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National Government Services

NGS Medicare Virtual Conference

Fall 2021

Laboratory Compliance

11/9/2021

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Today's Presenters

- NGS Provider Outreach and Education
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  - Nathan L Kennedy Jr, CHC, CPC,CPPM, CPB, CPMA, AAPC Approved Instructor

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Objectives

- Recognize coding problems and issues and adopting appropriate claim submissions management system
- Understand your compliance role in laboratory billing to reduce or eliminate improper claim submissions to prevent appeals, fraud and abuse from occurring

Agenda

- Introduction and overview
- Clinical Laboratory Improvement Act
- Codes and modifiers
- Medicare Coverage Database
- National Coverage Determinations
- Specimen Collections

Laboratory Types

- Clinical Laboratory Services
  - Clinical laboratory services involve examination of samples obtained from human body for interpretation of medical condition and to make decision for its prevention, diagnosis, and treatment
- Diagnostic Laboratory Services
  - Diagnostic laboratory services are different from simple clinical tests. Clinical tests require a pathologist and lab technician to run and interpret samples whereas, diagnostic tests require a physician or other certified professional to perform the same

Laboratory Types

- Just like the type of lab services are different, types of labs themselves, are also different
- When working with primary physician, there may be some amount of lab testing
- If the physician's office has a certified lab, then providers may bill for significant number of lab procedures including E/M services

Laboratories Performing Lab Tests

- Independent Laboratories
  - Operate independently out of physician's office, a hospital, or any external facility are termed as Independent laboratories
- Physician Office Laboratories
  - Operate within physician's office, to perform testing procedures are referred to as physician office labs
- Clinical Laboratories
  - Specialties utilize different biological tests to determine a patient's medical condition by using specimens obtained from them and also referred to as CLIA labs

Laboratories Performing Lab Tests

- Referring Laboratories
  - Labs that receives specimen for testing purposes but further refers to sample for testing to different lab is termed as referring labs
- Reference Laboratories
  - Labs that receive referred sample from referring laboratory are known as reference labs. They can also be considered as a type of physician office labs as they depend upon an external facility to perform testing
- Medicare-Approved Laboratories
  - Labs meet the criteria laid down by Medicare, and are quite popular among providers. They also have CLIA certification which makes them the first choice for referring labs, hospitals and other physician practices

Laboratory Written Orders

- All tests must have written order on file
- Any verbal order for tests including tests added on to specimen already in lab, must be followed by written order
- Only appropriate tests actually performed may be billed

Clinical Laboratory Improvement Act

Clinical Laboratory Improvement Act

- CLIA mandates and regulates laboratories that test patient specimens and ensures laboratories produce accurate and reliable test results
  - Certificate of Waiver (COW)
  - Certificate for Provider Performed Microscopy Procedures (PPMP)
  - Certificate of Registration (COR)
  - Certificate of Compliance (COC)
  - Certificate of Accreditation (COA)

CLIA Waived

- Waived laboratories must
  - Enroll in the CLIA program
  - Pay applicable certificate fees every two years
  - Follow manufacturer's test instructions
    - Enter CLIA in item 23
- Clinical Laboratory Improvement Amendments (CLIA)

80000-89999: Pathology/Laboratory Services

- 80047–80081: Organ or Disease Oriented Panels
- 80150–80299: Therapeutic Drug Assays
- 80305–80377: Drug Assay Procedures
- 80400–80439: Evocative/Suppression Testing Procedures
- 80500–80502: Clinical Pathology Consultations
- 81000–81099: Urinalysis Procedures
- 81105–81479: Molecular Pathology Procedures
- 81410–81471: Genomic Sequencing Procedures and Other Molecular Multi analyte Assays
- 81490–81599: Multi analyte Assays with Algorithmic Analyses
- 82009–84999: Chemistry Procedures

80000-89999: Pathology/Laboratory Services

- 85002–85999: Hematology and Coagulation
- 86000–86849: Immunology
- 85850–86999: Transfusion Medicine
- 87003–87999: Microbiology
- 88000–88099: Anatomic Pathology
- 88104–88199: Cytopathology
- 88230–88299: Cytogenetic Studies

80000-89999: Pathology/Laboratory Services

- 88300–88399: Surgical Pathology
- 88720–88749: In Vivo (Transcutaneous) Lab Procedures
- 89049–89240: Other Procedures
- 89250–89398: Reproductive Medicine Procedures
- 0001U–0017U: Proprietary Laboratory Analyses

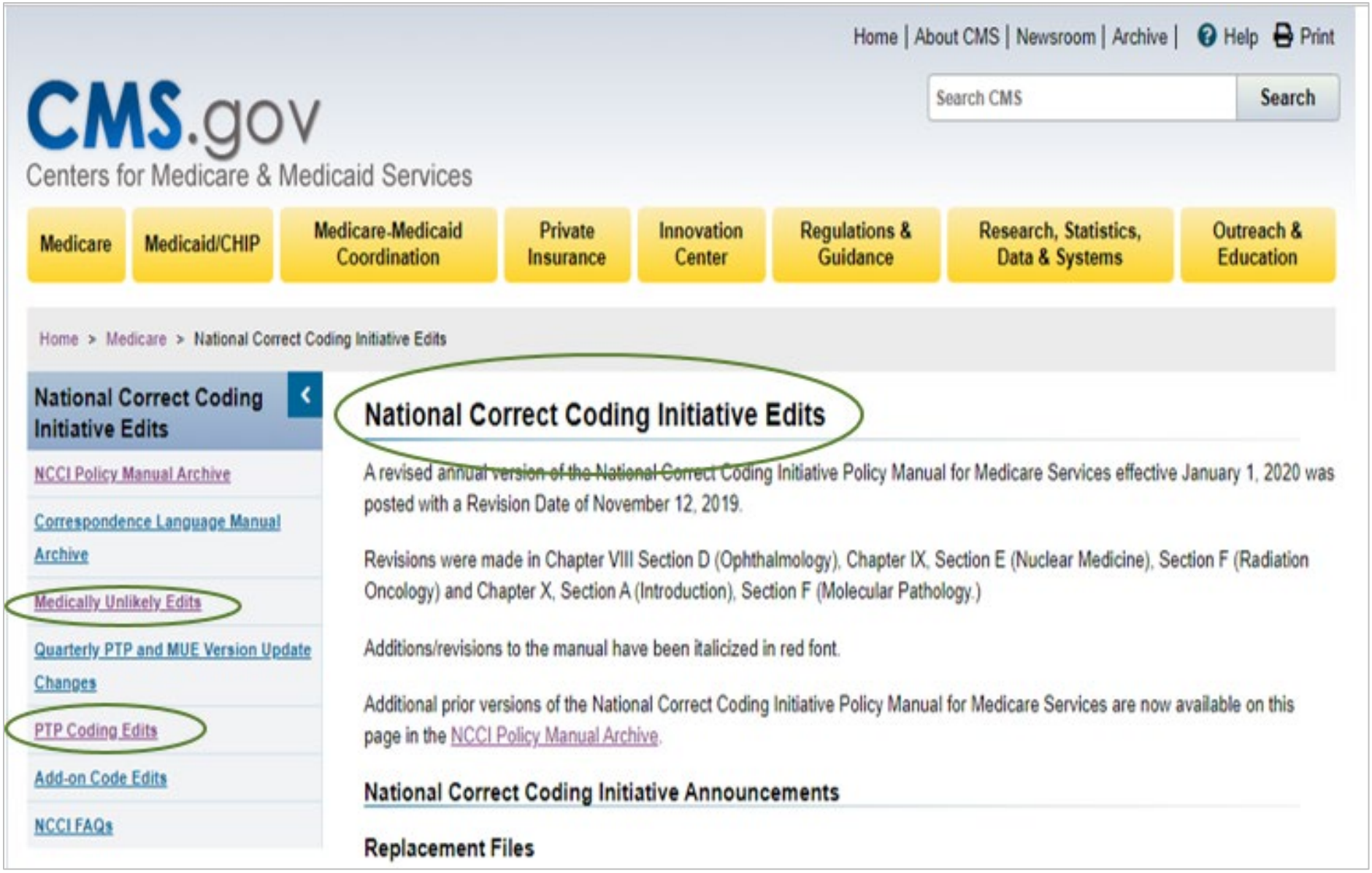
Introduction and Overview

- Clinical laboratory services must be
  - Approved by provide specific type of test being performed
  - Ordered promptly by physician or qualified non physician practitioner treating patient
  - Reasonable and necessary

Introduction and Overview

- Outpatient clinical laboratory services are
  - Paid on fee schedule
  - Participating laboratory
  - Ordered by physician or qualified nonphysician practitioner
  - Must accept assignment
  - Neither the annual deductible nor the 20% coinsurance applies to
    - Clinical laboratory tests performed by a physician, laboratory, or other entity paid on an assigned basis
    - Specimen collection fees
    - Travel allowance related to laboratory tests (e.g., collecting specimen)

Medically Unlikely Edits and Correct Coding Initiative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Medically Unlikely Edits
Quarterly PTP and MUE Version Update Changes
PTP Coding Edits
Add-on Code Edits
NCCI FAQs
National Correct Coding Initiative Edits
A revised annual version of the National Correct Coding Initiative Policy Manual for Medicare Services effective January 1, 2020 was posted with a Revision Date of November 12, 2019.
Revisions were made in Chapter VIII Section D (Ophthalmology), Chapter IX, Section E (Nuclear Medicine), Section F (Radiation Oncology) and Chapter X, Section A (Introduction), Section F (Molecular Pathology.)
Additions/revisions to the manual have been italicized in red font.
Additional prior versions of the National Correct Coding Initiative Policy Manual for Medicare Services are now available on this page in the NCCI Policy Manual Archive.
National Correct Coding Initiative Announcements
Replacement Files

Medically Unlikely Edits

- MUEs used by Medicare Administrative Contractors to reduce improper payment rate for Part B claims
- Maximum units of service provider report under most circumstances for a single beneficiary on a single date of service

MUE Adjudication Indicator 1

- MUE Adjudication Indicator of “1” indicates edit is claim line
  - Appropriate use of NCCI modifiers (e.g., 59, 76, 77, 91, anatomic) may be used to report same code on separate lines of claim
  - Medical records must support total units for date of service and use of modifiers

MUE Adjudication Indicator 2

- MUE edits with MUE Adjudication Indicator of “2” (Date of Service Edit: Policy)
  - MUE value is absolute date of service limit that may not be bypassed with modifier
  - MUE edit limits with an MAI of “2” have been rigorously reviewed within CMS
  - Units in excess of MUE value on date of service would be considered impossible because of code definition, anatomical consideration, CMS statute, regulation or sub-regulatory guidance

MUE Adjudication Indicator 3

- MUE edits with MUE Adjudication Indicator (MAI) “3” (Date of Service Edit: Clinical)
  - Medically highly unlikely more units than MUE value would ever be performed on same date of service; same patient
  - Quantity limits based on clinical benchmarks and criteria (e.g., nature of service, prescribing information) combined with data
  - MUE limits will be applied during claim processing

HCPCS/CPT Code 1	Practitioner Services MUE Values 2	MUE Adjudication Indicator 3	MUE Rationale 4
80048	2	3 Date of Service Edit: Clinical	Clinical: Data
81536	11	3 Date of Service Edit: Clinical	Clinical: Data
82024	4	3 Date of Service Edit: Clinical	Code Descriptor / CPT Instruction
82525	2	3 Date of Service Edit: Clinical	Nature of Analyte
82528	1	3 Date of Service Edit: Clinical	Nature of Analyte
82530	4	3 Date of Service Edit: Clinical	Code Descriptor / CPT Instruction
82533	5	3 Date of Service Edit: Clinical	Code Descriptor / CPT Instruction
82540	1	3 Date of Service Edit: Clinical	Nature of Analyte
82542	6	3 Date of Service Edit: Clinical	Clinical: Data
82550	3	3 Date of Service Edit: Clinical	Clinical: Data
83516	4	3 Date of Service Edit: Clinical	Clinical: CMS Workgroup
83518	1	3 Date of Service Edit: Clinical	Clinical: Data
83519	5	3 Date of Service Edit: Clinical	Clinical: Data
83520	9	3 Date of Service Edit: Clinical	Clinical: Data
86001	20	3 Date of Service Edit: Clinical	Clinical: CMS Workgroup
86005	2	3 Date of Service Edit: Clinical	Clinical: Data

CMS National Correct Coding Initiative

- CMS developed NCCI to promote national correct coding methodologies and to control improper coding leading to inappropriate payment in Part B claims
- Purpose of NCCI PTP edits is to prevent improper payment when incorrect code combinations are reported

Column 1	Column 2	*=in existence	Effective	Deletion	Modifier	PTP Edit Rationale
1	2	prior to 1996	Date	Date	0=not allowed	
		3		*=no data	1=allowed	
			4	5	9=not applicable	
80048	80051		20000605	20060930	1	Mutually exclusive procedures
80048	80051		20061001	*	1	HCPCS/CPT procedure code definition
80048	82310		20000605	*	1	Laboratory panel
80048	82374		20000605	*	1	Laboratory panel
80048	82435		20000605	*	1	Laboratory panel
80048	82565		20000605	*	1	Laboratory panel
80048	82947		20000605	*	1	Laboratory panel
80048	84132		20000605	*	1	Laboratory panel
80048	84295		20000605	*	1	Laboratory panel
80048	84520		20000605	*	1	Laboratory panel
80048	96523		20190401	*	0	CPT Manual or CMS manual coding instruction

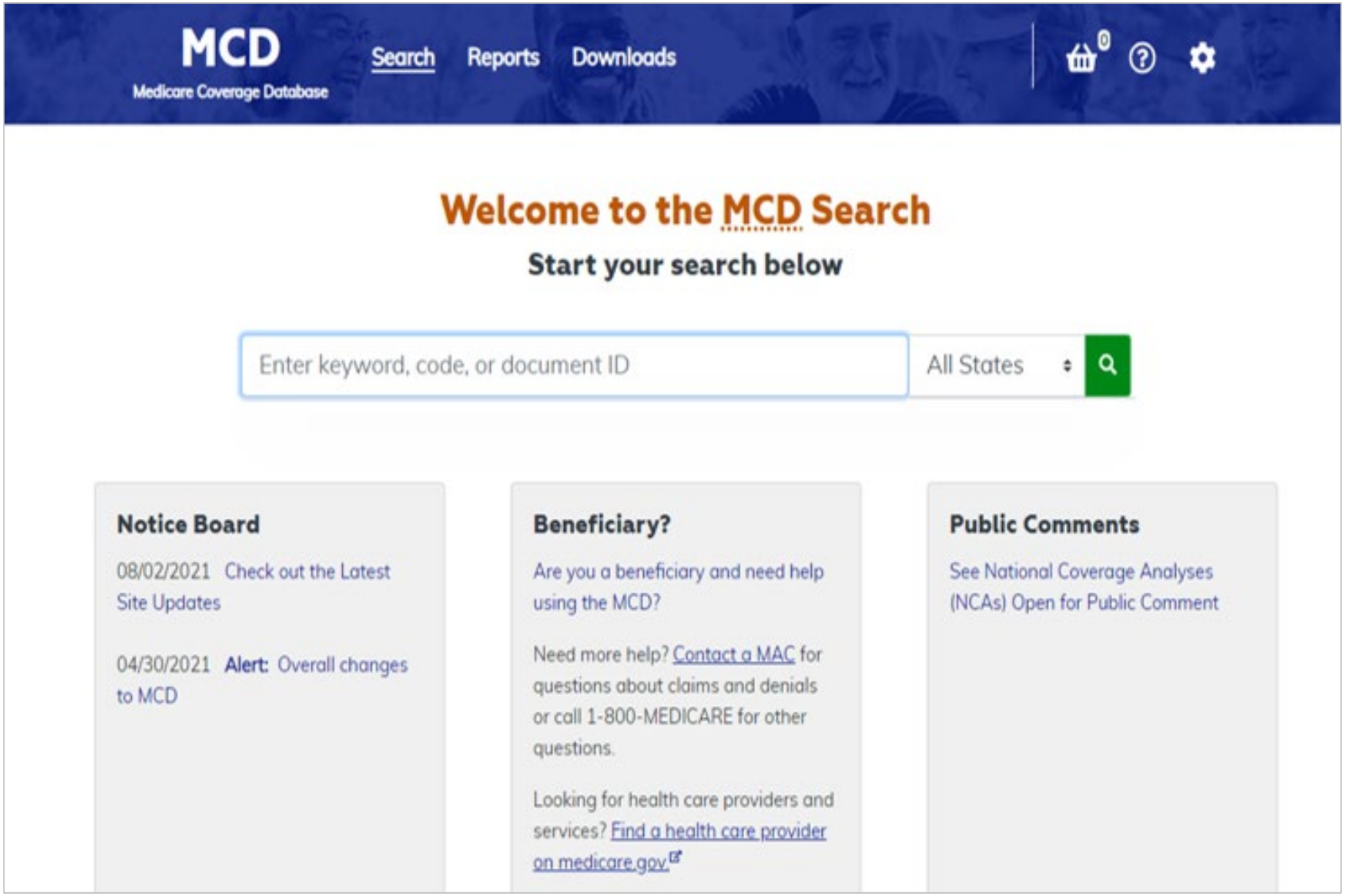
Medicare Coverage Database and National Coverage Determinations

Medicare Coverage Database

- Contains all national coverage documents, Medicare coverage and general information
  - National coverage determinations, national coverage analyses, coding analyses for labs, Medicare evidence development & coverage advisory committee meetings, and Medicare coverage guidance documents
- Database also include LCDs mandated at contractor level and those guidelines are only applicable to certain jurisdiction

National Coverage Determinations

- NCDs are nationwide determination of whether Medicare will pay for service
- Developed by CMS to describe circumstances for Medicare coverage for specific medical service or procedure
- NCDs outline conditions for which service is considered to be covered or not covered and issues program instruction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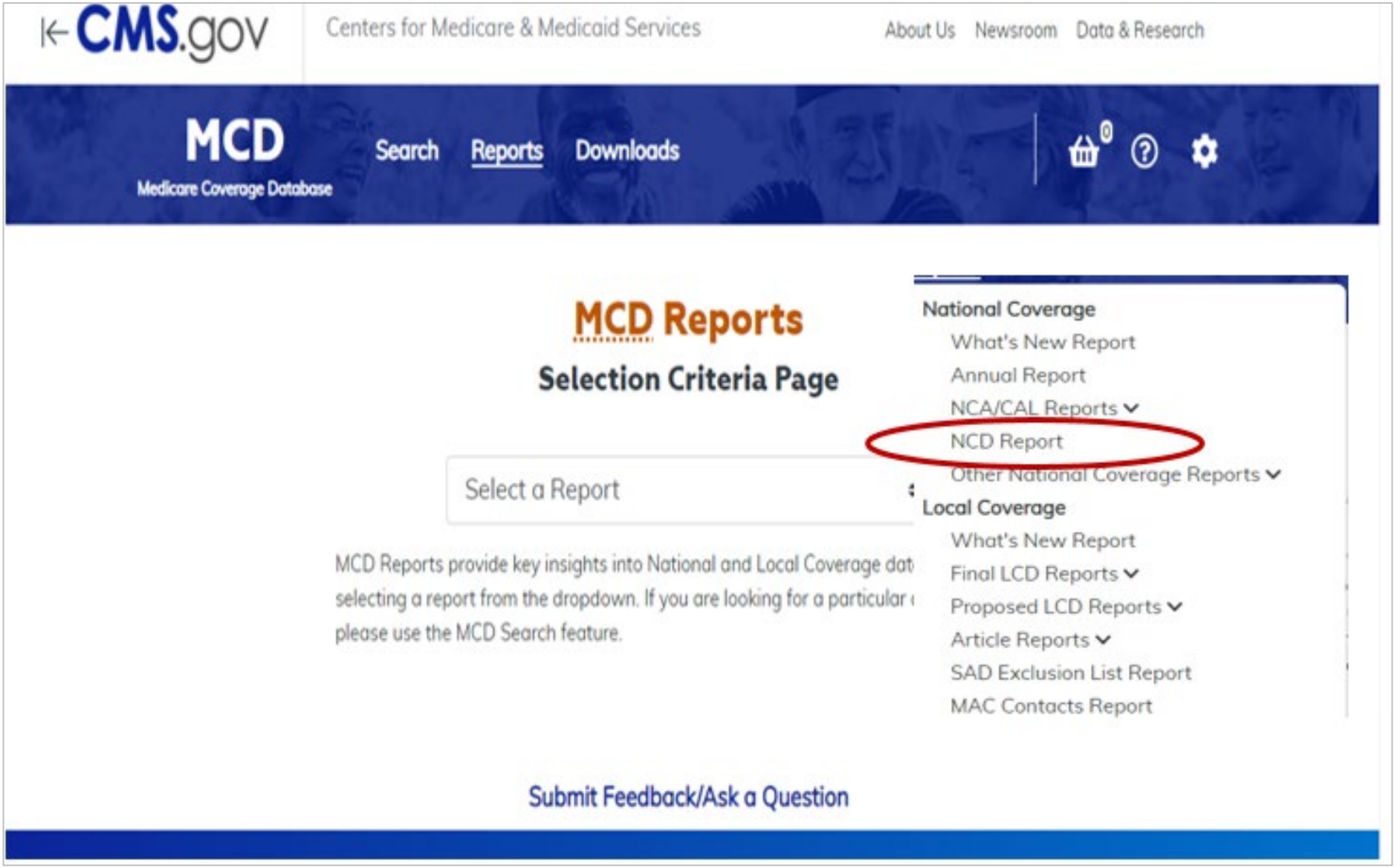
Public Comments
See National Coverage Analyses (NCAs) Open for Public Comment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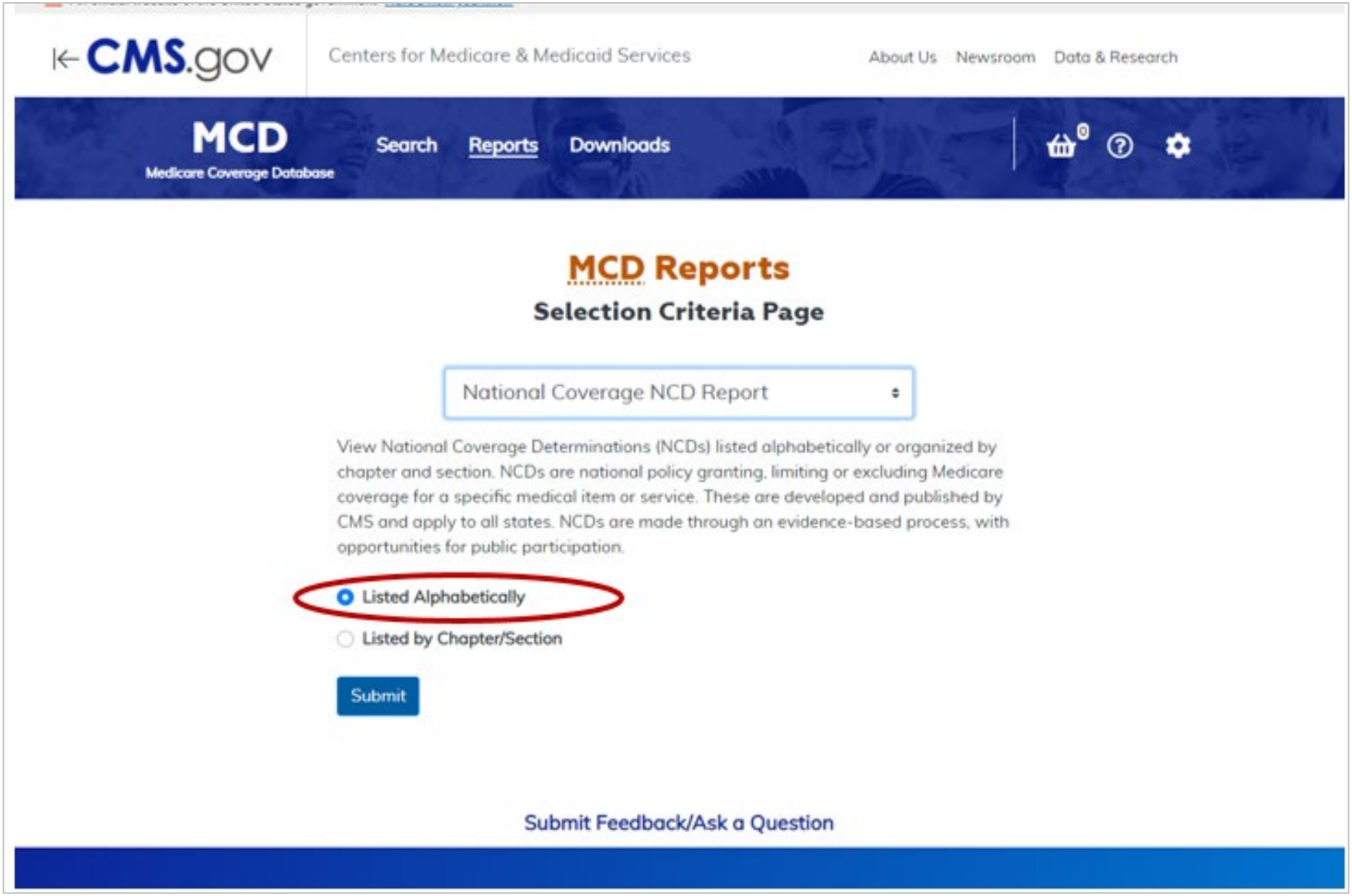
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View National Coverage Determinations (NCDs) listed alphabetically or organized by chapter and section. NCDs are national policy granting, limiting or excluding Medicare coverage for a specific medical item or service. These are developed and published by CMS and apply to all states. NCDs are made through an evidence-based process, with opportunities for public participation.
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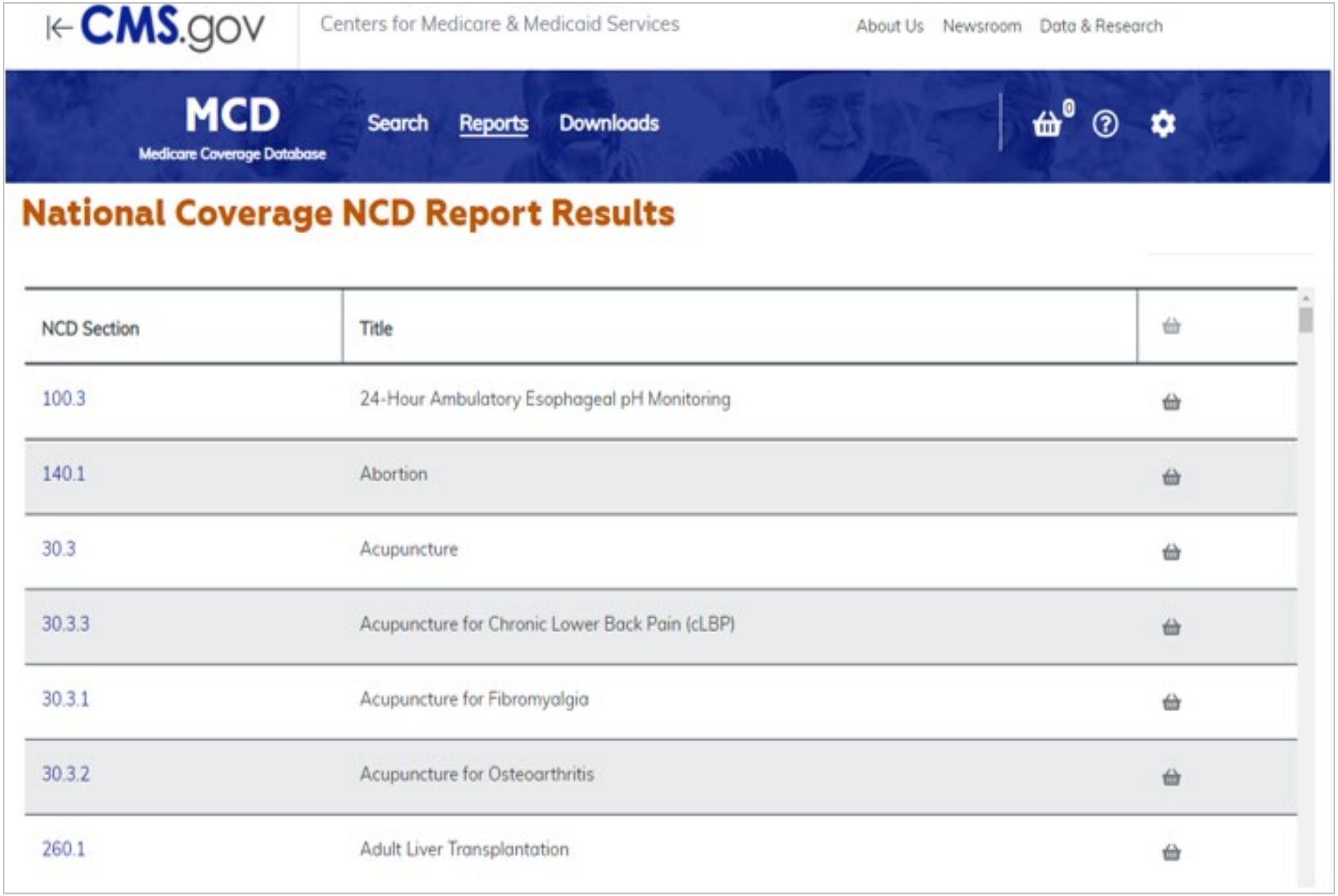
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140.1
Abortion
30.3
Acupuncture
30.3.3
Acupuncture for Chronic Lower Back Pain (cLBP)
30.3.1
Acupuncture for Fibromyalgia
30.3.2
Acupuncture for Osteoarthritis
260.1
Adult Liver Transplantation

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Screening Tests

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Laboratory Modifiers

CLIA Waived Test

- Modifier QW
  - Not all CLIA-waived tests require modifier QW
- Tests granted waived status under CLIA
  - Tests Granted Waived Status Under CLIA - CPT codes

Reference Outside Laboratory

- Modifier 90
  - Diagnostic tests subject to anti-markup price limitations
  - CMS IOM 100-04, *Medicare Claims Processing Manual*, Chapter 1 General Billing Requirements, Section 10.1.1.2
- Item 32 or the electronic equivalent must reflect the place where the test was performed

Repeat Clinical Diagnostic Laboratory Services

- Modifier 91
  - Repeated lab procedures
  - Same day
  - Medically necessary
- Do not use modifier 91 to report
  - Laboratory errors
  - Quality control
  - Confirmation of results

Alternative Laboratory Platform Testing

- Modifier 92
  - Laboratory testing being performed using kit or transportable instrument consists of a single use, disposable analytical chamber
  - Service may be identified by adding modifier 92 to the usual laboratory procedure code
    - HIV testing 86701–86703
  - Test does not require permanent dedicated space
    - By its design it may be hand carried/transported to vicinity of patient for immediate testing at site, although location of the testing is not in itself determinative use of this modifier

Tests Ordered Individually

- Modifier QP
  - Documentation is on file showing that laboratory test(s) ordered individually or ordered as a CPT-recognized panel other than automated profile codes

Laboratory Round Trip

- Modifier LR
  - Laboratories should submit HCPCS modifier LR as informational purposes only to indicate “Round Trip”
  - When using HCPCs code P9604; travel allowance, prorated trip charge
- CMS IOM, Publication 100-04, *Medicare Claims Processing Manual,* Chapter 16 - Laboratory Services

Specimen Collections

Specimens Collection

- Date specimen was collected
- Specimens collected over span of dates, use date collection ended
- Exceptions
  - Date test performed on stored specimens
  - Date for chemotherapy sensitivity test performed on live tissue
  - Date for advanced diagnostic laboratory tests and molecular pathology tests

Stored Specimens

- Stored less than or equal to 30 calendar days from collection, date of test must be date test was performed only if
  - Test is ordered by physician at least 14 days following date of patient's discharge from hospital
  - Specimen was collected while patient was undergoing hospital surgical procedure
  - It was medically inappropriate to have collected sample other than during hospital procedure for which patient was admitted

Thank You!

- Follow-up email
  - Attendees will be provided a Medicare University Course Code
- Questions?

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