

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[CMS-9151-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October Through December 2024

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published in the 3-month period, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed

information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone number
I CMS Manual Instructions	Ronda Allen-Bonner	(410) 786-4657
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410) 786-7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	William Parham	(410) 786-4669
VII Medicare-Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX Medicare's Active Coverage-Related Guidance Documents	Lori Ashby, MA	(410) 786-6322
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786-3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786-3365
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786-3365
All Other Information	Annette Brewer	(410) 786-6580

SUPPLEMENTARY INFORMATION:**I. Background**

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If

assessing a website proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

The Director of the Office of Strategic Operations and Regulatory Affairs of the Centers for Medicare & Medicaid Services (CMS), Kathleen Cantwell, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,
Federal Register Liaison, Department of Health and Human Services.

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous

quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: January 30, 2024 (89 FR 5897), April 29, 2024 (89 FR 33356), July 22, 2024 (89 FR 59104) and November 7, 2024 (89 FR 88282). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (October Through December 2024)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How To Obtain Manuals

The internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The

remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

How To Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>.

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the

nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual A Social Determinants of Health Risk Assessment in the Annual Wellness Visit Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule (CMS-Pub. 100-02) Transmittal No. 12865.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

Please Note: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal No.	Manual/subject/publication No.
Medicare General Information (CMS-Pub. 100-01)	
12980	Update to Medicare Deductible, Coinsurance and Premium Rates for Calendar Year (CY) 2025.
13880	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13881	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13883	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13884	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13885	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
Medicare Benefit Policy (CMS-Pub. 100-02)	
12860	Technical Revision Only to the Medicare Benefit Policy (MBP) Manual, Publication (Pub) 100-02, Chapter 15, section 50.4.2 Unlabeled Use of Drug.
12865	A Social Determinants of Health Risk Assessment in the Annual Wellness Visit Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule.
12999	Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2025.
13003	Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2.
13011	Updates to No Legal Obligation to Pay for or Provide Services and Examples of Application of Government Entity Exclusion (Pub. 100-02, chapter 16, sections 40 and 50.3.3 and newly created section 40.7) and Claims Submitted for Items or Services Furnished to Medicare Beneficiaries in State or Local Custody Under a Penal Authority (Pub. 100-04, chapter 1, section 10.4).

Transmittal No.	Manual/subject/publication No.
Medicare National Coverage Determination (CMS–Pub. 100–03)	
12868	Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS) National Coverage Determination (NCD) 110.23
12987	National Coverage Determination (NCD) 210.15—Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention.
Medicare Claims Processing (CMS–Pub. 100–04)	
12864	October 2024 Update of the Ambulatory Surgical Center [ASC] Payment System.
12865	A Social Determinants of Health Risk Assessment in the Annual Wellness Visit Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule.
12868	Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS) National Coverage Determination (NCD) 110.23.
12869	Fiscal Year (FY) 2025 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) PPS Changes.
12870	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update Fiscal Year (FY) 2025.
12883	Update to the Internet Only Manual (IOM) Publication (Pub.) 100–04, Chapter 18 Section 170.1 and Chapter 32 Section 340.2 for Coding Revisions to the National Coverage Determinations (NCDs)—January 2025 Change Request (CR) 13706.
12886	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12887	Correction to Editing for Inpatient Part B Ancillary 12X Claims When Part A Benefits Exhaust and Manual Updates for Billing of Inpatient Pre-Entitlement Days.
12889	Allowing Home Health (HH) Telehealth Services During an Inpatient Stay.
12890	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12895	2025 Annual Update of Per-Beneficiary Threshold Amounts.
12896	Ambulance Inflation Factor (AIF) for Calendar Year (CY) 2025 and Productivity Adjustment.
12909	Corrections to Change Request (CR) 7270—Changes to the Time Limits for Filing Medicare Fee For Service Claims.
12910	Calendar Year (CY) 2025 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures.
12911	Home Health Prospective Payment System (HH PPS) Rate Update for Calendar Year (CY) 2025.
12914	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12915	Expanding the Number of Home Health (HH) Period of Care Records—Analysis Only.
12923	Calendar Year (CY) 2025 Home Infusion Therapy (HIT) Payment Rates and Instructions for Retrieving the January 2025 Home Infusion Therapy (HIT) Services Payment Rates Through the CMS Mainframe Telecommunications System.
12926	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12931	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions.
12934	Medicare Change of Status Notice (MCSN) Manual Instructions.
12935	New Waived Tests.
12936	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12945	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12948	Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndromes (MDS) National Coverage Determination (NCD) 110.23.
12949	National Fee Schedule for Medicare Part B Vaccine Administration CMS—January 2025”.
12950	Update to Rural Health Clinic (RHC) All Inclusive Rate (AIR) Payment Limit for Calendar Year (CY) 2025.
12951	Update to the Federally Qualified Health Center (FQHC) Prospective Payment System (PPS) for Calendar Year (CY) 2025.
12957	Implementation of System Changes for the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI) for Calendar Year (CY) 2025.
12961	Updates to the Publication 100–04 Claims Processing Manual in the Internet Only Manual (IOM) to Remove Obsolete Language Related to Medicare Fee-for-Service (FFS) Systems Claims Edits.
12964	January 2025 Annual Rural Emergency Hospital (REH) Monthly Facility Payment Amount.
12967	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12970	Claim Status Category Codes (CSCC) and Claim Status Codes (CSC) Update.
12974	Manual Update for Pneumococcal Vaccine for 21-Valent Conjugate Vaccine.
12975	Summary of Policies in the Calendar Year (CY) 2025 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, CT Modifier Reduction List, and Preventive Services.
12976	April 2025 Update to the Inpatient Prospective Payment System (IPPS) For Correction to Total Pass-Through Amounts Reported on the Provider Specific File (PSF) to Include Allogeneic Stem Cell Costs.
12977	April 2025 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder.
12978	April 2025 Bi-Annual Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM).
12979	Implementation of System Changes for the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI) for Calendar Year (CY) 2025.
12980	2025 Annual Update to the Therapy Code List.
12981	Implement Operating Rules—Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule—Update from Council for Affordable Quality Healthcare (CAQH) CORE.
12982	Quarterly Update to Home Health (HH) Grouper.
12987	Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention.
12988	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update.
12990	Update to the Internet Only Manual (IOM) Publication (Pub.) 100–04, Chapter 32 Sections 90, 190.2 and 300.2 for Coding Revisions to the National Coverage Determinations (NCDs)—April 2025 (1 of 2) Change Request (CR) 13818.
12991	Calendar Year 2025 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule.
12992	Calendar Year (CY) 2025 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment.

Transmittal No.	Manual/subject/publication No.
12993	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)—April 2025.
12994	April 2025 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files.
12995	April 2025 Update to the Medicare Severity—Diagnosis Related Group (MS—DRG) Grouper and Medicare Code Editor (MCE) Version 42.1.
12998	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 31.1, Effective April 1, 2025.
13002	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13010	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13011	Updates to No Legal Obligation to Pay for or Provide Services and Examples of Application of Government Entity Exclusion (Pub. 100–02, chapter 16, sections 40 and 50.3.3 and newly created section 40.7) and Claims Submitted for Items or Services Furnished to Medicare Beneficiaries in State or Local Custody Under a Penal Authority (Pub. 100–04, chapter 1, section 10.4).
13012	Internet Only Manual (IOM) Update to 100–04 Chapter 12, Section 30.5—Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions.
13019	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13025	Update to the Internet Only Manual (IOM) Publication (Pub.) 100–04, Chapter 18 Section 60.3 and Chapter 32 Sections 11.3.5, 60.4.1, 60.5.2, 320.2 and 412.1 for Coding Revisions to the National Coverage Determinations (NCDs)—April 2025 (2 of 2) Change Request (CR) 13828.
13026	Billing Instructions Related to Expedited Determinations Based on Medicare Change of Status Notifications (MCSNs).
Medicare Secondary Payer (CMS–Pub. 100–05)	
12880	Changes to The Electronic Correspondence Referral System (ECRS) to Remove the Drug Supplemental Type ‘O’ (Other) as a Valid Option from Batch Submissions.
12891	The Recovery and Adjustment of Medicare Claims where the Department of Veteran Affairs (VA) also Made Payment Using the Medicare Duplicate Payment (DP) Process.
13016	Updates to the Medicare Carrier System (MCS), the Viable Information Processing Systems Medicare Systems (VMS) and the Common Working File (CWF) Processes to Capture and Further Automate the Medicare Secondary Payer (MSP) Processes.
Medicare Financial Management (CMS–Pub. 100–06)	
12968	Requirements for Adjusting/Demanding and Reporting Office of the Inspector General (OIG) Identified Overpayments.
12969	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System.
13001	The Fiscal Year 2025 Updates for the CMS Internet Only Manual (IOM) Publication (Pub.) 100–06, Medicare Financial Management Manual, Chapter 7—Internal Control Requirements.
Medicare State Operations Manual (CMS–Pub. 100–07)	
	None.
Medicare Program Integrity (CMS–Pub. 100–08)	
12872	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12873	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12985	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12996	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12997	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13000	Updates of Chapter 4 and Exhibits in Publication (Pub.) 100–08, Including the Unified Program Integrity Contractor (UPIC) and Medical Review Accuracy Contractor (MRAC) Coordination Process.
13004	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13005	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13006	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13007	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13008	Chapter 3 Revisions (Segment 1) in Publication (Pub.) 100–08 Program Integrity Manual (PIM).
13018	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
Medicare Contractor Beneficiary and Provider Communications (CMS–Pub. 100–09)	
	None.
Medicare Quality Improvement Organization (CMS–Pub. 100–10)	
	None.
Medicare Program of All-Inclusive Care for the Elderly (CMS–Pub. 100–11)	
	None.

Transmittal No.	Manual/subject/publication No.
Medicare End Stage Renal Disease Network Organizations (CMS–Pub. 100–14)	
	None.
Medicaid Program Integrity Disease Network Organizations (CMS–Pub. 100–15)	
	None.
Medicare Managed Care (CMS–Pub. 100–16)	
	None.
Medicare Business Partners Systems Security (CMS–Pub. 100–17)	
	None.
Medicare Prescription Drug Benefit (CMS–Pub. 100–18)	
	None.
Demonstrations (CMS–Pub. 100–19)	
12983	Making Care Primary (MCP) Informational Unsolicited Responses (IURs).
One Time Notification (CMS–Pub. 100–20)	
12862	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12867	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12878	Reporting Identifiers for the Healthcare Integrated General Ledger Accounting System (HIGLAS) Payments Reported for Periodic Interim Payment (PIP) Claims.
12879	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12881	Tax Equity and Fiscal Responsibility Act (TEFRA) Reimbursement to Inpatient Prospective Payment System (IPPS) -Excluded Hospitals for Excess Costs Related to Providing CAR T-cell Therapy.
12882	Implementation of a New National Uniform Billing Committee (NUBC) Condition Code “KX”, “Documentation on file. Requirements specified in the medical policy have been met.” and Implementation of a New NUBC Value Code “92”, “Invoice Cost of Drug/Biologic. For use with Revenue Category 0636 when required by federal regulation.”.
12884	Phase 4: Implementation to Expand Monetary Amount Fields Related to Billing and Payment to Accommodate 10-Digits in Length (\$99,999,999.99).
12885	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12889	Correction to Pulmonary Rehabilitation Services for Indian Health Services (IHS).
12899	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12903	International Classification of Diseases, 10th Revision (ICD–10) and Other Coding Revisions to National Coverage Determinations (NCDs)—April 2025 (CR 1 of 2).
12904	International Classification of Diseases, 10th Revision (ICD–10) and Other Coding Revisions to National Coverage Determinations (NCDs)—April 2025 (CR 2 of 2).
12908	Implementation of the Award for the Jurisdiction D Durable Medical Equipment Medicare Administrative Contractor (JD DME MAC).
12916	User Enhancement Change Request (UECR): Update the Multi-Carrier System (MCS) System Control Facility (SCF) System Element (SE) for Diagnosis Validation.
12917	User Enhancement Change Request (UECR): Update the Summary Report—Healthcare Integrated General Ledger Accounting System (HIGLAS) 824 Status Notification Error Report (H99RJSUM).
12918	User Enhancement Change Request (UECR): Update Multi-Carrier System (MCS) Import File Copy Request Screen.
12919	Fiscal Intermediary Shared System (FISS)—User Enhancement Change Request (UECR)—Expand Reason Code Narrative Length.
12920	Fiscal Intermediary Shared System (FISS)—User Enhancement Change Request (UECR)—Expand Provider Name Field on Provider Address Screen.
12921	User Enhancement Change Request (UECR): Update Multi-Carrier System (MCS) Portal Re-Openings Negative/Zero Adjustments Report (H99RBPRZ).
12922	Fiscal Intermediary Shared System (FISS)—Delete Obsolete Reason Codes—Part 6.
12924	Implementation of the Award for the Jurisdiction J (J–J) Part A and Part B Medicare Administrative Contractor (JJ A/B MAC).
12932	Implementation of the Award for the Jurisdiction J (J–J) Part A and Part B Medicare Administrative Contractor (JJ A/B MAC).
12937	User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Add Testing/Production Region Identifier Field on Screens.
12938	User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Add Testing/Production Region Identifier Field on Screens.
12939	User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Improve Processing of Capped Rental Items Billed with RT (right)/LT (left) Modifiers.
12940	Fiscal Intermediary Shared System (FISS)—Delete Obsolete Reason Codes—Part 5.
12941	Updates to Allow Category II Codes to be Submitted on Rural Health Clinic (RHC) Claims.
12942	User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Update the Quality Assurance (QA) subsystem to Automate Setting Date Ranges on the QA Selection—Date Card Screen (VMAP/2/2).
12944	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12947	Implementation of a New National Uniform Billing Committee (NUBC) Condition Code “KX”, “Documentation on file. Requirements specified in the medical policy have been met.” and Implementation of a New NUBC Value Code “92”, “Invoice Cost of Drug/Biologic. For use with Revenue Category 0636 when required by federal regulation.”.

Transmittal No.	Manual/subject/publication No.
12955	Implementation CR—To Send Provider-Based Practice Location Types to the Fiscal Intermediary Shared System (FISS) on Provider Enrollment Chain & Ownership System (PECOS) Extract Files and for FISS to Process so Medicare Administrative Contractors (MACs) Do Not Have to Check Manually for These Locations.
12958	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12960	All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service (IHS) and Tribal Hospitals.
12965	User Management in the Medicare Adjudication Portal (MAP) for 837D Dental Claims.
12973	User Management in the Medicare Adjudication Portal (MAP) for 837D Dental Claims.
12984	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12986	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12989	Phase 4: Implementation to Expand Monetary Amount Fields Related to Billing and Payment to Accommodate 10-Digits in Length (\$99,999,999.99).
13009	User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Improve Processing of Capped Rental Items Billed with RT (right)/LT (left) Modifiers.
13014	Update to Billing Requirements for Intensive Outpatient Program (IOP) Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
13015	Allow Payment for Healthcare Common Procedure Coding System (HCPCS) Code G2211 when Certain Part B Preventive Services are Provided on the Same Day.
13017	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13027	Adjustments in the Medicare Adjudication Portal (MAP) for 837D Dental Claims (Phase 2).
Medicare Quality Reporting Incentive Programs (CMS—Pub. 100–22)	
	None.
State Payment of Medicare Premiums (CMS—Pub. 100–24)	
	None.
Information Security Acceptable Risk Safeguards (CMS—Pub. 100–25)	
	None.

For questions or additional information, contact Ismael Torres (410–786–1864).

Addendum II: Regulation Documents Published in the Federal Register (July Through September 2024)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through *GPO Access*. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <http://www.gpoaccess.gov/fr/index.html>. The following website <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

For questions or additional information, contact Terri Plumb (410–786–4481).

Addendum III: CMS Rulings (October Through December 2024)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>.

For questions or additional information, contact Tiffany Lafferty (410–786–7548).

Addendum IV: Medicare National Coverage Determinations (October Through December 2024)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD

is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Additional information on NCDs, including open NCDs and pending NCDs, can be found on the NCD Dashboard, which is posted on the CMS website at <https://www.cms.gov/files/document/ncd-dashboard.pdf>. For the purposes of this quarterly notice, we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/.

For questions or additional information, contact Wanda Belle, MPA (410–786–7491).

Title	NCDM section	Transmittal No.	Issue date	Effective date
National Coverage Determination (NCD) 210.15—Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention	210.15	12987	12/05/2024	04/07/2025

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October Through December 2024)

(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (October Through December 2024)

All approval numbers are available to the public at *Reginfo.gov*. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain.

For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities (October Through December 2024)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. There were no additions, deletions, or editorial changes to the listing for Medicare-approved carotid stent facilities for this 3-month period. This information is available at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (October Through December 2024)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (October Through December 2024)

CMS published three final guidance documents on August 7, 2024, to provide a framework for more predictable and transparent evidence development and encourage innovation and accelerate beneficiary access to new items and services. The documents are available at:

Coverage with Evidence Development: <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38>.

CMS National Coverage Analysis Evidence Review: <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=37>.

Clinical Endpoints Guidance: Knee Osteoarthritis: <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=36>.

For questions or additional information, contact Lori Ashby, MA (410 786 6322).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (October Through December 2024)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at <http://www.cms.gov>.

For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (October Through December 2024)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on positron emission tomography (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilities/NOPR/list.asp#TopOfPage>.

For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (October Through December 2024)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage

for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-

approved facilities that meet our standards that have occurred in the 3-month period. This information is available at <http://www.cms.gov/>

MedicareApprovedFacilitie/VAD/list.asp#TopOfPage.

For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider No.	Date of initial certification	Date of re-certification	State
The following are new facilities				
The Valley Hospital, 4 Valley Health Plaza, Paramus, NJ 07652; <i>Other information:</i> DNV ID #: C701535; <i>Previous Re-certification Dates:</i> n/a.	310012	09/04/2024	n/a	NJ
Saint Francis Hospital, 6161 South Yale Avenue, Tulsa, OK 74136; <i>Other information:</i> DNV ID #: C675228; <i>Previous Re-certification Dates:</i> n/a.	370091	09/10/2024	n/a	OK
East Jefferson General Hospital, 4200 Houma Blvd., Metairie, LA 70006; <i>Other information:</i> DNV ID #: C694266; <i>Previous Re-certification Dates:</i> n/a.	190176	11/12/2024	n/a	LA
Cooper University Hospital, 1 Cooper Plaza, Camden, NJ 08103; <i>Other information:</i> DNV ID #: C653305; <i>Previous Re-certification Dates:</i> n/a.	31-0014	11/14/2024	n/a	NJ
The following facilities have editorial changes (in bold)				
Ascension Seton, 1201 West 38th Street, Austin, TX 78705-1056; <i>Other information:</i> Joint Commission ID #8939; <i>Previous Re-certification Dates:</i> 03/06/2009; 07/15/2011; 09/04/2013; 10/20/2015; 10/03/2017; 10/23/2019; 04/13/2022.	450056	03/06/2009	07/17/2024	TX
Lehigh Valley Hospital, 1200 S Cedar Crest Boulevard, Allentown, PA 18105; <i>Other information:</i> Joint Commission ID #4880; <i>Previous Re-certification Dates:</i> 10/29/2013; 11/10/2015; 12/12/2017; 03/04/2020; 05/28/2022.	390133	10/29/2013	07/31/2024	PA
Mount Sinai Hospital, One Gustave L. Levy Place, New York, NY 10029-6574; <i>Other information:</i> Joint Commission ID #5829; <i>Previous Re-certification Dates:</i> 11/25/2008; 02/08/2011; 03/20/2013; 03/31/2015; 06/08/2017; 08/07/2019; 03/23/2022.	330024	11/25/2008	08/14/2024	NY
UPMC Presbyterian Shadyside, 200 Lothrop Street, Pittsburgh, PA 15213; <i>Other information:</i> Joint Commission ID #6169; <i>Previous Re-certification Dates:</i> 06/10/2008; 05/21/2010; 04/12/2012; 03/25/2014; 04/13/2016; 03/20/2018; 12/09/2020; 06/03/2022.	390164	06/10/2008	08/14/2024	PA
Advocate Christ Medical Center, 4440 W 95th Street, Oak Lawn, IL 60453; <i>Other information:</i> DNV ID #: 10000504196-MSD-DNV-USA; <i>Previous Re-certification Dates:</i> 9/28/2015; 10/01/2018; 10/21/2021.	140208	09/28/2015	10/01/2024	IL
University of Texas Medical Branch, 301 University Blvd., Galveston, TX 77555; <i>Other information:</i> Joint Commission ID #9058; <i>Previous Re-certification Dates:</i> 01/31/2012; 01/28/2014; 02/23/2016; 01/30/2018; 10/08/2020; 06/08/2022.	450018	01/31/2012	08/28/2024	TX
University of California, Davis Medical Center, 2315 Stockton Boulevard, Sacramento, CA 95817; <i>Other information:</i> Joint Commission ID #10055; <i>Previous Re-certification Dates:</i> 10/06/2015; 02/06/2018; 12/10/2020; 09/14/2022.	050599	10/06/2015	09/18/2024	CA
Carolinas Medical Center, 1000 Blythe Boulevard, Charlotte, NC 28232; <i>Other information:</i> Joint Commission ID #6480; <i>Previous Re-certification Dates:</i> 05/11/2010; 05/11/2012; 04/22/2014; 04/12/2016; 04/24/2018; 12/17/2020; 08/03/2022.	340113	05/11/2010	09/11/2024	NC
MedStar Washington Hospital Center, 110 Irving St. NW, Washington, DC 20010; <i>Other information:</i> Joint Commission ID #6308; <i>Previous Re-certification Dates:</i> 04/22/2008; 04/06/2010; 03/23/2012; 03/04/2014; 05/03/2016; 05/22/2018; 12/17/2020; 07/08/2022.	090011	04/22/2008	11/06/2024	DC
WellSpan York Hospital, 1001 South George Street, York, PA 17405; <i>Other information:</i> Joint Commission ID #6228; <i>Previous Re-certification Dates:</i> 11/19/2013; 12/15/2015; 01/23/2018; 03/14/2020; 06/18/2022.	390046	11/19/2013	09/11/2024	PA
NYU Langone Hospitals, 550 First Avenue, New York, NY 10016; <i>Other information:</i> Joint Commission ID #5820; <i>Previous Re-certification Dates:</i> 02/14/2012; 01/14/2014; 03/08/2016; 03/27/2018; 8/26/2020; 07/27/2022.	330214	02/14/2012	11/06/2024	NY
Jersey Shore University Medical Center, 1945 Corlies Avenue, Neptune, NJ 07753; <i>Other information:</i> DNV ID #: C727737; <i>Previous Re-certification Dates:</i> 10/16/2018; 10/14/2021.	310073	10/16/2018	09/17/2024	NJ
Rochester General Hospital, 1425 Portland Ave., Rochester, NY 14621; <i>Other information:</i> DNV ID #: C729533; <i>Previous Re-certification Dates:</i> 10/29/2018; 10/28/2021.	33-0125	10/29/2018	09/19/2024	NY
Public Health Trust of Dade County Florida dba Jackson Memorial Hospital, 1611 Northwest 12th Avenue, Miami, FL 33136-1094; <i>Other information:</i> Joint Commission ID #6850; <i>Previous Re-certification Dates:</i> 10/22/2009; 10/21/2011; 11/06/2013; 12/08/2015; 12/08/2017; 3/3/2020; 05/22/2022.	100022	10/22/2009	09/11/2024	FL
The Johns Hopkins Hospital, 600 N Wolfe Street, Baltimore, MD 21287; <i>Other information:</i> Joint Commission ID #6252; <i>Previous Re-certification Dates:</i> 12/11/2007; 12/15/2009; 11/29/2011; 12/03/2013; 01/12/2016; 02/13/2018; 10/24/2020; 06/15/2022.	210009	12/11/2007	08/21/2024	MD
Baptist Health Medical Center—Little Rock, 9601 Baptist Health Drive, Little Rock, AR 72205-7299; <i>Other information:</i> Joint Commission ID #8656; <i>Previous Re-certification Dates:</i> 11/10/2009; 11/08/2011; 12/11/2013; 01/12/2016; 12/15/2017; 02/12/2020; 05/07/2022.	040114	11/10/2009	09/11/2024	AR

Facility	Provider No.	Date of initial certification	Date of re-certification	State
Summa Health, 95 Arch Street, Suite 205, Akron, OH 44304; <i>Other information:</i> DNV ID #: C738012; <i>Previous Re-certification Dates:</i> 11/16/2021.	360020	11/16/2021	11/07/2024	OH
Westchester Health Care Corporation, 100 Woods Road, Valhalla, NY 10595; <i>Other information:</i> Joint Commission ID #2518; <i>Previous Re-certification Dates:</i> 11/19/2009; 11/15/2011; 12/03/2013; 12/08/2015; 12/19/2017; 03/07/2020; 06/30/2022.	330234	11/19/2009	09/25/2024	NY
Scott & White Memorial Hospital, 2401 S 31st St., Temple, TX 76508-0001; <i>Other information:</i> Joint Commission ID #9241; <i>Previous Re-certification Dates:</i> 12/07/2011; 12/03/2013; 01/12/2016; 12/19/2017; 03/05/2020; 07/02/2022.	450054	12/07/2011	09/06/2024	TX

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October Through December 2024)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. For the purposes of this quarterly notice, there are no additions and deletions to a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. This information is available at www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October Through December 2024)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary

for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one comorbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October Through December 2024)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage.

For questions or additional information, contact David Dolan, MBA (410-786-3365).

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BILLING CODE 4120-01-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1352]

Certain Selective Thyroid Hormone Receptor-Beta Agonists, Processes for Manufacturing or Relating to Same, and Products Containing Same; Notice of a Commission Determination To Review a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined to review a final initial determination ("FID") issued by the presiding Chief Administrative Law Judge ("Chief ALJ"), finding a violation of section 337 of the Tariff Act of 1930, as amended. The Commission requests written submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT:

Houda Morad, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation