

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 requires federal agencies to publish a 60-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.

**Information Collection**

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title:* Hospital Wage Index Occupational Mix Survey; *Use:* Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Social Security Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals’ employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

CMS takes the data collected from the approximately 3,200 IPPS providers participating in the Medicare program and runs the data through mathematical formulas to create the occupational mix adjustment to the wage index. CMS informs hospitals of the occupational mix adjusted wage indexes through notice and comment rulemaking each year. *Form Number:* CMS–10079 (OMB Control Number: 0938–0907); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 3,200; *Number of Responses:* 3,200; *Total Annual Hours:* 1,536,000. (For policy questions regarding this collection contact Noel Manlove at 410–786–5161.)

2. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title:* Basic Health Program (BHP) Supporting Regulations; *Use:* In accordance with Section 1331 of the Patient Protection and Affordability Care Act, Public Law 111–148 (ACA), BHP is federally funded by determining the amount of payments that the federal government would have made through premium tax credits and cost-sharing reductions for people enrolled in BHP had they instead been enrolled in an Exchange. States must submit a BHP Blueprint to CMS for certification prior to the state implementing a BHP and must submit a revised Blueprint in the event that a state seeks to make significant changes that alter program operations; the BHP benefit package; or enrollment, disenrollment, and verification policies described in the Blueprint. Such States must also submit a BHP annual report. In addition to the reinstatement, this 2022 iteration proposes changes that are associated with the March 12, 2014 (79 FR 14112) BHP final rule that have not previously received PRA approval; *Form Number:* CMS–10510 (OMB

Control Number: 0938–1218); *Frequency:* Monthly and annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 2; *Number of Responses:* 27; *Total Annual Hours:* 2,568. (For policy questions regarding this collection contact Cassie Lagorio at 443–721–8022.)

Dated: July 29, 2022.  
**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2022–16681 Filed 8–3–22; 8:45 am]  
**BILLING CODE 4120–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS–9137–N]

**Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2022**

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

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2022, 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 .....	Ismael Torres .....	(410) 786–1864
II Regulation Documents Published in the <b>Federal Register</b> .....	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 .....	JoAnna Baldwin, MS .....	(410) 786–7205
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

Addenda	Contact	Phone No.
All Other Information .....	Annette Brewer .....	(410) 786-6580

**SUPPLEMENTARY INFORMATION:**

**I. Background**

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

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

**II. Format for the Quarterly Issuance Notices**

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

sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

**III. How To Use the Notice**

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

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

Dated: July 28, 2022.

**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: August 17, 2021 (86 FR 45986), November 18, 2021 (86 FR 64492), February 9, 2022 (87 FR 7458) and May 13, 2022 (87 FR 29327). 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 (April through June 2022)**

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 for Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2 (CMS-Pub. 100-02) Transmittal No. 11399.

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).

Transmittal Number	Manual/Subject/Publication Number
11395	<b>Medicare General Information (CMS-Pub. 100-01)</b> Updated Instructions for the Change Request Implementation Report (CRIR) and Technical Direction Letter (TDL) Compliance Report (TCR)
11438	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction <b>Medicare Benefit Policy (CMS-Pub. 100-02)</b>
11355	Update to Publication 100-04, Chapter 18 and Publication 100-02, Chapter 15, Section to Add Data Regarding Novel Coronavirus (COVID-19) and its Administration to Current Claims Processing Requirements and Other General Updates Supplementary Medical Insurance (SMI) Provisions Immunizations Services and Supplies Furnished Incident To a Physician's/NPP's Professional Service Preventive and Screening Services
11386	Update to Chapter 7, "Home Health Services," of the Medicare Benefit Policy Manual (Pub 100-02) Submission of the Notice of Admission (NOA) Requirements for Submission of NOA Definition of an Allowed Practitioner

<p>Screening Pap Smears: Diagnoses Codes Diagnoses Codes Stem Cell Transplantation IICPCS and Diagnosis Coding for Stem Cell Transplantation -ICD-10-CM Applicable Suggested MSN and RA Messages Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS) General ICD-10 Diagnosis Codes for Vagus Nerve Stimulation (Covered since DOS on and after July 1, 1999) Vagus Nerve Stimulation for TRD for Battery Replacement Professional Billing Requirements Institutional Billing Requirements Medicare Summary Notice (MSN), Remittance Advice Remark Code (RARC) and Claim Adjustment Reason Code (CARC) Messages Advance Beneficiary Notice and HINN Information Other Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims Claims Processing Requirements for PILD for Outpatient Facilities A/B MAC (A) Revenue Code A/B MAC Billing HCPCS Codes A/B MAC Diagnosis and Procedure Code Requirements Payment Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARC), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Processing General Information Institutional Claims Bill Type and Revenue Coding Information Common Working File (CWF) FISS, and Multi-Carrier System (MCS) Editing Update to Publication 100-04, Chapter 18 and Publication 100-02, Chapter 15, Section to Add Data Regarding Novel Coronavirus (COVID-19) and its Administration to Current Claims Processing Requirements and Other General Updates Table of Contents Table of Preventive and Screening Services Pneumococcal Pneumonia, Influenza Virus, Hepatitis B, and Coronavirus Disease (COVID-19) Vaccines and Administration Coverage Requirements COVID-19 Vaccine Billing Requirements Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes Claims Received with Missing Data Claims Submitted to MACs Using Institutional Formats Payment for Pneumococcal Pneumonia Virus, Influenza Virus, Hepatitis B Virus and, COVID-19 Vaccines and Their Administration on Institutional Claims Special Instructions for Independent and Provider-Based Rural Health Clinics/Federally Qualified Health Center (RHCs/FQHCs) Institutional Claims Submitted by Home Health Agencies and Hospices Payment Procedures for Renal Dialysis Facilities (RDF) Hepatitis B Vaccine Furnished to ESRD Patients Claims Submitted to MACs (Part B) MAC (Part B) Indicators for the Common Working File (CWF) MAC (Part B) Payment Requirements</p>	<p>11355</p>
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<p>11399</p>	<p>Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2 An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage Pulmonary Rehabilitation (PR) Program Services Furnished On or After January 1, 2010 Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010 Update to Chapter 7, "Home Health Services," of the Medicare Benefit Policy Manual (Pub 100-02) Submission of the Notice of Admission (NOA) Requirements for Submission of NOA</p>
<p>11426</p>	<p>Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2</p>
<p>11447</p>	<p><b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b> Revisions to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) and 240.2.2 (Home Oxygen Use for Cluster Headache) An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage Medical Nutrition Therapy Enteral and Parenteral Nutritional Therapy Positron Emission Tomography (PET) Scans</p>
<p>11448</p>	<p>National Coverage Determination (NCD) 210.14 Reconsideration – Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) Lung Cancer Screening with Low Dose Computed Tomography (LDCT)</p>
<p>11263</p>	<p>An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage Medical Nutrition Therapy Enteral and Parenteral Nutritional Therapy Positron Emission Tomography (PET) Scans</p>
<p>11272</p>	<p>National Coverage Determination (NCD) 210.14 Reconsideration – Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) Lung Cancer Screening with Low Dose Computed Tomography (LDCT)</p>
<p>11388</p>	<p>An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage Medical Nutrition Therapy Enteral and Parenteral Nutritional Therapy Positron Emission Tomography (PET) Scans</p>
<p>11426</p>	<p>Revisions to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) and 240.2.2 (Home Oxygen Use for Cluster Headache) Home Use of Oxygen Home Oxygen Use to Treat Cluster Headache (CH)</p>
<p>11429</p>	<p><b>Medicare Claims Processing (CMS-Pub. 100-04)</b> Corrections to Home Health Billing for Denial Notices and Calculation of 60-Day Gaps in Services Day Gaps in Services Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction</p>
<p>11341</p>	<p>Revisions to Chapters 3, "Inpatient Hospital Billing" of the Medicare Claims Processing Manual (Pub 100-04), 18, "Preventive and Screening Services" of the Medicare Claims Processing Manual (Pub 100-04), and 32 "Billing Requirements for Special Services" of the Medicare Claims Processing Manual (Pub 100-04) to Update Coding Stem Cell Transplantation Autologous Stem Cell Transplantation (AutSCT) HCPCS and Diagnosis Codes for Mammography Services</p>
<p>11344</p>	<p>Revisions to Chapters 3, "Inpatient Hospital Billing" of the Medicare Claims Processing Manual (Pub 100-04), 18, "Preventive and Screening Services" of the Medicare Claims Processing Manual (Pub 100-04), and 32 "Billing Requirements for Special Services" of the Medicare Claims Processing Manual (Pub 100-04) to Update Coding Stem Cell Transplantation Autologous Stem Cell Transplantation (AutSCT) HCPCS and Diagnosis Codes for Mammography Services</p>
<p>11348</p>	<p>Revisions to Chapters 3, "Inpatient Hospital Billing" of the Medicare Claims Processing Manual (Pub 100-04), 18, "Preventive and Screening Services" of the Medicare Claims Processing Manual (Pub 100-04), and 32 "Billing Requirements for Special Services" of the Medicare Claims Processing Manual (Pub 100-04) to Update Coding Stem Cell Transplantation Autologous Stem Cell Transplantation (AutSCT) HCPCS and Diagnosis Codes for Mammography Services</p>

<p>Suggested MSN and RA Messages                  Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)                  General                  ICD-10 Diagnosis Codes for Vagus Nerve Stimulation (Covered since DOS on and after July 1, 1999)                  Vagus Nerve Stimulation for TRD for Battery Replacement Professional Billing Requirements                  Medicare Summary Notice (MSN), Remittance Advice Remark Code (RARC) and Claim Adjustment Reason Code (CARC) Messages                  Advance Beneficiary Notice and HINN Information                  Other                  Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional Claims                  Claims Processing Requirements for PILD for Outpatient Facilities                  A/B MAC (A) Revenue Code                  A/B MAC Billing HCPCS Codes                  A/B MAC Diagnosis and Procedure Code Requirements                  Payment Requirements                  Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages                  Claims Processing General Information                  Institutional Claims Bill Type and Revenue Coding Information                  Common Working File (CWF) FISS, and Multi-Carrier System (MCS) Editing</p>	<p>11396                  Update to Chapters 3, 4, 27 and 37 of Publication (Pub.) 100-04 Medicare Claims Processing Manual to Remove Reference to the Term "OSCAR"                  Swing-Bed Services                  Affected Medicare Providers                  Affected Medicare Providers                  Inputs/Outputs to PRICER                  Addendum A - Provider Specific File                  Outpatient Provider Specific File                  Consolidated Claims Crossover Process                  Use of Legacy Provider Numbers After National Provider Identifiers (NPIs) Are Fully Implemented                  Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2022                  Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment                  Quarterly Update to the End-Stage Renal Disease Prospective Payment System (ESRD PPS)                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July 2022 Update                  Issued to a specific audience, not posted to Internet/Intranet due to a</p>
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<p>Simplified Roster Claims for Mass Immunizers                  Roster Claims Submitted to MACs (Part B) for Mass Immunization                  Centralized Billing for Influenza, Pneumococcal and COVID-19 Virus Vaccinations to MACs (Part B)                  Claims Submitted to MACs (Part A) for Mass Immunizations of Influenza, Pneumococcal, and/or COVID-19 Virus Vaccinations                  Simplified Billing for Influenza, Pneumococcal and COVID-19 Virus Vaccination Services by HHAS                  Hospital Inpatient Roster Billing                  Electronic Roster Claims                  CWF Edits on MAC (Part A) Claims                  CWF Edits on MAC (Part B) Claims                  CWF Crossover Edits for MAC (Part B) Claims Medicare Summary Notice (MSN)</p>	<p>11360                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  11362                  Claims Processing Instructions for the New Hepatitis B Vaccine Code 90759                  11363                  New Waived Tests                  11365                  Update of Internet Only Manual (IOM), Pub. 100-04, Chapter 15 – Ambulance Fiscal Intermediary Shared System (FISS) Guidelines Confidentiality of Instruction                  11370                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  11371                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  11372                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  11375                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  11382                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  11384                  Update to the Payment for Grandfathered Tribal Federally Qualified Health Centers (FOHCs) for Calendar Year (CY) 2022                  11387                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  11388                  National Coverage Determination (NCD) 210.14 Reconsideration – Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)                  Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages                  Common Working File (CWF) Edits                  Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction                  11389                  Revisions to Chapters 3, "Inpatient Hospital Billing" of the Medicare Claims Processing Manual (Pub 100-04), 18, "Preventive and Screening Services" of the Medicare Claims Processing Manual (Pub 100-04), and 32 "Billing Requirements for Special Services" of the Medicare Claims Processing Manual (Pub 100-04) to Update Coding                  Stem Cell Transplantation                  Autologous Stem Cell Transplantation (AutSCT)                  HCPCS and Diagnosis Codes for Mammography Services                  Screening Pap Smears: Diagnoses Codes                  Diagnoses Codes                  Stem Cell Transplantation                  HCPCS and Diagnosis Coding for Stem Cell Transplantation -ICD-10-CM Applicable</p>
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11427	Rural Health Centers (RHCs)/Federally Qualified Health Centers (FQHCs) Special Billing Instructions Common Working File (CWF) Edits Claims Processing Manual Update - Pub. 100-04 for Elimination of Certificates of Medical Necessity (CMNs) and Durable Medical Equipment Forms (DIFs) Claims Processing Requirements - General DME General Information Where to Bill DMEPOS and PEN Items and Services General Payment Rules Payment for Replacement of Equipment General Documentation Requirements Remittance Advice Codes Technical Requirements Common Working File (CWF) Operations Special Billing Instructions for the DMEPOS Competitive Bidding Program Requirements for Processing VA Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Claims Oxygen and Oxygen Equipment Claims Processing Requirements - General Home Infusion Drugs: Healthcare Common Procedural Coding System (HCPCS) Drug Codes July 2022 Integrated Outpatient Code Editor (IOCE) Specifications Version 23.2 July 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS) Comprehensive APCs October 2022 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder New/Modifications to the Place of Service (POS) Codes for Telehealth Shared System Support Hours for Application Programming Interfaces (APIs) Place of Service Codes (POS) and Definitions Annual (2023) Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions Revisions to Chapters 3, "Inpatient Hospital Billing" of the Medicare Claims Processing Manual (Pub 100-04), 18, "Preventive and Screening Services" of the Medicare Claims Processing Manual (Pub 100-04), and 32 "Billing Requirements for Special Services" of the Medicare Claims Processing Manual (Pub 100-04) to Update Coding Modifications to the National Coordination of Benefits Agreement (COBA) Medicare Claims Crossover Process July Quarterly Update for 2022 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule July 2022 Update of the Ambulatory Surgical Center (ASC) Payment System (OPPS) July 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS) Internet Only Manual Update to Publication 100-04, Chapter 16, Sections 70.5, 70.8, and 70.9 to Remove References to the Clinical Laboratory Improvement Amendments (CLIA) Files CLIA Categories and Subcategories Certificate of Waiver HCPCS Subject to and Excluded from CLIA Edits Sensitivity of Instruction Changes to the Laboratory National Coverage Determination (NCD) Edit
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11414	Confidentiality of Instruction Claims Processing Manual Update - Pub. 100-04 for Elimination of Certificates of Medical Necessity (CMNs) and Durable Medical Equipment Forms (DIFs) Claims Processing Requirements - General DME General Information Where to Bill DMEPOS and PEN Items and Services General Payment Rules Payment for Replacement of Equipment General Documentation Requirements Remittance Advice Codes Technical Requirements Common Working File (CWF) Operations Special Billing Instructions for the DMEPOS Competitive Bidding Program Requirements for Processing VA Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Claims Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Quarterly Update to Home Health (HH) Grouper Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports Quarterly Update to the End-Stage Renal Disease Prospective Payment System (ESRD PPS) Update to the Payment for Grandfathered Tribal Federally Qualified Health Centers (FQHCs) for Calendar Year (CY) 2022 An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage Cardiac Rehabilitation (CR) Programs, Intensive Cardiac Rehabilitation (ICR) Programs, and Pulmonary Rehabilitation (PR) Programs CR Program Services Furnished On or Before December 31, 2009 Coding Requirements for CR Services Furnished On or Before Dec. 31, 2009 CR Program Services Furnished On or After January 1, 2010 Coding Requirements for CR Services Furnished On or After January 1, 2010 Claims Processing Requirements for CR and ICR Services Furnished On or After January 1, 2010 Frequency Edits for CR and ICR Claims ICR Program Services Furnished On or After January 1, 2010 Coding Requirements for ICR Services Furnished On or After January 1, 2010 PR Program Services Furnished On or After January 1, 2010 Coding Requirements for PR Services Furnished On or After January 1, 2010 Edits for PR Services Exceeding 72 Sessions General Conditions and Limitations on Coverage Referrals for MNT Services Payment for MNT Services Edits for CR Services Exceeding 36 Sessions Medical Nutrition Therapy (MNT) Services Dietitians and Nutritionists Performing MNT Services General Claims Processing Information
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	Contractor Staff When Incentive Reward Program (IRP) is Questioned in Pub. 100-08 Investigations Medical Review for Program Integrity Purposes Requests for Information From Outside Organizations Guidelines for Incentive Reward Program Complaint Tracking Reward Payment Audit
11359	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11379	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11380	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11404	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11422	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11428	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11431	Publication (Pub.) 100-08, Chapter 5 Update - Planned Elimination of Certificates of Medical Necessity (CMN) and Durable Medical Equipment Information (DIE) Forms
11432	Transition of Enrollment and Certification Activities for Various Certified Provider and Supplier Types and Transactions Community Mental Health Centers (CMHCs) Comprehensive Outpatient Rehabilitation Facilities (CORFs) Federally Qualified Health Centers (FQHCs) Home Health Agencies (HHAs) HHA Ownership Changes HHA Capitalization Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT) Skilled Nursing Facilities (SNFs) Ambulatory Surgical Centers (ASCs) Portable X-Ray Suppliers (PXRSS) Changes of Ownership (CHOWs) – Transitioned
11441	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11444	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11449	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11454	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
<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 End Stage Renal Disease Network Organizations (CMS Pub 100-14)</b>	
None	
<b>Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)</b>	
None	
<b>Medicare Managed Care (CMS-Pub. 100-16)</b>	
None	
<b>Medicare Business Partners Systems Security (CMS-Pub. 100-17)</b>	
11394	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions

	Software for October 2022 Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP), and PC Print Update 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 Combined Common Edits/Enhancements Modules (CCEM) Code Set Update Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11466	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11467	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11468	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 28.3, Effective October 1, 2022
11469	July 2022 Update of the Ambulatory Surgical Center (ASC) Payment System
11470	<b>Medicare Secondary Payer (CMS-Pub. 100-05)</b>
11471	Updating the Common Working File (CWF) Logic Tied to Medicare Secondary Payer (MSP) Investigational Records to Match Newly Revised Development Timeframes Overview of CWF MSP Processing Medicare Secondary Payer (MSP) Maintenance Transaction Record/Medicare Contractor MSP Auxiliary File Update Responsibility
11472	Automation of the Medicare Duplicate Primary Payment (DPP) Process
11481	Update the International Classification of Diseases, Tenth Revision (ICD-10) 2023 Tables in the Common Working File (CWF) for Purposes of Processing Non-Group Health Plan (NGHP) Medicare Secondary Payer (MSP) Records and Claims
11335	<b>Medicare Financial Management (CMS-Pub. 100-06)</b> Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11349	Notice of New Interest Rate for Medicare Overpayments and Underpayments 3rd Qtr Notification for FY 2022
11462	Federal Paper Tax Levy Federal Payment Levy Program – IRS Tax Levy Requests
206	<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b> Revisions to the State Operations Manual (SOM) Appendix L - Ambulatory Surgical Centers and Chapter 9 Exhibits – Exhibit 351.
11338	<b>Medicare Program Integrity (CMS-Pub. 100-08)</b> Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11351	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11352	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11353	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11354	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11357	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11358	Updates of Chapter 4 in Publication (Pub.) 100-08, Including Update to Medicare Program Integrity Contractor Investigative Timeliness Requirement, and Updates to Exhibit 5 - Background Information for

11450	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11458	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
	<b>Medicare Prescription Drug Benefit (CMS-Pub. 100-18)</b>
	None
	<b>Demonstrations (CMS-Pub. 100-19)</b>
11383	Calendar Year 2023 Modifications/Improvements to Value-Based Insurance Design (VBID) Model – Implementation
11385	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
	<b>One Time Notification (CMS-Pub. 100-20)</b>
11333	User Change Request (UCR): Fiscal Intermediary Shared System (FISS) – Claim Page 2 Adjustment Document Control Number (AD DCN) to Match the Claim Page 6 Cross Reference DCN (XREF DCN)
11336	Request for Read-Only Access to the CMS Shared Systems for the Comprehensive Error Rate Testing (CERT) Review Contractor (RC)
11337	Electronic Transmission of Medicare Administrative Contractor Provider Enrollment Recommendations of Approval
11339	Payment for Critical Access Hospitals (CAHs) Ancillary Services Submitted on I2X Type of Bill (TOB) Claim
11340	Updates to Current Inpatient Claim Edits
11342	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs) -- July 2022
11343	System Limitation Update for Centralized Flu Billers (CFB), Pneumococcal and Covid-19 Vaccinations
11345	Instruction to the Multi-Carrier System Maintainer to Remove Edits 055D and 179D from the I199RDEA1 and I199RDEA2 Reports
11346	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- Fiscal Years (FYs) 2021-2022
11347	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11350	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11356	New State Codes for California
11361	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11364	Common Working File (CWF) Editing - National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds
11367	Section 127 of the Consolidated Appropriations Act: Graduate Medical Education (GME) Payment for Rural Track Programs (RTPs)
11368	User CR: ViPS Medicare System (VMS) - Allow Updates to the Submitted Medicare Beneficiary Identifier (MBI)
11369	User CR: MCS - SCF Claim Field Update for Rendering Provider Number
11373	Update the Common Working File Utilization Reject 86x7 and 86x6
11374	Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter As Certain Colorectal Cancer Screening Tests
11376	Medicare Summary Notice (MSN) Created with Wrong Beneficiary Data – Update Beneficiary Data Streamlining Logic
11377	Updating Reason Code 32287 Edit in the Fiscal Intermediary Shared System (FISS) to Allow Processing of Claims Containing COVID-19 Vaccine and Other Vaccines When Billed on the Same Claim
11378	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity

	of Instructions
11390	Implementation of the Award for the Jurisdiction K (J-K) Part A and Part B Medicare Administrative Contractor (JK A/B MAC)
11391	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs) -- July 2022
11393	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11400	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--October 2022 Update
11409	User Enhancement - Update the Multi-Carrier System (MCS) to Display the Full History of a Claims' Audit Trail Location
11412	User Enhancement Multi-Carrier System (MCS) - Update the Procedure Code File Maintenance Screen Movement Functionality
11413	User CR: ViPS Medicare System (VMS) - Improve Transportation within VMS Subsystems
11416	User Change Request (UCR): Fiscal Intermediary Shared System (FISS) - Off-line History Retrieval of Canceled Claims
11418	Interns and Residents Information System (IRIS) XML Format
11421	Updates to Current Inpatient Claim Edits
11433	Update to Addition of Disposition Category "U" to Recovery Audit Contractor Data Warehouse (RACDW) Appeals Layout File - This CR Rescinds and Fully Replaces CR 12528.
11442	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11453	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--July 2021
11460	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--October 2022 Update
11461	National Coverage Determination (NCD) 90.2, Next Generation Sequencing (NGS)
	<b>Medicare Quality Reporting Incentive Programs (CMS-Pub. 100-22)</b>
	None
	<b>State Payment of Medicare Premiums (CMS-Pub. 100-24)</b>
	None
	<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)</b>
	None

**Addendum II: Regulation Documents Published in the Federal Register (January through March 2022)**

**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](http://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.

This information is available on our website at: <https://www.cms.gov/files/document/regs2q22qpu.pdf>

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

**Addendum III: CMS Rulings (April through June 2022)**

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

The rulings can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

**Addendum IV: Medicare National Coverage Determinations (April through June 2022)**

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. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: [www.cms.gov/medicare-coverage-database/](http://www.cms.gov/medicare-coverage-database/). For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)	NCD 210.14	R11388	04/29/2022	02/10/2022

**Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2022)**

(Inclusion of this addenda is under discussion internally.)

**Addendum VI: Approval Numbers for Collections of Information (April through June 2022)**

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 (April through June 2022)**

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. This information is available at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Date Approved	State
<b>The following facilities are new listings for this quarter.</b>			
Paoli Hospital 255 W. Lancaster Avenue Paoli, PA, 19301	390153	05/03/2022	PA
French Hospital Medical Center 1911 Johnson Avenue San Luis Obispo, CA 93401	050323	03/01/2022	CA

Facility	Provider Number	Date Approved	State
FROM: Saint Thomas Midtown Hospital TO: <b>Ascension Saint Thomas Midtown</b> 2000 Church Street Nashville, TN 37236	440082	02/08/2018	TN
Ascension Saint Thomas Hospital 4220 Harding Road Nashville, TN 37202	440082	<b>03/10/2022</b>	TN
FROM: <b>Memorial Hospital of Tampa</b> TO: <b>HCA Florida South Tampa Hospital</b> 2901 Swann Avenue Tampa FL, 33609	1871935072	07/15/2011	FL
FROM: <b>South Bay Hospital</b> TO: <b>HCA Florida South Shore Hospital</b> 4016 Sun City Center Boulevard Sun City Center, FL 33573	100259	03/05/2013	FL
FROM: <b>Carillon New River Valley Medical Center</b> TO: <b>New River Valley Medical Center</b> 2900 Lamb Circle Christianburg, VA 24073	1295868792	06/15/2021	VA

**Addendum VIII:**

**American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2022)**

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 (April through June 2022)**

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the

Facility	Provider Number	Date Approved	State
Medical City Heart Hospital 11970 North Central Expressway Dallas TX 75243	450647	05/02/2022	TX
Stafford Hospital 101 Hospital Center Boulevard Stafford, VA 22554	490140	07/11/2021	VA
Merit Health River Oaks 1030 River Oaks Drive Flowood, MS 39232	150138	05/24/2022	MS
Ascension Saint Thomas Hospital West 4220 Harding Road Nashville, TN 37202	440082	03/10/2022	TN
Metropolitan Methodist Hospital 1310 McCullough Avenue San Antonio, TX 78212	1124074273	05/24/2022	TX
Baylor Medical Center at Waxahachie d/b/a Baylor Scott & White Medical Center - Waxahachie 2400 N Interstate Highway 35 E Waxahachie, TX 75165	450372	05/31/2022	TX
Adventist Health Simi Valley 2975 Sycamore Drive Simi Valley, CA 93065	050236	01/24/2022	CA
Northbay Healthcare 1200 B. Gale Wilson Boulevard Fairfield, CA 94533	1780736736	10/24/2021	CA
Murray Calloway County Hospital 803 Poplar Street Murray, KY 42071	180027	06/28/2022	KY
Mount Auburn Hospital 330 Mount Auburn Street Cambridge, MA 02138	220002	06/28/2022	MA
Spotsylvania Regional Medical Center 4600 Spotsylvania Parkway Fredericksburg, VA 22408	490141	06/28/2022	VA
Three Crosses Regional Hospital 2560 Samaritan Drive Las Cruces, NM 88001	1487248050	06/28/2022	NM
HCA Florida Sarasota Doctors Hospital 5731 Bee Ridge Road Sarasota, FL 34233	122515044	06/28/2022	FL
<b>The following facilities have editorial changes (in bold).</b>			
FROM: <b>Middle Tennessee Medical Center</b> TO: <b>Ascension Saint Thomas Rutherford Hospital</b> <b>400 North Highland Avenue</b> <b>Murfreesboro, TN 37133-1178</b>	44-0053	05/09/2006	TN
Ascension Saint Thomas Hospital Rutherford FROM: <b>400 North Highland Avenue</b> TO: <b>1700 Medical Center Parkway</b> Murfreesboro, TN 37129	440053	05/09/2006	TN

national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

**Addendum X:**

**List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2022)**

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) (April through June 2022)**

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 (April through June 2022)**

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/Medicare/ApprovedFacilities/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 facility is new for this quarter.</b>				
Orlando Health Heart and Vascular Institute 52 W Underwood St Orlando, FL, 32806  Other information: DNV certificate #: 10000497866-MSC-DNV-USA	100006	04/15/2022	N/A	FL
<b>The following facilities have editorial changes (in bold).</b>				
University of Washington Medical Center 1959 Northeast Pacific Street, Box 356151 Seattle, WA 98195-6151  Other information: Joint Commission ID # 9626  Previous Re-certification Dates: 02/10/2009; 10/18/2011; 11/22/2013; 12/08/2015; 12/05/2017; 11/20/2019	500008	02/10/2009	<b>01/26/2022</b>	WA
Pitt County Memorial Hospital, Incorporated DBA Vidant Medical Center 2100 Stantonsburg Road Greenville, NC 27835-6028  Other information: Joint Commission ID # 6506  Previous Re-certification Dates: 09/26/2017, 12/17/2019	340040	09/26/2017	<b>02/09/2022</b>	NC
University of Chicago Medical Center 5841 South Maryland Avenue	140088	02/24/2009	<b>01/22/2022</b>	IL

180040	11/14/2008	02/23/2022	KY
<p><b>FROM: Jewish Hospital and St. Mary's Healthcare;</b>  <b>TO: UofL Health - Louisville, Inc.</b>                  200 Abraham Flexner Way                  Louisville, KY 40202</p> <p>Other information:                  Joint Commission ID # 7765</p> <p>Previous Re-certification                  Dates: 11/14/2008;                  03/22/2011; 02/26/2013;                  03/24/2015; 05/23/2017;                  08/06/2019</p>	02/04/2009	03/05/2022	AZ
360006	07/14/2015	02/26/2022	OH
<p>Riverside Methodist Hospital                  3535 Olentangy River Road                  Columbus, OH 43214-3998</p> <p>Other information:                  Joint Commission ID # 7030</p> <p>Previous Re-certification                  Dates: 02/04/2009;                  04/27/2011; 03/15/2013;                  02/24/2015; 04/18/2017;                  07/12/2019</p>	01/27/2009	02/19/2022	TN
440048	01/27/2009	02/19/2022	TN
<p>Baptist Memorial Hospital - Memphis                  6019 Walnut Grove Road                  Memphis, TN 38120</p> <p>Other information:                  Joint Commission ID # 7869</p> <p>Previous Re-certification                  Dates: 01/27/2009;                  05/20/2011; 04/17/2013;                  06/02/2015; 07/25/2017;                  09/17/2019</p>	05/28/2009	03/10/2022	LA
190036	05/28/2009	03/10/2022	LA
<p>Ochsner Clinic Foundation                  1516 Jefferson Highway                  New Orleans, LA 70121</p> <p>Other information:                  Joint Commission ID # 8777</p>			

670025	06/15/2011	01/28/2022	TX
<p>Chicago, IL 60637</p> <p>Other information:                  Joint Commission ID # 7315</p> <p>Previous Re-certification                  Dates: 02/24/2009;                  08/17/2011; 09/04/2013;                  09/15/2015; 10/24/2017;                  12/17/2019</p> <p>Texas Heart Hospital of the Southwest, LLP                  1100 Allied Drive                  Plano, TX 75093</p>	08/18/2019	02/12/2022	GA
110010	08/18/2019	02/12/2022	GA
<p>Emory University Hospital                  1364 Clifton Road NE                  Atlanta, GA 30322</p> <p>Other information:                  Joint Commission ID # 6689</p> <p>Previous Re-certification                  Dates: 06/15/2011;                  07/09/2013; 07/14/2015;                  08/22/2017; 09/07/2019</p>	03/13/2009	02/03/2022	CA
050696	03/13/2009	02/03/2022	CA
<p>Keck Hospital of USC                  1500 San Pablo Street                  Los Angeles, CA 90033</p> <p>Other information:                  Joint Commission ID # 5033</p> <p>Previous Re-certification                  Dates: 03/13/2009;                  08/16/2011; 09/10/2013;                  10/06/2015; 10/20/2017;                  12/04/2019</p>			

<p>Florida Health Sciences Center Inc. 1 Tampa General Circle Tampa, FL 33606</p> <p>Other information: Joint Commission ID # 6934</p> <p>Previous Re-certification Dates: 12/19/2008; 04/05/2011; 04/09/2013; 04/21/2015; 06/06/2017; 07/24/2019</p>	100128	12/19/2008	01/20/2022	FL
<p>Northwestern Memorial Hospital 251 E. Huron Street Chicago, IL 60611</p> <p>Other information: Joint Commission ID # 7267</p> <p>Previous Re-certification Dates: 01/30/2009; 06/17/2011; 05/31/2013; 06/09/2015; 08/18/2017; 11/06/2019</p>	140281	01/30/2022	03/26/2022	IL
<p>Baylor University Medical Center (BUMC) 3500 Gaston Avenue Dallas, TX 75246</p> <p>Other information: Joint Commission ID # 8993</p> <p>Previous Re-certification Dates: 08/21/2007; 08/27/2009; 10/07/2011; 11/20/2013; 11/10/2015; 10/31/2017; 12/18/2019</p>	450021	08/21/2007	03/24/2022	TX
<p><b>FROM: New York-Presbyterian/Weill Cornell Medical Center</b> <b>TO: New York-Presbyterian Hospital</b> 525 East 68th Street New York, NY 10065</p> <p>Other information: Joint Commission ID # 5838</p> <p>Previous Re-certification Dates: 03/03/2009; 07/14/2011; 08/21/2013; 09/23/2015; 10/25/2017; 01/24/2020</p>	330101	03/03/2009	03/31/2022	NY

<p>Previous Re-certification Dates: 05/28/2009; 11/09/2011; 12/12/2013; 01/05/2016; 12/12/2017; 03/12/2020</p> <p><b>FROM: Largo Medical Center</b> <b>TO: HCA Florida Largo Hospital</b> 201 14th Street SW Largo, FL 33770</p> <p>Other information: DNV certificate #: C533100</p> <p>Previous Re-certification Dates: 04/04/2019</p>	100248	04/04/2019	05/05/2022	FL
<p>Banner - University Medical Center Phoenix 1111 East McDowell Road Phoenix, AZ 85006</p> <p>Other information: Joint Commission ID # 9489</p> <p>Previous Re-certification Dates: 05/19/2011; 05/07/2013; 06/09/2015; 07/25/2017; 07/10/2019</p>	030002	05/19/2011	03/03/2022	AZ
<p>Cedars-Sinai Health System 8700 Beverly Blvd. Los Angeles, CA 90048</p> <p>Other information: Joint Commission ID # 9792</p> <p>Previous Re-certification Dates: 12/11/2008; 06/21/2011; 06/11/2013; 05/29/2015; 07/11/2017; 09/11/2019</p>	050625	12/11/2008	02/26/2022	CA
<p>OHSU 3181 SW Sam Jackson Park Road MBS 2012M Portland, OR, 97239</p> <p>Other information: DNV Certificate #: 10000477450-MSC-DNV-USA</p> <p>Previous Re-certification Dates: 11/11/2008; 02/15/2011; 02/12/2013; 03/03/2015; 04/18/2017; 05/17/2019</p>	100248	11/11/2008	04/22/2022	OR

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 ASMBS in the 3-month period. This information is available at [www.cms.gov/Medicare-ApprovedFacilities/BSF/list.asp#TopOfPage](http://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 (April through June 2022)**

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](http://www.cms.gov/Medicare-ApprovedFacilities/PETDT/list.asp#TopOfPage). For questions or additional information, contact David Dolan, MBA (410-786-3365).

Providence Sacred Heart Medical Center & Children's Hospital 101 West 8th Avenue Spokane, WA 99204  Other information: Joint commission ID #: 9638 Previous Re-certification Dates: 03/10/2009; 08/17/2011; 08/06/2013; 07/14/2015; 09/12/2017; 11/05/2019	500054	03/10/2009	04/20/2022	WA
Spectrum Health Hospitals 100 Michigan Street, NE Grand Rapids, MI 49503  Other information: Joint Commission ID # 277668  Previous Re-certification Dates: 04/26/2011; 06/18/2013; 05/19/2015; 06/20/2017; 09/25/2019	230038	04/26/2011	04/07/2022	MI

**Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2022)**

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. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at [www.cms.gov/Medicare-ApprovedFacilities/LVRS/list.asp#TopOfPage](http://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 (April through June 2022)**

[FR Doc. 2022-16717 Filed 8-3-22; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****[Docket No. FDA-2013-N-0297]****Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Production, Storage and Transportation of Shell Eggs (Preventing Salmonella Enteritidis (SE))****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by September 6, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0660. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Production, Storage and Transportation of Shell Eggs (Preventing Salmonella Enteritidis (SE))**

OMB Control Number 0910-0660—  
Extension—21 CFR 118.10 and 118.11

This information collection supports Agency regulations in part 118 (21 CFR

part 118), Production, Storage, and Transportation of Shell Eggs, and Form FDA 3733, Shell Egg Producer Registration Form. The Public Health Service Act (PHS Act) (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce such regulations as “are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State” (section 361(a) of the PHS Act (42 U.S.C. 264(a))). This authority has been delegated to the Commissioner of Food and Drugs. Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(4)), a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

Under part 118, shell egg producers are required to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation. Shell egg producers also are required to maintain records concerning their compliance with part 118 and to register with FDA. As described in more detail about each information collection provision of part 118, each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, must refrigerate, register, and keep certain records. Farms that do not send all their eggs to treatment are also required to have an SE prevention plan and to test for SE.

Section 118.10 of FDA’s regulations requires recordkeeping for all measures the farm takes to prevent SE in its flocks. Since many existing farms participate in voluntary egg quality assurance programs, those respondents may not have to collect any additional information. Records are maintained on file at each farm site and examined there periodically by FDA inspectors.

Section 118.10 also requires each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated, to design and implement an SE prevention plan.

Section 118.10 requires recordkeeping for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken.

Finally, § 118.11 of FDA’s regulations requires that each farm covered by § 118.1(a) register with FDA using Form FDA 3733. The term “Form FDA 3733” refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at <https://www.access.fda.gov>. We strongly encourage electronic registration because it is faster and more convenient. The system can accept electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer receives confirmation of electronic registration instantaneously once all the required fields on the registration screen are completed. However, paper registrations will also be accepted. Form FDA 3733 is available for download for registration by mail, fax, or CD-ROM. For more information, we invite you to visit our websites at: <https://www.fda.gov/food/registration-food-facilities-and-other-submissions/shell-egg-producer-registration> and <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ShellEggProducerRegistration/ucm217952.htm>.

Recordkeeping and registration are necessary for the success of the SE prevention measures. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Further, they are essential for us to be able to determine compliance. Information provided under these regulations helps us to quickly notify the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support our enforcement activities.

*Description of Respondents:* Respondents to this information collection include farm sites with 3,000 or more egg laying hens that sell raw eggs to the table egg market, other than directly to the consumer.

In the **Federal Register** of January 19, 2022 (87 FR 2797), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received, however only one was responsive to the four information collection topics solicited.

The comment suggested that farms could save money by pooling samples while conducting environmental testing, proffering a 2015 research article. FDA reviewed the 2015 research article by Kinde et al. and had additional questions about the equivalency of pooled versus non-pooled samples. This