

manner. The Act provides us with 210 calendar days after the date of receipt of a completed application to complete our survey activities and application review process. Within the 210-day period, we will publish an approval or denial of the application in the **Federal Register**.

III. Collection of Information Requirements

This document does not impose any new or revised “collection of information” requirements or burden. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). With respect to the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will

respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, 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, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–08722 Filed 5–14–25; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9154–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 2025

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

ACTION: Notice.

SUMMARY: This quarterly notice lists Centers for Medicare & Medicaid Services (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 No.
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	Renee Swann	(410) 786–4492

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 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: April 29, 2024 (89 FR 33356), July 22, 2024 (89 FR 59104), November 7, 2024 (89 FR 88282) and February 19, 2025 (90 FR 9902). 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 (January Through March 2025)

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 Qualifications for Speech-Language Pathologists Furnishing Outpatient Speech-Language Pathology Services (CMS–Pub. 100–02) Transmittal No. 13051.

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.

These Change Request (CR) are being released on a limited approved basis due to the moratorium.

Transmittal No.	Manual/subject/publication No.
Medicare General Information (CMS–Pub. 100–01)	
13065	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13080	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
Medicare Benefit Policy (CMS–Pub. 100–02)	
13051	Qualifications for Speech-Language Pathologists Furnishing Outpatient Speech-Language Pathology Services.
13088	Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs (OTPs).
13121	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.
13133	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update.
13147	Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs (OTPs).

Transmittal No.	Manual/subject/publication No.
Medicare National Coverage Determination (CMS–Pub. 100–03)	
None.	
Medicare Claims Processing (CMS–Pub. 100–04)	
12914	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12982	Quarterly Update to Home Health (HH) Grouper.
13013	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13032	January 2025 Update of the Hospital Outpatient Prospective Payment System (OPPS).
13037	Clinical Laboratory Fee Schedule—Medicare Travel Allowance Fees for Collection of Specimens and New Updates for 2025.
13038	April 2025 Quarterly Update to Healthcare Common Procedure Coding System (HCPCS) Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement.
13039	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13040	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13042	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13044	January 2025 Update of the Ambulatory Surgical Center [ASC] Payment System.
13045	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.
13050	Internet Only Manual Update, Pub. 100–04, Chapter 3 (Inpatient Hospital Billing), Sections 20.1.2.7, 140.2.10, 150.28, 190.7.2.5, and Chapter 4 (Part B Hospital) Section 10.7.2.4 Procedures for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments.
13055	CR 13923, Payment for Part B Preventive Vaccines and their Administration on the Claim for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
13059	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13061	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13063	Instructions for Retrieving the January 2025 Opioid Treatment Program (OTP) Payment Rates Through the CMS Mainframe Telecommunications System.
13067	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13068	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13072	Instructions for Downloading the Medicare ZIP Code File for April 2025 Files.
13073	Enhancing Compliance and Payment Accuracy for Physician Services in Skilled Nursing Facilities.
13074	Principal Diagnosis Code Reporting Update for Hospice and Manual Updates to Sections 30.3, 40.2, and 50 of Chapter 11 of the Claims Processing Manual: Processing Hospice Claims.
13078	Roster Billing for Hepatitis B—July 2025 Release.
13079	January 2025 Update of the Ambulatory Surgical Center [ASC] Payment System.
13082	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions.
13084	Update to the Internet Only Manual (IOM) Publication (Pub.) 100–04 Chapter 3, Inpatient Hospital Billing, Section 20.2.1.
13088	Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs (OTPs).
13089	Manual Updates Regarding Home Health Adjustments and Skilled Nursing Facility, Home Health and Hospice Pricer Information.
13090	April 2025 Coding Updates for the Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS).
13091	Roster Billing for Hepatitis B—July 2025 Release.
13101	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.
13102	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits.
13103	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB)—April 2025 Update.
13104	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment.
13106	Non-systems Internet Only Manual (IOM) Chapter 25 Changes.
13115	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2025.
13116	July 2025 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder.
13123	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13127	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure- to-Procedure (PTP) Edits, version 31.2, Effective July 1, 2025.
13135	April 2025 Update of the Hospital Outpatient Prospective Payment System (OPPS).
13147	Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs (OTPs).
13148	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.
Medicare Secondary Payer (CMS–Pub. 100–05)	
13046	The Recovery and Adjustment of Medicare Claims where the Department of Veteran Affairs (VA) also Made Payment Using the Medicare Duplicate Payment (DP) Process.
13070	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)	
13047	Notice of New Interest Rate for Medicare Overpayments and Underpayments—2nd Quarter Notification for FY 2025.
13071	Updates to the Internet Only Manual (IOM) Publication 100–06 Chapters 3 Overpayments and 4 Debt Collection.
Medicare State Operations Manual (CMS–Pub. 100–07)	
None.	
Medicare Program Integrity (CMS–Pub. 100–08)	
13048	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13049	Documentation for Claims for Replacement of Essential Accessories for Beneficiary-Owned Continuous Glucose Monitors (CGMs).
13060	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13062	Sixteenth General Update to Provider Enrollment Instructions in Chapter 10 of CMS Publication 100–08.
13080	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13085	Update to Provider Enrollment Appeals and Rebuttals Processing Instructions and Model Letters.
13139	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.

Transmittal No.	Manual/subject/publication No.
Medicare Contractor Beneficiary and Provider Communications (CMS–Pub. 100–09)	
13109	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year (FY) 2023 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCHs).
Medicare Quality Improvement Organization (CMS–Pub. 100–10)	
13086	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
Medicare Program of All-Inclusive Care for the Elderly (CMS–Pub. 100–11)	
	None.
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)	
13054	Update—Federally Qualified Health Center (FQHC) Participation in and Payment Under the Maryland Primary Care Program (MDPCP) for Healthcare Common Procedure Coding System (HCPCS) Codes 99453 and 99454.
13064	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13114	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13132	Update—Federally Qualified Health Center (FQHC) Participation in and Payment Under the Maryland Primary Care Program (MDPCP) for Healthcare Common Procedure Coding System (HCPCS) Codes 99453 and 99454.
13138	Accountable Care Organization (ACO) Primary Care Flex Model CO PC Flex Model).
One Time Notification (CMS–Pub. 100–20)	
12770	Updating Calendar Year (CY) 2025 Medicare Diabetes Prevention Program (MDPP) Inflation Payment Rates.
12958	Updates to Billing for Care Coordination Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
13034	Phase 4: Implementation to Expand Monetary Amount Fields Related to Billing and Payment to Accommodate 10-Digits in Length (\$99,999,999.99).
13035	Extensions of Certain Temporary Changes to the Low-Volume Hospital Payment Adjustment and the Medicare-Dependent Hospital (MDH) Program under the Inpatient Prospective Payment System (IPPS) provided by the American Relief Act, 2025.
13036	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13041	Editing for Duplicate Processing for Practitioner Professional Services and Critical Access Hospital (CAH) Professional Services.
13043	Fiscal Intermediary Shared System (FISS) Changes to Automate the Application of Condition Code ZC for Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapy Cases Involving a Clinical Trial of a Different Product.
13052	CR 13787, User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Create Error Message in the Beneficiary Information Tracking System (BITS) to Limit the Prior Authorization (PA) Healthcare Common Procedure Coding System (HCPCS) within a Unique Tracking Number (UTN).
13053	CR 13788, User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Copy Over Existing SuperOp Sequences (Active/Inactive/Archived).
13054	CR 13932, Update—Federally Qualified Health Center (FQHC) Participation in and Payment Under the Maryland Primary Care Program (MDPCP) for Healthcare Common Procedure Coding System (HCPCS) codes 99453 and 99454.
13056	CR 13852, Fiscal Intermediary Shared System (FISS) User Enhancement Change Request (UECR)—Creation of New Reason Codes to Validate the National Provider Identifier (NPI) on Prior Authorization (PA) Unique Tracking Numbers (UTNs) and Claims.
13057	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13058	CR 13779, User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Updates to the Automated Paperless Exception System (APEX) Request Screen (APEX/1).
13069	Fiscal Intermediary Shared System (FISS) User Enhancement Change Request (UECR)—Create a New Additional Development Request (ADR) Location Prior Authorization (PA) Claims.
13075	Phase 5: Implementation to Expand Monetary Amount Fields Related to Billing and Payment to Accommodate 10-Digits in Length (\$99,999,999.99).
13081	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13083	Rejections in the Medicare Adjudication Portal (MAP).
13087	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13092	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13095	Reporting Identifiers for the Healthcare Integrated General Ledger Accounting System (HIGLAS) Payments Reported for Periodic Interim Payment (PIP) Claims 13096 Utilization of KX Modifier Medicare Physician Fee Schedule Payment for Dental Services Inextricably Linked to Covered Medical Services.
13096	Implementation of the Award for the Jurisdiction J (J–J) Part A and Part B Medicare Administrative Contractor (JJ A/B MAC).
13097	International Classification of Diseases, 10th Revision (ICD–10) and Other Coding Revisions to National Coverage Determinations (NCDs)—July 2025.
13098	Remove Part B Batch Eligibility Process (HELG) from the Common Working File (CWF).
13100	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
13112	User Management in the Medicare Adjudication Portal (MAP) for 837D Dental Claims.
13113	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.

Transmittal No.	Manual/subject/publication No.
13128	User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Create Error Message in the Beneficiary Information Tracking System (BITS) to Limit the Prior Authorization (PA) Healthcare Common Procedure Coding System (HCPCS) within a Unique Tracking Number (UTN).
13130	Revision to the Cost Report Acceptability Checklists—This CR Rescinds and Fully Replaces CR 11644.
13146	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
Medicare Quality Reporting Incentive Programs (CMS—Pub. 100–22)	
13076	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
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 Ronda Allen-Bonner (410–786–4657).

Addendum II: Regulation Documents Published in the Federal Register (January Through March 2025)

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 Gittel Treitel (410–786–4673).

Addendum III: CMS Rulings (January Through March 2025)

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 <https://www.cms.gov/medicare/regulations-guidance/cms-rulemaking/rulings>.

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

Addendum IV: Medicare National Coverage Determinations (January Through March 2025)

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/medicare/coverage/determination-process>.

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.

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

Title	NCDM section	Transmittal No.	Issue date	Effective date
N/A	N/A	N/A	N/A	N/A

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January Through March 2025)

(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (January Through March 2025)

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 (January Through March 2025)

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/Medicare/ApprovedFacilitie/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 (January Through March 2025)

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 (January Through March 2025)

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 (January Through March 2025)

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) (January Through March 2025)

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 (January Through March 2025)

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/MedicareApprovedFacilities/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				
HonorHealth Scottsdale Shea, Medical Center, 9003 E. Shea Blvd., Scottsdale, AZ 85260; Other information: DNV ID #: C691982; Previous Re-certification Dates: n/a.	030087	03/04/2025	n/a	AZ
Medical City Fort Worth, 900 Eighth Avenue, Fort Worth, TX 76104; Other information: DNV ID #: C750130; Previous Re-certification Dates: n/a.	450672	03/05/2025	n/a	TX
The following facilities have editorial changes (in bold).				
Christ Hospital, 2139 Auburn Avenue, Cincinnati, OH 45219; Other information: Joint Commission ID #6987; Previous Re-certification Dates: 02/17/2012; 02/20/2014; 04/05/2016; 03/20/2018; 2/26/21; 07/09/2022.	360163	02/17/2012	10/23/2024	OH
Medical University of South Carolina Medical Center, 169 Ashley Avenue, Charleston, SC 29425; Other information: Joint Commission ID #6584; Previous Re-certification Dates: 09/23/2010; 09/07/2012; 08/05/2014; 09/13/2016; 09/26/2018; 03/24/2021; 07/21/2022.	420004	09/23/2010	09/21/2024	SC
Ascension Saint Thomas Hospital, 4220 Harding Pike, Nashville, TN 37205; Other information: Joint Commission ID #7891; Previous Re-certification Dates: 06/22/2010; 06/22/2012; 05/20/2014; 07/13/2016; 01/14/2021; 09/03/2022.	440082	06/22/2010	10/19/2024	TN
Penn State Milton S. Hershey Medical Center, 500 University Drive, Hershey, PA 17033; Other information: Joint Commission ID #6075; Previous Re-certification Dates: 04/01/2008; 03/24/2010; 03/16/2012; 04/08/2014; 06/07/2016; 05/22/2018; 9/11/2020; 06/30/2022.	390256	10/29/2003	10/09/2024	PA
The University of Kansas Hospital Authority, 4000 Cambridge Street, Kansas City, KS 66160-7200; Other information: Joint Commission ID #: 8567; Previous Re-certification Dates: 03/08/2016; 03/06/2018; 07/20/2022.	170040	03/08/2016	10/23/2024	KS
Abington Memorial Hospital, 1200 Old York Road, Abington, PA 19001; Other information: Joint Commission ID #: 6013; Previous Re-certification Dates: 06/28/2012; 06/03/2014; 06/28/2016; 05/22/2018; 07/16/2022.	390231	07/10/2012	10/30/2024	PA
Bethesda North Hospital, 10500 Montgomery Road, Cincinnati, OH 45242; Other information: DNV ID #: C755357; Previous Re-certification Dates: 12/16/2021.	360179	12/16/2021	12/13/2024	OH
Deborah Heart and Lung Center, 200 Trenton Road, Browns Mills, NJ 08051; Other information: DNV ID #: C522707; Previous Re-certification Dates: 02/05/2019; 02/10/2022.	310031	02/05/2019	01/09/2025	NJ
Medical City Dallas, 7777 Forest Lane, Dallas, TX 75230; Other information: Joint Commission ID #9008; Previous Re-certification Dates: 09/09/2008; 08/10/2010; 07/17/2012; 06/27/2014; 07/12/2016; 4/3/2021; 10/20/2022.	450647	09/09/2008	12/04/2024	TX
Lutheran Hospital of Indiana, 7950 West Jefferson Boulevard, Fort Wayne, IN 46804; Other information: Joint Commission ID #7157; Previous Re-certification Dates: 09/14/2010; 10/24/2012; 10/21/2014; 11/01/2016; 05/05/2021; 09/22/2022.	150017	09/14/2010	12/11/2024	IN
Froedtert Memorial Lutheran Hospital, Inc, 9200 West Wisconsin Avenue, Milwaukee, WI 53226; Other information: Joint Commission ID #: 7718; Previous Re-certification Dates: 07/31/2012; 07/08/2014; 08/09/2016; 2021-01-07; 09/14/2022.	520177	07/31/2012	12/11/2024	WI

Facility	Provider No.	Date of initial certification	Date of re-certification	State
Memorial Regional Hospital, 3501 Johnson Street, Hollywood, FL 33021; Other information: Joint Commission ID #: 6811; Previous Re-certification Dates: 08/20/2014; 08/11/2016; 03/27/2021; 10/19/2022.	100038	08/20/2014	12/04/2024	FL
Loma Linda University Medical Center, 11234 Anderson Street, Loma Linda, CA 92354; Other information: Joint Commission #: 9898; Previous Re-certification Dates: 02/07/2012; 01/23/2014; 02/23/2016; 04/10/2018; 05/15/2021; 11/23/2012.	050327	11/23/2012	12/14/2024	CA
California Pacific Medical Center-Van Ness Campus, 1101 Van Ness Avenue, San Francisco, CA 94109; Other information: Joint Commission ID #5152; Previous Re-certification Dates: 12/08/2009; 11/11/2011; 01/07/2014; 02/09/2016; 03/20/2018; 02/20/2021; 11/09/2022.	050047	10/20/2009	12/11/2024	CA
Mayo Clinic Hospital—Rochester, 1216 Second Street SW, Rochester, MN 55902–1906; Other information: Joint Commission ID #: 8181; Previous Re-certification Dates: 02/26/2008; 02/09/2010; 02/21/2012; 02/21/2014; 04/05/2016; 03/23/2018; 03/20/2021; 11/03/2022.	240010	02/26/2008	12/18/2024	MN
Barnes-Jewish Hospital, 1 Barnes Jewish Plaza, Saint Louis, MO 63110; Other information: Joint Commission ID #: 8387; Previous Re-certification Dates: 08/21/2008; 07/27/2010; 07/17/2012; 08/05/2014; 09/13/2016; 11/10/2017; 10–22–2020; 10/05/2022.	260032	08/21/2008	12/11/2024	MO
Indiana University Health, Inc., 1701 North Senate Boulevard, Indianapolis, IN 46202; Other information: Joint Commission ID #: 188549; Previous Re-certification Dates: 08/12/2008; 08/17/2010; 08/17/2012; 08/19/2014; 10/04/2016; 05/29/21; 01/20/2023.	150056	08/12/2008	02/22/2025	IN
Adventist Health System/Sunbelt Inc. dba AdventHealth, 601 East Rollins Street, Orlando, FL 32803; Other information: Joint Commission ID #6873; Previous Re-certification Dates: 10/24/2012; 10/07/2014; 11/15/2016; 01/30/2019; 06/12/2021.	100007	10/24/2012	05/20/2023	FL
Bon Secours St. Mary's Hospital, 5801 Brems Road, Richmond, VA 23226; Other information: Joint Commission ID #: 6387; Previous Re-certification Dates: 12/15/2011; 12/17/2013; 01/26/2016; 02/21/2018; 06/11/2021.	490059	12/15/2011	03/04/2023	VA
North Shore University Hospital, 300 Community Drive, Manhasset, NY 11030; Other information: Joint Commission ID #: 2091; Previous Re-certification Dates: 09/27/2016; 9/19/2018; 06/26/2021.	330106	09/27/2016	03/29/2023	NY
University of Iowa Hospitals and Clinics, 200 Hawkins Drive, Iowa City, IA 52242; Other information: Joint Commission ID #: 8266; Previous Re-certification Dates: 06/22/2010; 07/26/2012; 07/29/2014; 08/02/2016; 7/11/2018; 4/8/2021; 10/14/2022.	160058	06/22/2010	11/16/2024	IA

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (January Through March 2025)

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 (January Through March 2025)

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 co-morbidity 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 ASBS 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 (January Through March 2025)

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 15, 2025.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA