part A/B)
  - Part B:
    - Labs and other tests
- First Coast Service Options (JN Part A/B)
  - Part B:
    - Clinical Labs (G0480-G0483: Drug test(s), definitive)
- Practice Tips
  - Communicate with the MAC throughout the process
  - Timely submit the requested records
  - TPE reviews and overpayment determinations may be appealed through the Medicare appeal process.

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Medicare Overpayment Determination – Prior to Appeal

- **Post payment review results and determination of Overpayment Letter**
  - This letter is not a demand for overpayment, but explains the contractor's determination.
- **Overpayment Demand Letter**
  - Following the determination letter, providers receive an Overpayment Demand letter. This starts the clock with respect to the appeals process.
- **Provider Rebuttal**
  - 15 days to file the rebuttal in order to halt recoupment.

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Medicare Appeals Process

1. Request for Redetermination with MAC
2. Request for Reconsideration with QIC
3. Request for Administrative Law Judge (ALJ) Hearing
4. Medicare Appeals Council
5. Federal District Court

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Latest Policy and Regulatory Changes to the Medicare Appeals Process

Overview of the Final Rule and Considerations for Practitioners and Appellants

- **Submission of New Evidence**

•42 C.F.R. 405.1028: Submission and Examination of New Evidence
  - Good cause requirement
  - If no good cause, the evidence is excluded from the record and not considered in reaching a decision.

•Revised regulations reinforce the good cause requirement and clarify circumstances for finding good cause.

•Purpose of the new regulations:
  - To clearly indicate that providers and suppliers should submit all evidence that is relevant to their appeal as early as possible in the appeal process and to clarify instances where an ALJ or attorney adjudicator may find good cause for introduction of new evidence at the OMHA level.

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Latest Policy and Regulatory Changes to the Medicare Appeals Process

Overview of the Final Rule and Considerations for Practitioners and Appellants

- **CMS Contractor Participation in ALJ Proceedings**

•Regulations permit CMS and CMS contractors to participate in ALJ hearings
  42 C.F.R. 405.1010: When CMS or its contractors may participate in an ALJ hearing;
  42 C.F.R. 405.1012: When CMS or its contractors may be a party to a hearing;

•Newly revised regulations: limit participation in ALJ hearings to either CMS or a single CMS contractor, unless ALJ finds that participation of both parties are necessary.

•If multiple CMS entities file for participation in an ALJ hearing where one party is eligible, "only the first entity to file a response to the notice of hearing…may participate in the oral hearing."

•CMS and/or multiple contractors may submit position papers or other written testimony for the ALJ hearing without limitation.

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Reforms – Expanded SCF Program

- Expanded Settlement the Conference Facilitation (SCF) program earlier this year
- SCF **Appellant** Eligibility Criteria:
  - Medicare provider or supplier with a NPI and PTAN
  - 25 or more SCF eligible appeals pending at OMHA and the Council combined; or less than 25 SCF eligible appeals pending at OMHA or the Council and at least one appeal has more than $9,000 billed charges.
  - Appellant cannot have filed for bankruptcy and/or expect to file for bankruptcy
  - Appellant may be excluded if Appellant has or had False Claims litigation or investigations pending against them, or other program integrity concerns.

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Latest Policy and Regulatory Changes to the Medicare Appeals Process – Expanded SCF Program

SCF **Appeals** Eligibility Criteria

- Request for ALJ hearing or Council review filed on or before March 31, 2019, arising from Medicare Part A or Part B QIC reconsideration decision.
- Jurisdictional requirements for OMHA or Council review must be met;
- Appeals must not be scheduled for an ALJ hearing or an ALJ hearing must not have been conducted;
- Billed amount of each individual claim must be $1 million or less. If statistical sample, the extrapolated overpayment amount stated in the initial demand must be $1 million or less
  - Settlement agreements over $100K will be subject to DOJ approval
- Appeal must not be involved with Statistical Sampling Initiative or actively engaged in another CMS Medicare Appeals initiative available March 31, 2019, e.g. LVA, QIC Demonstration project, etc.
- Beneficiary must not have been found liable after the initial determination or participated in the reconsideration.
- Appeal must not involve items, services, drugs, or biologicals billed under unlisted, unclassified, or miscellaneous codes.
- Appeals must not involve payment disputes.
- Appeals can not arise from QIC or ALJ dismissal order.

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Latest Policy and Regulatory Changes to the Medicare Appeals Process – Expanded SCF Program

SCF Express v. Settlement Conference

SCF Express:

- CMS provides a settlement offer based on preliminary data (e.g. ALJ overturn rates, type of claim or service, etc.)
- Only appellants with appealed claims that have billed amount(s) or an extrapolated overpayment of $100K or less are eligible for SCF express.
- Appellant has 7 days to accept or decline CMS' offer. If appellant declines the offer, the case will proceed to a settlement conference.

Settlement Conference:

- Pre-settlement conference
- If billed amounts or extrapolated overpayment is $100K or less, if an agreement is reached, both parties will sign the agreement the day of the conference.
- If billed amounts of extrapolated overpayment is $100K or more, the facilitator will draft proposed agreement and it is subject to DOJ approval before the parties can execute the agreement.

If no agreement is reached, the appeals will return to the previously assigned adjudicator, if applicable, or to the OMHA and Council docket for future assignment in the order in which the request for review was received.

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Latest Policy and Regulatory Changes to the Medicare Appeals Process – Statistical Sampling Initiative

- Alternative method for resolving large numbers of appealed claims
  - OMHA-procured statistician pulls a random sample of claims
  - Random assignment of Administrative Law Judges
    - 250-750 claims: panel of 2 ALJs
    - 750 claims or more: panel of 3 to 4ALJs
  - Outcomes are extrapolated to the universe of appealed claims
- Currently available for providers with at least 250 *claims* pending at OMHA, all in one of the following categories:
- Pre-payment claim denials; or
- Post-payment (overpayment) non-RAC claim denials; or
- Post-payment (overpayment) RAC claim denials from a single RAC

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Latest Policy and Regulatory Changes to the Medicare Appeals Process – Statistical Sampling Initiative

- *Requesting Statistical Sampling*
  - Complete a written request for statistical sampling and a spreadsheet providing detailed information about the claims to be considered for the sampling process
  - Submit written consent to the use of statistical sampling

❖ *Practice Tips*

- Initial statistics
- Prehearing conference
- Number of judges
- Interplay with SCF

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Medicare Advantage (Part C) Plan Appeals

- **Participating providers**
  - Appeals process determined by contract between provider and Medicare Advantage Organization
  - Internal and external review process
- **Non-participating providers**
  - Process governed by CMS
  - A non-contracted provider, on his or her own behalf, is permitted to file a standard appeal for a denied claim only if the provider completes a waiver of liability statement, which provides that the provider will not bill the enrollee regardless of the outcome of the appeal. *Medicare Managed Care Manual (chapter 13)*.
  - Appeals Process:
    - Organization determination
    - Health Plan reconsideration
    - Independent Review Entity (IRE) reconsideration
    - Administrative Law Judge Hearing
    - Medicare Appeals Council
    - Federal District Court
- Member (beneficiary) appeals (w/ provider representative)

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Medicaid/Medicaid Managed Care Appeals

- Medicaid
  - Varies by state
  - Typically set forth in each state's Medicaid laws/rules and/or Administrative Procedure Act
  - Generally, process includes internal written appeal followed by administrative hearing
- Medicaid Managed Care
  - "Each Medicaid managed care organization shall establish an internal grievance procedure under which an enrollee who is eligible for medical assistance under the State plan under this subchapter, or a provider on behalf of such an enrollee, may challenge the denial of coverage of or payment for such assistance"
    - *42 U.S.C. §1396u-2(b)(4)*
  - "A State plan for medical assistance must provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness"
    - *42 U.S.C. §1396a(a)(3)*
  - Medicaid Managed Care – "Grievance System"
    - 42 CFR §§ 438.400-438.424

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Commercial Payor Audits

- Appeals process is typically based on the payor's policies and procedures and/or payor contract.
- Often begins with a request for information/records request
- Overpayment determination and demand is in one letter
- There may or may not be strict response deadlines – be sure to check policies/contract to ensure deadlines aren't missed.
- Typically flexibility if negotiating

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Medical Necessity Documentation

- Definition of Medical Necessity: 42USC 1395y(a) "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services –(1)(A) which, except for items and services described in succeeding subparagraphs, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member…"
- State definitions vary by state
- Upon request for review, it is the BILLING provider's responsibility to obtain supporting documentation from a referring physician's office or from an inpatient facility - CMS MPIM Ch. 3 Section 3.2.3.3
- Insufficient documentation errors
  - Incomplete progress notes (i.e. unsigned, undated, insufficient detail)
  - Unauthenticated medical records (i.e. no signature or invalid signature)

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Covered Service - Diagnostic Tests

- Medicare Part B will cover "medical and other health services" which includes "diagnostic services" and "diagnostic laboratory tests." Social Security Act §§ 1832(a)(2)(B), 1861(s)(2)-(3).
- Excluded from coverage are services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1)(A); 42 CFR § 411.15(k)(1).

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Covered Service – Diagnostic Tests

- **42 CFR § 410.32**
  - (a) - 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. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.
  - (b)(1) - Basic rule. Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Services furnished without the required level of supervision are not reasonable and necessary (see §411.15(k)(1) of this chapter).

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Medical Necessity

- **Medicare Program Integrity Manual – Chapter 13**
  - Section 13.3 – Individual Claim Determinations
    - When making individual claim determinations, the contractor shall determine whether the item or service in question is covered by based on an LCD or the clinical judgment of the medical reviewer.
    - An item or service may be covered by a contractor if it meets all of the conditions listed § 13.5.1, Reasonable and Necessary Provisions in LCDs
  - Section 13.5.1 – Reasonable and Necessary Provisions in LCDs
    - An item or service may be covered by a contractor LCD if:
      - It is reasonable and necessary under 1862(a)(1)(A) of The Act. Only reasonable and necessary provisions are considered part of the LCD.

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Medical Necessity

Medicare Program Integrity Manual – Chapter 13

Section 13.5.1 – Reasonable and Necessary Provisions in LCDs

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

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Medical Necessity

Medicare Program Integrity Manual – Chapter 13

Section 13.7.1 – Evidence Supporting LCDs

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

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Toxicology Laboratory Audits

- Basic concepts of Drug Testing
  - Qualitative Drug Test – testing used to detect the presence of a drug in the body; can use either blood or urine sample
  - Presumptive UDT – used when medically necessary to determine the presence or absence of drugs or drug classes
    - Methods include CLIA-waived platforms (cards, dipsticks, cups), FDA Approved Analysis, Laboratory Developed Test
  - Definitive UDT – used when medically necessary to identify specific medications, illicit substances and metabolites; reports results of drugs absent or present in concentrations of ng/ml.
    - Methods include High Performance Liquid Chromatography coupled with Tandem Mass Spectrometry (LC-MS/MS)
  - Drugs or classes of drugs commonly assayed by qualitative tests, followed by confirmation with a second method, are: alcohols, amphetamines, barbiturates/sedatives, benzodiazepines, cocaine and metabolites, methadone, antihistamines, stimulants, opioid analgesics, salicylates, cardiovascular drugs, antipsychotics, cyclic antidepressants, and others.

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Toxicology Laboratory Audits

- Reimbursement Issues
  - Medical Necessity
  - Documentation
  - Orders
  - Coding
  - Physician Signatures and Attestations
  - Compliance with **the controlling** Local Coverage Determinations
  - Frequency / Utilization
  - State law / Medicaid frequency requirements
- Audit / Appeal Strategies
  - Ensure Documentation
  - Valid Signatures
  - Retaining expert witness
  - Attack statistical sampling (if applicable)
  - Early presentation of evidence; develop arguments as early as possible; before ALJ hearing at QIC and contractor levels of appeal.

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Toxicology Laboratory Audits

Valid Physician Order

- Per 42 CFR 410.32, all diagnostic tests, including diagnostic laboratory tests, must be ordered by the physician who is treating the beneficiary for a specific medical problem and uses the results in the management of the beneficiary's specific medical problem.
- Medicare Benefit Policy Manual, Chapter 15, Section 80.6 defines an order as:
  - " [A] communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/practitioner (e.g., if test X is negative, then perform test Y). An order may be delivered via the following forms of communication:
    - A written document signed by the treating physician/practitioner, which is hand delivered, mailed, or faxed to the testing facility; NOTE: No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services;
    - A telephone call by the treating physician/practitioner or his/her office to the testing facility; and
    - An electronic mail by the treating physician/practitioner or his/her office to the testing facility.
  - If the order is communicated via telephone, both the treating physician/practitioner or his/her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records. While **a physician order is not required to be signed**, the physician must clearly document, in the medical record, his or her intent that the test be performed." (**emphasis** added)

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Toxicology Laboratory Audits – Novitas Solutions, Inc. LCD for Qualitative Drug Testing (L32050)

- Novitas Solutions, Inc. LCD for Qualitative Drug Testing (L32050)
  - Original Effective Date: 11/11/11
  - Retired 9/30/15
- Indications
- Documentation Requirements
- Limitations of coverage

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Toxicology Laboratory Audits – Novitas Solutions, Inc. LCD for Controlled Substance Monitoring and Drugs of Abuse Testing (L35006)

- LCD for Controlled Substance Monitoring and Drugs of Abuse Testing (L35006)
  - Original Effective Date: 10/1/15
  - Revision Effective Date: 3/8/18
- Presumptive UDT v. Definitive UDT
- Indications
- Diagnosis and treatment for substance abuse or dependence
- Treatment for patients on chronic opioid therapy
- Covered and non-covered services
- Documentation requirements
- Utilization guidelines

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Genetic Testing – Issues in Reimbursement

- Is the Genetic Test:
  - A Covered Service?
  - Medically Necessary and Reasonable?
  - Documented?
    - Physician Order / Requisition
    - Physician Attestation
    - Supporting Medical Records
  - Covered by an LCD?
  - Indicated?
  - Subject to the MolDX Program?
  - Assigned a CPT Code(s)?
  - Other Payer Requirements?

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Genetic Testing- Palmetto GBA-MolDX

Molecular Diagnostic Services Program – MolDX

- The purpose of the MolDX program is to identify tests, determine coverage, and determine reimbursement.
- MolDx recognizes that molecular diagnostic tests "present challenges because the Clinical Laboratory Fee Schedule pricing methodology does not account for the unique characteristics of these test."
- To establish consistency in coverage and pricing decisions for molecular diagnostic tests, laboratories must bill with the correct CPT/HCPCS code and must also apply for and obtain a unique test identifier prior to billing for most molecular diagnostic tests.
- Currently implemented in 7 Medicare jurisdictions
  - JE A/B MAC (California, Nevada, Hawaii and the US Pacific Territories of Guam, American Samoa and the Northern Marianas) administered by Noridian Healthcare Solutions
  - JF A/B MAC (Oregon, Washington, Idaho, Utah, Montana, Wyoming, Nevada, Arizona, North Dakota, South Dakota, Alaska, and the Aleutian Islands) administered by Noridian Healthcare Solutions
  - JM A/B MAC (North Carolina, South Carolina, Virginia, and West Virginia) administered by Palmetto GBA
  - J5 A/B MAC (Iowa, Kansas, Missouri, and Nebraska) administered by WPS Government Health Administrators
  - J8 A/B MAC (Michigan and Indiana) administered by WPS Government Health Administrators
  - J15 A/B MAC (Ohio and Kentucky) administered by CGS Administrators, LLC
  - JJ MAC (Georgia, Tennessee, and Alabama) administered by Palmetto GBA
- Labs that perform services for patients in the above-listed jurisdictions have been notified to begin DEX Z-Code registration. Claims submitted after June 1, 2018, must have a Z-Code.

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Genetic Testing- Local Coverage Determinations

- Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36161)
  - Original Effective Date: 4/15/2016
- Local Coverage Determination (LCD): Biomarkers Overview (L35062)
  - Original Effective Date: 10/1/2015
- Important Considerations:
  - Coverage Indications
  - Limitations on Coverage
  - Coding Information
    - CPT/HCPCS Codes
    - ICD-9/ICD-10 Codes that Support Medical Necessity
  - Documentation Requirements

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Genetic Testing – Next Generation Sequencing (NGS)

CMS Decision Memo for NGS for Medicare Beneficiaries with Advanced Cancer (CAG-00450N) (3/16/18)

- CMS determined that NGS as a diagnostic laboratory test is reasonable and necessary and covered nationally, when performed in a CLIA-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:
- Patient has:
  1. either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and
  2. either not been previously tested using the same NGS test for the same primary diagnosis of cancer or repeat testing using the same NGS test only when a new primary cancer diagnosis is made by the treating physician; and
  3. decided to seek further cancer treatment (e.g., therapeutic chemotherapy).
- The diagnostic laboratory test using NGS must have:
  1. FDA approval or clearance as a companion in vitro diagnostic; and
  2. an FDA approved or cleared indication for use in that patient's cancer; and
  3. results provided to the treating physician for management of the patient using a report template to specify treatment options.

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Additional Defenses for Laboratories

Provider Without Fault

- Social Security Act section 1870 provides that an overpayment to an individual will not be adjusted or recovered if that payment is to "an individual who is without fault" if that adjustment or recovery would "defeat the purposes [of the Act] or would be against equity and good conscience."
- A provider will be considered without fault if it complied with all pertinent regulations, made full disclosure of all material facts, and, on the basis of the information available, had a reasonable basis for assuming that the payment was correct.
- "Fault" is defined by the federal regulations as:
  - (a) An incorrect statement made by the individual which he knew or should have known to be incorrect; or
  - (b) Failure to furnish information which he knew or should have known to be material; or
  - (c) With respect to the overpaid individual only, acceptance of a payment, which he knew or could have been expected to know, was incorrect.
- *In re AMC Clinical Laboratory, Inc,* ALJ Dec. No. 000-99-0690 (Health and Human Serv. Feb. 28 1990)
  - ALJ held that section 1870 of the Act and its associated regulations applied to an independent clinical laboratory, and that the lab's lack of fault in performing non-medically necessary tests entitled it to retain alleged overpayments from Medicare.

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Additional Defenses for Laboratories

- Waiver of Liability
  - Section 1879 of the Social Security Act:
    - (a) Where –
      - [1] a determination is made that … payment may not be made under Part A or Part B of this title for any expenses incurred for items or services furnished an individual by a provider of services …; and
      - [2] both such individual and such provider of services … **did not know, and could not reasonably have expected to know**, that payment would not be made for such items or services under Part A or B,
      - then to the extent permitted by this title, **payment shall, notwithstanding such determination, be made for such items or services** ….

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Additional Defenses for Laboratories

- Waiver of Liability, cont'd
  - There is a presumption that a provider is unaware that services would not be covered, which can be rebutted by notice from the fiscal intermediary that services will not be covered or by demonstrating that it was "clear and obvious that the provider should have known" that services would not be covered. 42 U.S.C § 1395pp(f).
  - A provider **cannot** claim waiver when it has received notice from the carrier, notice from the utilization review committee, or knowledge that the service will not be covered based on experience, actual notice or constructive notice. 42 C.F.R. § 411.406.
  - Notice may be demonstrated by receipt of written CMS notices and bulletins, Federal Register publications or "knowledge of what are considered acceptable standards of practice by the local medical community." *Id.*

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Additional Defenses for Laboratories

- *United States v. Boston Heart Diagnostics Corporation*, 2017 U.S. Dist. LEXIS 202982.
  - The issue was whether a lab had false claims liability for performing services ordered by a treating physician.
  - The Court stated "Upon review of HHS's explanations of the regulation, the Court concludes that HHS's view supports the Court's conclusion that, although laboratories, as the entity submitting a claim for payment, are required by statute to certify the medical necessity of the tests at issue, see id. ('[A]ll entities that bill the Medicare program are held liable when they bill for services and are not able to produce documentation of the medical necessity of the service.'), neither the Medicare statute nor the regulation regarding laboratories require laboratories to independently determine the medical necessity of the tests billed."

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60 Day Rule/Reverse False Claims

60-Day Final Rule – Interplay between Overpayments and Audits

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

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

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60 Day Rule/Reverse False Claims

60-Day Final Rule

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

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

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

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Case Study – Medical Necessity

- Background: A doctor ordered genetic testing. The laboratory took the position that regardless of LCD L36310 or the literature, the laboratory does not make medical necessity determinations and is entitled to rely on the treating physicians' determination of medical necessity; thus, the laboratory is entitled to payment, citing *Boston Heart.*
- As cited by the Court in *Boston Heart,* the Final Rule explains:
  - Section 1862(a)(1)(A) of the Act provides that, notwithstanding any other provision of the Act, payment may not be made for services that are not reasonable and necessary for the diagnosis or treatment of illness or injury. Presently, all entities that bill the Medicare program are held liable when they bill for services and are not able to produce documentation of the medical necessity of the service. Although the [Negotiated Rulemaking] Committee discussed at length the special circumstances related to laboratories, which frequently do not have direct contact with the patient, the Committee recognized that the law does not provide the authority to exempt laboratories from the provision related to medical necessity.

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American Hospital Association, et al. v. Azar, 2018 U.S. Dist. Lexis 186853 (D.D.C. 2018)

•Procedural History:

- Filed in 2014 by AHA and a group of hospitals
- U.S. District Court to the U.S. Court of Appeals to the U.S. District Court
- On November 1, 2018, U.S. District Court ordered HHS to clear the Medicare backlog by the end of 2022. HHS must reduce the current backlog according to the following timetable:
  - FY 2019-19%
  - FY 2020- 49%
  - FY 2021- 75%
  - FY 2022- eliminate backlog

•The Court found the reduction and then elimination of the backlog possible because Congress appropriated $182.3 million in March 2018 for the purpose of addressing the backlog. HHS can request the Court to modify the order if funding is reduced such that it would be impossible to comply with the timetable.

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Significant Cases

Hospice Savannah, Inc. v. Burwell, 4:15-cv-00253-JRH-GRS, 2015 U.S. Dist. LEXIS 125970 (S.D. Ga. September 21, 2015)

•Plaintiff is a non-profit hospice.

•AdvanceMed found that the hospice received an extrapolated overpayment of $8.6 million, which was upheld at the redetermination and reconsideration levels of appeal.

•CMS sought to recoup 100% of the hospice's current and future Medicare payments while its request for an ALJ hearing was pending.

•District Court granted a temporary restraining order in favor of the hospice, enjoining CMS from withholding, recouping, offsetting, or otherwise failing to pay the hospice for any current Medicare receivables.

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Significant Cases

Family Rehabilitation, Inc. v. Azar, No. 17-11337 (5th Cir. Mar. 27, 2018)

•Family Rehab filed a lawsuit for an injunction against recoupment after it lost at the first two levels of appeal.

•The Fifth Circuit overturned a District Court decision dismissing Family Rehabilitation's suit for lack of subject matter jurisdiction.

•The Fifth Circuit found that the request to stay recoupment was a "collateral claim," meaning it was not related to the merits of the underlying appeal, and the district court could stay recoupment pending the ALJ hearing.

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Significant Cases

Adams EMS, Inc. v. Azar, 4:18-cv-01443-H (S.D. Tex. July 11, 2018)

- Adams EMS filed a temporary restraining order seeking suspension of recoupment while its appeal was pending at the ALJ level. It argued that allowing HHS to recoup while it "has been entirely deprived of its right to pursue a meaningful administrative appeal of its overpayment" violates due process.
- Court determined that Adams EMS had a property interest in its earned Medicare payments and found that it would be irreparably harmed without injunctive relief.

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Questions?

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