

Communications Act, noncommercial educational (NCE) stations are also entitled to assert mandatory carriage rights on cable systems located within the station's market; however, noncommercial TV broadcast stations are not entitled to retransmission consent.

In 2019, the Commission adopted new rules governing the delivery and form of carriage election notices. Electronic Delivery of MVPD Communications, Modernization of Media Regulation Initiative, MB Docket Nos. 17–105, 17–317, Report and Order and Further Notice of Proposed Rulemaking, FCC 19–69, 34 FCC Rcd 5922(2019) (2019 Report and Order). That decision modernized the carriage election notice rules by moving the process online for most broadcasters and multichannel video programming distributors (MVPDs), but the Commission sought comment on how to apply these updated rules to certain small broadcast stations and MVPDs.

In 2020, the Commission adopted a Report and Order that resolved the remaining issues regarding carriage election notice rules for small broadcast stations and MVPDs. Electronic Delivery of MVPD Communications, Modernization of Media Regulation Initiative, MB Docket Nos. 17–105, 17–317, Report and Order, FCC 20–14, 2020 WL 948697 (rel. Feb. 25, 2020) (2020 Report and Order). Pursuant to that decision, the obligations of certain small broadcasters and MVPDs were slightly modified.

The Commission is seeking an extension without change of this currently approved collection for the full three-year period.

Federal Communications Commission.

**Marlene Dortch,**  
Secretary.

[FR Doc. 2025–21618 Filed 11–28–25; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Savings and Loan Holding Company

The notificants listed below have applied under the Change in Bank Control Act (“Act”) (12 U.S.C. 1817(j)) and of the Board’s Regulation LL (12 CFR 238.31) to acquire shares of a savings and loan holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board’s Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Deputy Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 16, 2025.

*A. Federal Reserve Bank of Chicago*  
(Colette A. Fried, Assistant Vice President) 230 South LaSalle Street,

Chicago, Illinois 60690–1414.

Comments can also be sent electronically to

[Comments.applications@chi.frb.org](mailto:Comments.applications@chi.frb.org):

1. *James J. White, Westside, Iowa*; to acquire voting shares of Halbur Bancshares, Inc., and thereby indirectly acquire voting shares of Westside State Bank, both of Westside, Iowa.

Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Associate Secretary of the Board.*

[FR Doc. 2025–21669 Filed 11–28–25; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS–9156–N]

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July through September 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 Number
<b>I. CMS Manual Instructions</b>	Ronda Allen-Bonner	(410) 786-4657
<b>II. Regulation Documents Published in the Federal Register</b>	Gittel Treitel	(410) 786-4673
<b>III. CMS Rulings</b>	Tiffany Lafferty	(410) 786-7548
<b>IV. Medicare National Coverage Determinations</b>	Wanda Belle, MPA	(410) 786-7491
<b>V. FDA-Approved Category B IDEs</b>	John Manlove	(410) 786-6877
<b>VI. Collections of Information</b>	William Parham	(410) 786-4669
<b>VII. Medicare –Approved Carotid Stent Facilities</b>	Sarah Fulton, MHS	(410) 786-2749
<b>VIII. American College of Cardiology-National Cardiovascular Data Registry Sites</b>	Sarah Fulton, MHS	(410) 786-2749
<b>IX. Medicare’s Active Coverage-Related Guidance Documents</b>	Lori Ashby, MA	(410) 786-6322
<b>X. One-time Notices Regarding National Coverage Provisions</b>	JoAnna Baldwin, MS	(410) 786-7205
<b>XI. National Oncologic Positron Emission Tomography Registry Sites</b>	David Dolan, MBA	(410) 786-3365
<b>XII. Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities</b>	David Dolan, MBA	(410) 786-3365
<b>XIII. Medicare-Approved Lung Volume Reduction Surgery Facilities</b>	Sarah Fulton, MHS	(410) 786-2749
<b>XIV. Medicare-Approved Bariatric Surgery Facilities</b>	Sarah Fulton, MHS	(410) 786-2749
<b>XV. Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials</b>	David Dolan, MBA	(410) 786-3365
<b>All Other Information</b>	Gaysha Brooks	(410) 786-9649

**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.

**BILLING CODE 4120-01-P**

### 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: November 7, 2024 (89 FR 88282), February 19, 2025 (90 FR 9902), May 16, 2025 (90 FR 21043), and August 5, 2025 (90 FR 37516). 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 (July through September 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 the Omnibus Change Request (CR) Covering Updates for the Medicare Physician Fee Schedule (MPFS) Rule 2025: (1) Updates to Colorectal Cancer Screening and Hepatitis B Vaccine Policies (CMS-Pub. 100-02) Transmittal No. 13295.

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](http://www.cms.gov/Manuals).

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

Transmittal Number	Manual/Subject/Publication Number
	Medicare General Information (CMS-Pub. 100-01)
	None
	Medicare Benefit Policy (CMS-Pub. 100-02)
13295	Omnibus Change Request (CR) Covering Updates for the Medicare Physician Fee Schedule (MPFS) Rule 2025: (1) Updates to Colorectal Cancer Screening and Hepatitis B Vaccine Policies
	Medicare National Coverage Determination (CMS-Pub. 100-03)
13343	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)
13366	NCD 20.38 - Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)
13374	Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)
13427	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)

13344	July 2025 Update of the Ambulatory Surgical Center (ASC) Payment System
13349	Influenza Vaccine Payment Allowances - Annual Update for 2025-2026 Season
13350	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
13361	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2025 Update
13362	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
13364	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
13365	National Fee Schedule for Vaccine Administration Quarterly Update - October 2025
13366	NCD 20.38 - Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TFER)
13374	Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)
13376	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13377	January 2026 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
13378	Quarterly Update to Home Health (HH) Grouper
13379	Annual Clotting Factor Furnishing Fee Update 2026
13380	Changing the Frequency of No-Pay Medicare Summary Notice (MSN) Mailings from Every 120 Days to Every 180 Days
13388	October Quarterly Update for 2025 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
13391	Enhancing Compliance and Payment Accuracy for Physician Services in Skilled Nursing Facilities
13395	Allowing Additional Revenue Codes for Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI) beginning in Calendar Year (CY) 2025
13398	Fiscal Year (FY) 2026 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) PPS Changes
13412	Laboratory Specimen Collection Travel Allowance Billing to the Tenth of a Mile
13414	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13416	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13418	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
13420	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
13421	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
13422	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13424	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

Medicare Claims Processing (CMS-Pub. 100-04)	
13270	October 2025 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
13292	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2025
13293	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
13294	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - October 2025
13295	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2025
13295	Omnibus Change Request (CR) Covering Updates for the Medicare Physician Fee Schedule (MPFS) Rule 2025: (1) Updates to Colorectal Cancer Screening and Hepatitis B Vaccine Policies
13296	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13297	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13299	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13304	Technical Revisions Only to the Claims Processing Manual (CPM), Publication (Pub) 100-04, Chapter 18 and Chapter 32
13309	I Fiscal Year (FY) 2026 Updates for Medical Severity Diagnosis Related Groups (MS-DRG) Subject to Inpatient Prospective Payment System (IPPS) Replaced Devices Offered Without Cost or With a Credit Policy
13310	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13312	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13313	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13314	Modifications to the National Coordination of Benefits Agreement (COBA) Medicare Claims Crossover Process
13315	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
13316	Update to Publication 100-04, Chapter 12, Section 30.6.7 to Establish Payment Criteria for Healthcare Common Procedure Coding System (HCPCS) Add-on Code G2211 Billed on the Same Day as Identified Preventive Services
13317	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Sections 150.4, 150.6, 200.2, 300.2, 400.2, 400.2.2, 400.2.3, 400.2.3.1, 400.2.4, and 400.3 for Coding Revisions to National Coverage Determinations (NCDs) - July 2025 Change Request (CR) 13939
13318	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13319	Allowing Additional Revenue Codes for Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI) beginning in Calendar Year (CY) 2025
13320	Laboratory Specimen Collection Travel Allowance Billing to the Tenth of a Mile
13326	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13331	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
13343	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)

13345	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13346	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13348	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13354	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13355	Removal of Gender References from CMS Publication (Pub.) 100-08, Chapter 10
13356	Suppliers Documentation for Claims for Refills of Essential Accessories for Beneficiary-Owned Continuous Positive Airway Pressure (CPAP), Respiratory Assist Devices (RADs), and Continuous Glucose Monitors (CGMs)
13357	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13358	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13363	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13370	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13371	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13372	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13382	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13384	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13387	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13391	Enhancing Compliance and Payment Accuracy for Physician Services in Skilled Nursing Facilities
13407	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13408	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13409	Update to Medical Review Instructions for Inpatient Hospital Claims in Chapter 6 of Publication (Pub.) 100-08, Program Integrity Manual (PIM)
13415	Provider Enrollment Updates to Chapter 10 of CMS Publication (Pub.) 100-08, Program Integrity Manual (PIM)
13435	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)</b>	
None	
<b>Medicare Quality Improvement Organization (CMS- Pub. 100-10)</b>	
None	
<b>Medicare Program of All-Inclusive Care for the Elderly (CMS- Pub. 100-11)</b>	
None	
<b>Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)</b>	
None	
<b>Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)</b>	
13385	Updates of Chapter 3 and the Appendices Chapter in Publication (Pub.) 100-

13423	Update to Pub 100-04, Chapter 18 - Preventive and Screening Services
13425	October 2025 Update of the Hospital Outpatient Prospective Payment System (OPPS)
13426	2026 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update
13427	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)
13428	Revised Start Date of the Expanded Outlier Reconciliation Criteria for the Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS
13429	October 2025 Update of the Ambulatory Surgical Center [ASC] Payment System
13431	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
13436	October Quarterly Update for 2025 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
<b>Medicare Secondary Payer (CMS-Pub. 100-05)</b>	
None	
<b>Medicare Financial Management (CMS-Pub. 100-06)</b>	
13268	The Fiscal Year 2025 CMS Internet Only Manual (IOM) Update to Publication (Pub.) 100-06, Chapter 5, 400.14 - Exhibit 14 - Protocol for Estimating Allowance for Uncollectible Accounts and 400.22 - Exhibit 22 - Accounts Receivable Trending Analysis Procedures
13303	Notice of New Interest Rate for Medicare Overpayments and Underpayments - 4th Quarter Notification for FY 2025
13305	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
13369	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13417	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b>	
None	
<b>Medicare Program Integrity (CMS-Pub. 100-08)</b>	
13291	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13302	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13306	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13311	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13321	Updates to the Medical Record Documentation Guidance Within Publication (Pub.) 100-08, Program Integrity Manual (PIM)
13322	Updates to Chapter 1, Section 1.4 of Publication (Pub) 100-08 - Program Integrity Manual (PIM) To Clarify the Contractor Medical Director's Primary Functions
13323	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13325	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13328	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
13332	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

	15, Including Updates to the Medicaid Proactive Project Development Process	
	<b>Medicare Managed Care (CMS-Pub. 100-16)</b>	
	None	
	<b>Medicare Business Partners Systems Security (CMS-Pub. 100-17)</b>	
13307	Pub 100-17 Medicare Business Partners Systems Security Manual Update <b>Medicare Prescription Drug Benefit (CMS-Pub. 100-18)</b>	
	None	
	<b>Demonstrations (CMS-Pub. 100-19)</b>	
13301	Transforming Episode Accountability Model (TEAM) 3-Day Skilled Nursing Facility (SNF) Waiver – Implementation	
13333	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13334	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13367	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13368	Transforming Episode Accountability Model (TEAM) 3-Day Skilled Nursing Facility (SNF) Waiver – Implementation	
13390	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13399	Transforming Episode Accountability Model (TEAM) 3-Day Skilled Nursing Facility (SNF) Waiver – Implementation	
13402	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13403	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13413	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction	
13434	Transforming Episode Accountability Model (TEAM) 3-Day Skilled Nursing Facility (SNF) Waiver – Implementation	
	<b>One Time Notification (CMS-Pub. 100-20)</b>	
13174	Continuation of System Changes to Automate Processing of Inpatient Claims for Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapy Cases	
13290	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13300	Fiscal Intermediary Shared System (FISS) - Delete Obsolete Reason Codes - Part 7	
13308	Update of a National Uniform Billing Committee (NUBC) Condition Code “63” - “Incarcerated Beneficiaries”	
13324	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13327	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs) - October 2025	
13329	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13330	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction	
13335	Hold Split Claims Pulled for Review in ViPS Medicare System (VMS) Online Quality Control (OQC)	
13336	Update the Multi-Carrier System (MCS) Criteria Location Movement Maintenance (CM) Screen	
13337	Issued to a specific audience, not posted to Internet/Intranet due to a	

13433	Patient Driven Payment Model (PDPM) Corrections to Interrupted Stay Edits to Include Prospective Payment System (PPS) Swing Bed Providers
13438	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)—January 2026 Update- CR 1 of 2
<b>Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)</b>	
13373	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>State Payment of Medicare Premiums (CMS-Pub.100-24)</b>	
	None
<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)</b>	
	None

For questions or additional information, contact Ronda Allen-Bonner (410-786-4657).

#### **Addendum II: Regulation Documents Published in the Federal Register (July through September 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/dsds](http://www.gpo.gov/dsds). 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 (July through September 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 (July through September 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. 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 Number	Issue Date	Effective Date
Repair for Tricuspid Transcatheter Edge-to-Edge	NCD 20.38	13366	08/14/2025	04/09/2025
Transcatheter Tricuspid Valve Replacement (TTVR)	NCD 20.37	13343	08/04/2025	03/19/2025

#### **Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2025)** (Inclusion of this addenda is under discussion internally.)

#### **Addendum VI: Approval Numbers for Collections of Information (July through September 2025)**

All approval numbers are available to the public at [Reginfo.gov](http://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](http://www.reginfo.gov/public/do/PRAMain).

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

**Addendum VII: Medicare-Approved Carotid Stent Facilities (July through September 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/ApprovedFacilities/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 (July through September 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 (July through September 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?mcid=38>

CMS National Coverage Analysis Evidence Review:

<https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcid=37>

Clinical Endpoints Guidance: Knee Osteoarthritis:

<https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcid=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 (July through September 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) (July through September 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/Medicare/ApprovedFacilities/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 (July through September 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 Number	Date of Initial Certification	Date of Re-certification	State
<b>The following facilities have editorial changes (in bold).</b>				
North Shore University Hospital 300 Community Drive Manhasset, NY 11030	330106	09/27/2016	<b>04/09/2025</b>	NY
Other information: Joint Commission ID # 2091				
Previous Re-certification Dates: 09/27/2016; 9/19/2018; 06/26/2021; 03/09/2023				
Sharp Memorial Hospital 7901 Frost Street San Diego, CA 92123	050100	10/17/2008	<b>03/22/2025</b>	CA
Other information: Joint Commission ID # 3910				
Previous Re-certification Dates: 07/17/2008; 06/29/2010; 08/14/2012; 09/09/2014; 08/09/2016; 8/15/2018; 6/5/2021; 03/28/2023				
Integrus Baptist Medical Center 3300 Northwest Expressway Oklahoma City, OK 73112	370028	08/13/2008	<b>04/09/2025</b>	OK
Other Information Joint Commission ID # 8872				
Previous Re-certification Dates: 08/12/2008;				

07/20/2010; 07/24/2012; 7/08/2014; 08/23/2016; 06/19/2021; 03/18/2023	220110	11/04/2008	<b>04/16/2025</b>	MA
Brigham and Women's Hospital 75 Francis Street Boston, MA 02115				
Other information: Joint Commission ID #5503				
Previous Re-certification Dates: 11/04/2008; 12/09/2010; 12/07/2012; 11/07/2014; 12/13/2016; 2/27/2019; 07/10/2021; 06/14/2023				
Bon Secours St. Mary's Hospital 5801 Bremono Road Richmond, VA 23226	490059	12/15/2011	<b>04/12/2025</b>	VA
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; 03/04/2023				
University of Cincinnati Medical Center 3188 Bellevue Avenue Cincinnati, OH 45219	360003	12-13-2011	<b>04/16/2025</b>	OH
Other information: Joint Commission ID #: 6988				
Previous Re-certification Dates: 12/13/2011; 01/07/2014; 02/23/2016; 03/13/2018; 05/19/2021; 03/16/2023				
University of Maryland Medical Center 22 South Greene Street Baltimore, MD 21201-1595	210002	09/16/2008	<b>04/23/2025</b>	MD
Other information: Joint Commission ID #: 6264				
Previous Re-certification Dates: 09/16/2008; 08/25/2010; 08/15/2012; 08/19/2014; 09/20/2016; 9/26/2018; 07/03/2021; 03/31/2023				

Previous Re-certification Dates: 12/12/2018; 08/19/2021; 04/20/2023					
Kaiser Foundation Hospital - Sunnyside 10180 SE Sunnyside Road Clackamas, OR 97015-9303	380091	09/13/2016	05/24/2025	OR	
Other information: Joint Commission ID #: 4858					
Previous Re-certification Dates: 09/13/2016; 09/19/2018; 08/25/2021; 05/03/2023					
Ohio State University Hospitals 410 West Tenth Avenue, DN 168 Columbus, OH 43210	360085	04/14/2006	06/04/2025	OH	
Other information: Joint Commission ID #7029					
Previous Re-certification Dates: 04/14/2006; 11/18/2008; 10/22/2010; 10/23/2012; 10/03/2014; 10/28/2016; 10/24/2018; 05/04/2021; 04/29/2023-					
Cleveland Clinic 9500 Euclid Avenue NA-4 Cleveland, OH 44195	360180	10/28/2008	05/21/2025	OH	
Other information: Joint Commission ID #7001					
Previous Re-certification Dates: 10/28/2008; 11/23/2010; 11/12/2012; 12/02/2014; 11/08/2016; 12/12/2018; 05/17/2023					
Virginia Commonwealth University Health System Authority 1250 East Marshall Street Richmond, VA 23298-0510	490032	11/04/2008	07/30/2025	VA	
Other information: Joint Commission ID #: 6381					
Previous Re-certification Dates: 11/04/2008; 12/14/2010; 12/21/2012; 12/16/2014; 02/14/2017; 04/10/2019; 07/19/2023					

Robert Wood Johnson University Hospital One Robert Wood Johnson Place New Brunswick, NJ 08903- 2601	310038	07/22/2010	05/08/2025	NJ	
Other information: Joint Commission ID #: 5969					
Previous Re-certification Dates: 07/22/2010; 07/20/2012; 06/17/2014; 07/19/2016; 07/08/2021; 04/22/2023					
Kaiser Foundation Hospital - Santa Clara 700 Lawrence Expressway Santa Clara, CA 95051	050071	03/25/2021	05/09/2025	CA	
Other information: Joint Commission ID #10123					
Previous Re-certification Dates: 03/25/2021; 03/25/2023					
<b>FROM: WellSpan York Hospital</b> <b>TO: York Hospital</b> 1001 South George Street York, PA 17403	390046	11/19/2013	06/10/2025	PA	
Other information: DNV ID# C755049					
Previous Re-certification Dates: 11/19/2013; 12/15/2015; 01/23/2018; 03/14/2020; 06/18/2022; 09/11/2024					
MaineHealth 22 Bramhall Street Portland, ME 04102	200009	11/05/2008	05/10/2025	ME	
Other information: Joint Commission ID #5445					
Previous Re-certification Dates: 11/05/2008; 09/27/2016; 10/3/2018; 07/08/2021; 04/08/2023					
TriStar Centennial Medical Center 2300 Patterson Street Nashville, TN 37203	440161	12/12/2018	05/14/2025	TN	
Other information: Joint Commission ID #: 7888					

District Hospital Partners, L.P. 900 23rd Street, NW Washington, DC 20037 Other information: Joint Commission ID # 6310 Previous Re-certification Dates: 9/12/2018; 07/10/2021; 04/20/2023	090001	09/12/2018	05/21/2025	DC
Duke University Health System, Inc 2301 Erwin Road Durham, NC 27710 Other information: Joint Commission ID #6490 Previous Re-certification Dates: 01/16/2009; 06/30/2011; 06/04/2043; 05/05/2015; 06/13/2017; 08/21/2019; 09/22/2021; 08/23/2023	340030	01/16/2009	07/23/2025	NC
Catholic Health Initiatives - Iowa, Corp. 1111 6th Avenue Des Moines, IA 50314 Other information: Joint Commission ID #8248 Previous Re-certification Dates: 01/06/2015; 02/14/2017; 3/27/2019; 07/01/2021; 06/03/2023	160083	01/06/2015	06/18/2025	IA
FROM: NorthShore University Health System TO: Endeavor Health Clinical Operations 2650 Ridge Ave Evanston, IL 60201 Other Information Join Commission #7343 Previous Re-certification Dates: 10/25/2016; 11/15/2018; 06/08/2023	140010	10/25/2016	06/25/2025	IL
Adventist Health System/Sunbelt Inc. dba AdventHealth 601 East Rollins Street Orlando, FL 32803 Other Information: Joint Commission ID #6873	100007	10/24/2012	06/19/2025	FL
Previous Re-certification Dates: 10/24/2012; 10/07/2014; 11/15/2016; 01/30/2019; 06/12/2021; 05/20/2023 HCA Florida JFK Hospital 5301 South Congress Avenue Atlanta, FL 33462 Other Information: Joint Commission ID #6836 Previous Recertification Dates: 01/24/2017; 3/6/2019; 03/03/2021; 05/10/2023	100080	01/24/2017	06/11/2025	FL
Henry Ford Health System 2799 West Grand Boulevard Detroit, MI 48202 Other Information: Joint Commission ID #7485 Previous Certification Dates: 10/30/2008; 10/21/2010; 11/06/2012; 10/28/2014; 12/20/2016; 3/13/2019; 07/29/2021; 06/16/2023	230053	01/06/2004	07/03/2025	MI
Abbott Northwestern Hospital 800 East 28th Street Minneapolis, MN 55407 Other Information: Joint Commission ID #8149 Previous Certification Dates: 11/16/2010; 11/29/2012; 11/18/2014; 12/06/2016; 2/13/2019; 07/28/2021; 07/15/2023	240057	11/16/2010	07/09/2025	MN
Fresno Community Hospital and Medical Center 2823 Fresno St Fresno, CA 93721 Other Information: Joint Commission ID #9832 Previous Certification Dates: 1/04/2014; 12/13/2016; 2/13/2019; 08/11/2021; 08/09/2023	050060	01/04/2014	07/16/2025	CA
Mainmonides Medical Center 4802 Tenth Avenue Brooklyn, NY 11219-2916	330194	08/24/2012	09/07/2025	NY

Other Information Joint Commission ID #5734 Previous Certification Dates: 08/23/2012; 07/29/2014; 09/13/2016; 10/11/2018; 10/27/2021; 10/18/2023	220086	04/25/2017	09/17/2025	MA
Beth Israel Deaconess Medical Center 330 Brookline Avenue Boston, MA 02215				
Other Information: Joint Commission ID #5501 Previous Certification Dates: 4/25/2017; 05/22/2019; 11/04/2021; 09/29/2023				

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)**  
**(July through September, 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/Medicare/ApprovedFacilities/LVRS/list.asp#TopOfPage](https://www.cms.gov/Medicare/ApprovedFacilities/LVRS/list.asp#TopOfPage). For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities**  
**(July through September 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 ASMB in the 3-month period. This information is available at

[www.cms.gov/Medicare/ApprovedFacilities/BSF/list.asp#TopOfPage](https://www.cms.gov/Medicare/ApprovedFacilities/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 (July through September 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/Medicare/ApprovedFacilities/PETDT/list.asp#TopOfPage](https://www.cms.gov/Medicare/ApprovedFacilities/PETDT/list.asp#TopOfPage).

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

[FR Doc. 2025–21622 Filed 11–28–25; 8:45 am]  
BILLING CODE 4120–01–C

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10690]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by December 31, 2025.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/>

#### *Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* CLIA Proficiency Testing (PT); *Use:* This is an extension package. The purpose of this package is to request Office of Management and Budget (OMB) approval for the information collection request (ICR) for proficiency testing (PT) and reapproval of PT programs. The ICR includes laboratories filling in PT submission forms for microbiology PT and document collection for a PT program if it needs to reapply for approval using the initial approval process.

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (Pub. L. 100–578) (CLIA'88), codified at 42 U.S.C. 263a, to ensure the accuracy and reliability of testing in all laboratories, including, but not limited to, those that participate in Medicare and Medicaid, that test human specimens for purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of health, of human beings. The Secretary established the initial regulations implementing CLIA on February 28, 1992 at 42 CFR part 493 (57 FR 7002). Among other things, those regulations required laboratories conducting moderate or high complexity testing to

enroll in an approved PT program for each specialty, subspecialty, and analyte or test for which the laboratory is certified under CLIA. PT evaluates a laboratory's performance by testing of unknown samples just as it would test patient samples.

A Health and Human Services (HHS)-approved PT program sends unknown samples to a laboratory for analysis. After testing, the laboratory reports its results to the PT program. The program grades the results using the CLIA grading criteria and provides the laboratory with its scores. PT is crucial to maintaining the quality of laboratory testing because it independently verifies the accuracy and reliability of laboratory testing, including the competency of testing personnel. PT referral was further addressed by enactment of the Taking Essential Steps for Testing Act of 2012 (Pub. L. 112–202, December 4, 2012) (TEST Act) and our implementing regulations (79 FR 25435 and 79 FR 27105). As of July 2025, there were 307,193 CLIA-certified laboratories, of which 33,990 Certificate of Compliance (CoC) and Certificate of Accreditation (CoA) laboratories were required to enroll in an HHS-approved PT program and comply with the PT regulations.

Testing has evolved significantly since 1992, and technology is now more accurate and precise than the methods in use at the time the PT regulations became effective for all laboratories in 1994. In addition, many tests for analytes for which PT was not initially required are now in routine clinical use. For example, tests for cardiac markers, such as troponins, and hemoglobin A1c test commonly used to monitor glycemic control in persons with diabetes, were not routinely performed prior to 1992. Recognizing these changes, we finalized revisions to our existing PT regulations in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance (CMS 3355–F) which published July 11, 2022 (87 FR 41194). Each PT program supplies laboratories with its forms required for enrolling in microbiology PT; and reapplication for approval has no standardized forms required.

The original CLIA regulation PRA Supporting Statement for CLIA (OMB control number: 0938–0612) did not include the collection requirements for microbiology PT provisions or PT programs included in this final rule. We determined during the proposed rule phase that this ICR would be needed to cover the additional information collections. We plan to include these two information collections when the