

(OMB control number: 0938–1249); *Frequency*: Annually; *Affected Public*: Public sector (Individuals and Households); Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents*: 314; *Total Annual Responses*: 314; *Total Annual Hours*: 384,014. For policy questions regarding this collection contact Nidhi Singh Shah at 301–492–5110.

Dated: February 4, 2022.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–02738 Filed 2–8–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9133–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October through December 2021

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 July through September 2021, 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 Federal Register .	Terri Plumb	(410) 786–4481
III CMS Rulings	Tiffany Lafferty	(410)786–7548
IV Medicare National Coverage Determinations.	Wanda Belle, MPA	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI Collections of Information	William Parham	(410) 786–4669
VII Medicare –Approved Carotid Stent Facilities.	Sarah Fulton, MHS	(410) 786–2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites.	Sarah Fulton, MHS	(410) 786–2749
IX Medicare’s Active Coverage-Related Guidance Documents.	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
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National

Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as

regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers

for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

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

The Director of the Office of Strategic Operations and Regulatory Affairs of the

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

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

BILLING CODE 4120-01-C

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: March 17, 2021 (86 FR 14629), May 3, 2021 (86 FR 23373), August 17, 2021 (86 FR 45986) and November 18, 2021 (86 FR 64492). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (October through December 2021)

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 Update to Medicare Deductible, Coinsurance and Premium Rates for Calendar Year (CY) 2022, use (CMS-Pub. 100-01) Transmittal No. 11136.

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

Fee-For Service Transmittal Numbers

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

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

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
11136	Update to Medicare Deductible, Coinsurance and Premium Rates for Calendar Year (CY) 2022
Medicare Benefit Policy (CMS-Pub. 100-02)	
	None
Medicare National Coverage Determination (CMS-Pub. 100-03)	
11119	National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds
Medicare Claims Processing (CMS-Pub. 100-04)	
12376	Revisions to Chapters 13, 18 And 32 To Update Coding Coverage for PET Scans for Dementia and Neurodegenerative Diseases Screening Pap Smears: Diagnoses Codes MSN Messages Remittance Advice Codes Screening Pelvic Examinations From January 1, 1998, Through June 30 2001 Diagnoses Codes MSN Messages

<p>Diagnosis Coding Remittance Advice Notices Counseling to Prevent Tobacco Use Healthcare Common Procedure Coding System [HCPCS] and Diagnosis Coding A/B MACs [B] Billing Requirements A/B MAC [A] and [HHH] Billing Requirements Claims Adjustment Reason Codes [CARCs], Remittance Advice Remark Codes [RARCs], Group Codes, and Medicare Summary Notices [MSNs] Common Working File [CWF] Diagnosis Code Reporting Billing Requirements Claim Adjustment Reason Codes [CARCs], Remittance Advice Remark Codes [RARCs], Group Codes, and Medicare Summary Notice [MSN] Messages Common Working File [CWF] Edits Ambulatory Blood Pressure Monitoring [ABPM] Billing Requirements Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities Bill Types Allowable Covered Diagnosis Codes Allowable Covered Procedure Codes Healthcare Common Procedure Coding System [HCPCS] Coverage for PET Scans for Dementia and Neurodegenerative Diseases Special Billing and Payment Requirements for A/B MACs [A] A/B MACs [B] Billing Requirements A/B MAC [A] and [HHH] Billing Requirements Claims Adjustment Reason Codes [CARCs], Remittance Advice Remark Codes [RARCs], Group Codes, and Medicare Summary Notices [MSNs] Common Working File [CWF] Diagnosis Code Reporting Billing Requirements Claim Adjustment Reason Codes [CARCs], Remittance Advice Remark Codes [RARCs], Group Codes, and Medicare Summary Notice [MSN] Messages Common Working File [CWF] Edits Ambulatory Blood Pressure Monitoring [ABPM] Billing Requirements Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities Bill Types Allowable Covered Diagnosis Codes Allowable Covered Procedure Codes Healthcare Common Procedure Coding System [HCPCS] Coverage for PET Scans for Dementia and Neurodegenerative Diseases Special Billing and Payment Requirements for A/B MACs [A] Diagnosis Codes Editing Instructions for A/B MACs [A] Correct Place of Service [POS] Code for PR Services on Professional Claims Requirements for PR Services on Institutional Claims Edits for PR Services Exceeding 72 Sessions ICD Procedure Codes for Bariatric Surgery for Treatment of Co- Morbid Conditions Related to Morbid Obesity [A/MACs only] ICD Diagnosis Codes for Bariatric Surgery ICD Diagnosis Codes for BMI □35 ICD Codes for Type II Diabetes Mellitus Complication Claims Guidance for Payment Medicare Summary Notices [MSNs] and Claim Adjustment Reason Codes</p>
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	<p>Carotid Artery Stenting [CAS] for Post-Approval Studies 510k Post-Approval Extension Studies using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting [CAS] Procedures Intracranial Percutaneous Transluminal Angioplasty [PTA] With Stenting Billing Requirements Payment Requirements Hospital Billing Instructions Practitioner Billing Instructions Claims Processing System Editing Claims Processing Requirements for OPT with Verteporfin Services on Professional Claims and Outpatient Facility Claims Claims Processing Requirements for OPT with Verteporfin Services on Inpatient Facility Claims Coding and Claims Processing for MTWA</p>
11022	Quarterly Update for the Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January 2022
11023	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11024	Instructions for Downloading the Medicare ZIP Code File for January 2022
11035	Revisions to Chapters 3, 18, and 32 to Update Coding
11036	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11937	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11038	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11039	Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2022 Annual Update Cost-of-Living
11042	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11043	Calendar Year (CY) 2022 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures
11044	Ambulance Inflation Factor (AIF) for Calendar Year (CY) 2022 and Productivity Adjustment
11046	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11048	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11049	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11052	2022 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update
11057	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11059	April 2022 Update to the Java Medicare Code Editor (MCE) for New Edit 20- Unspecified Code Edit Medicare Code Editor (MCE)
11061	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11062	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11063	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

11066	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11072	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11074	Calendar Year (CY) 2022 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPAR) Procedures
11075	Revision to Chapter 3 to Update Instructions for Handling Inpatient Rehabilitation Facility (IRF) Claims Shared Systems and CWF Edits Actions When a Claim Does Not Match the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI)
11077	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11079	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11080	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11082	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11084	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11085	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11089	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11090	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
11092	Claims Processing Instructions for the New Pneumococcal 20-valent Conjugate Vaccine Code 90677
11093	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11095	Implementation of the GV Modifier for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) for Billing Hospice Attending Physician Services
11107	2022 Annual Update of Per-Beneficiary Threshold Amounts
11109	Skilled Nursing Facility (SNF) Claims Processing Updates
11111	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
11113	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 3, Sections 90.1.2, 90.3, 90.3.1, and Addendum A Provider Specific File Provider Specific File Billing for Kidney Transplant and Acquisition Services Stem Cell Transplantation Allogeneic for Stem Cell Transplantation
11114	Instructions for Retrieving the January 2022 Medicare Physician Fee Schedule Database (MPFSDB) Files Through the CMS Mainframe Telecommunications System
11115	Summary of Policies in the Calendar Year (CY) 2022 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, CT Modifier Reduction List, and Preventive Services List
11116	April 2022 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
11117	Shared System Support Hours for Application Programming Interfaces (APIs)
11118	2022 Annual Update to the Therapy Code List
11119	National Coverage Determination (NCD) 270.3 Blood-Derived Products for

	Chronic, Non-Healing Wounds Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds Policy Healthcare Common Procedure Coding System (HCPCS) Codes, Diagnosis Coding and Frequency Requirements Types of Bill (TOB) Payment Method Place of Service (POS) for Professional Claims
11121	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
11122	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11122	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11129	Reduced Payment for Physical Therapy and Occupational Therapy Services Furnished In Whole or In Part by a Physical Therapist Assistant (PTA) or Occupational Therapy Assistant (OTA) Discipline Specific Outpatient Rehabilitation Modifiers - All Claims
11130	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11131	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11138	Quarterly Update to Home Health (HH) Grouper
11140	Update to the Internet Only Manual (IOM) Publication 100-04, Chapters 3 and 17
11146	Summary of Policies in the Calendar Year (CY) 2022 Medicare Physician Fee Schedule (MPFS) Final Rule, Telehealth Originating Site Facility Fee Payment Amount and Telehealth Services List, CT Modifier Reduction List, and Preventive Services List
11147	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
11149	January 2022 Integrated Outpatient Code Editor (I/OCE) Specifications Version 23.0
11150	January 2022 Update of the Hospital Outpatient Prospective Payment System (OPPS) General Coding and Billing Instructions and Explanations Explanations of Terms Complete List of Device Pass-through Category Codes Explanations of Certain Terms/Definitions Related to Device Pass-Through Category Codes Billing for Allogeneic Stem Cell Transplants
Medicare Secondary Payer (CMS-Pub. 100-05)	
11069	ECRS Updates to the Prescription Drug Assistance Request (PDAR) Fields; Medicare Secondary Payer Future Date Fields; Electronic File Transfer Naming Convention; Updated ICD-10 Diagnosis Codes for No-Fault Plan Insurance Type D and the Addition of Reason Code 94 Attachment 1 - ECRS Web User Guide, Software Version 6.7 Attachment 2 - ECRS Web Quick Reference Card, Version 2021/1 October
11070	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11073	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
Medicare Financial Management (CMS-Pub. 100-06)	

11051	Notice of New Interest Rate for Medicare Overpayments and Underpayments -1st Qtr Notification for FY 2022
11097	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
11112	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11124	Updates to Medicare Financial Management Manual Chapter 3, Section 140.1 Bankruptcy Forms
11133	Fiscal Year 2022 Updates for the CMS Internet Only Manual (IOM) Publication (Pub.) 100-06, Medicare Financial Management Manual, Chapter 7 - Internal Control Requirements
Medicare State Operations Manual (CMS-Pub. 100-07)	
	None
Medicare Program Integrity (CMS-Pub. 100-08)	
11014	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11020	Restructuring of Section 10.4 in Chapter 10 of Publication (Pub.) 100-08 10.2.3/Individual Practitioners Who Enroll Via the Form CMS-855I Medicare Enrollment - Contractor Processing Duties and Related Polic General Processing Functions Overview of the Process Receipt of Application Review of Application Initial Steps of Review of Application Data Verification Requesting Missing/Clarifying Data/Documentation (Development) Receiving Missing/Clarifying Data/Documentation (Response to Development) Provider/Supplier Fails to Submit Requested Data/Documentation Application Disposition Approval Returns Rejections Denial Denials – General Principles Denial Reasons Additional Denial Policies Voluntary and Involuntary Terminations Changes of Information Revalidations Revalidation Solicitations Non-Responses to Revalidation and Extension Requests Receipt and Processing of Revalidation Applications Reactivations Revocations Revocations – Background and General Requirements Revocation Effective Dates Revocation Reasons Reenrollment Bar Additional Revocation Policies Deactivations Deactivation Rebuttals
11031	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11032	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08 Quality of Care Issues and Potential Fraud Issues

	Provider Self Audits Signature Requirements Introduction Definitions Medicare Program Integrity Program Integrity Contractors Unified Program Integrity Contractor Investigations Medicare Drug Integrity Contractor Organizational Requirements Training for Law Enforcement Organizations Liability of Program Integrity Contractor Employees Anti-Fraud Training Training for Law Enforcement Organizations Procedural Requirements Maintain Controlled Filing System and Documentation
11040	Revisions to Certified Provider/Supplier Model Letters and Instructions for Processing Initial Skilled Nursing Facility (SNF) Enrollment Applications
11050	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11064	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11065	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11086	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11087	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11088	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11091	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11094	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11125	Update to Enrollment Processing Requirements for Certified Provider/Supplier Change of Ownership (CHOW) and Change of Information (COI) Application
11126	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11135	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11139	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11142	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08 Definitions Federally Qualified Health Centers (FQHCs) Home Health Agencies (HHAs) Independent Diagnostic Testing Facilities (IDTFs) Physician Assistants Returns Rejections Denial Reasons Additional Denial Policies Reactivations Revocation Reasons Reenrollment Bar

	Deactivations Deactivation Rebuttals Establishing Effective Dates Opting-Out of Medicare Application Fees
11153	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11154	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
11127	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year (FY) 2019 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long-Term Care Hospitals (LTCHs)
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Medicare Prescription Drug Benefit (CMS-Pub. 100-18)	
	None
Demonstrations (CMS-Pub. 100-19)	
11030	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11053	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11067	Intravenous Immune Globulin (IVIG) Demonstration Update for a New Drug Code J1554 ASCENIV
11071	Modifications/Improvements to Value-Based Insurance Design (VBID) Model – Implementation
11108	Managing Clinician PPA and KCF PBA Implementation
11128	ESRD Treatment Choices (ETC) Model Performance Payment Adjustment (PPA) - Facility Component (Implementation CR)
11143	Intravenous Immune Globulin (IVIG) Demonstration: Payment Update for 2022
11145	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
One Time Notification (CMS-Pub. 100-20)	
11010	Mobile Personal Identity Verification (PIV) Station Installation
11025	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--January 2022
11033	Implementation of the Award for the Jurisdiction L (J-L) Part A and Part B Medicare Administrative Contractor (JL A/B MAC)
11047	Correct Processing of Home Health Claims if the Request for Anticipated Payment (RAP) or Notice of Admission (NOA) Was More Than 30 Days Late and Correct Identification Critical Access Hospital Sub-Unit Discharges as Institutional Periods of Care
11054	Electronic Funds Transfer (EFT) Information from Provider Enrollment Chain and Ownership System (PECOS) to ViPS Medicare System (VMS):

	Implementation CR
11055	National Coverage Determination (NCD) 90.2, Next Generation Sequencing (NGS)
11060	Skilled Nursing Facility (SNF) Claims Processing Update to Fiscal Year End (FYE) Edits
11068	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs) -- April 2022 (CR 1 of 2)
11076	User Change Request (UCR): Fiscal Intermediary Shared System (FISS) – Workload Reports to Capture Optical Character Reader (OCR) and Paper Claim Counts Correctly
11078	User Change Request (UCR) - Fiscal Intermediary Shared System (FISS) – Implement New Search Functionality for Reason Codes, Expert Claims Processing System (ECPS) and Medical Policy Parameters (MPP)
11083	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs) -- April 2022 (CR 2 of 2 for April 2022)
11096	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11098	MAC Customer Experience (MCE) Provider Enrollment Survey Link
11100	User CR: Multi-Carrier System (MCS) - Beneficiary Age Data Element
11103	Clarifying Instructions for Billing and Processing and Payment of Claims Based on Locality of the Home Infusion Therapy (HIT) Service Visit
11104	User CR: Multi-Carrier System (MCS) - PSUP Query System Lookup
11110	Phase two: Undeliverable Medicare Summary Notices (UMSNs) – Beneficiary Do Not Forward Process
11123	Send Electronic Funds Transfer (EFT) Information from Provider Enrollment Chain and Ownership System (PECOS) to Fiscal Intermediary Shared System (FISS) - Implementation CR, Consolidation of January 2022 and April 2022 Releases.
11132	Medicare Diabetes Prevention Program (MDPP) Service Period Change from 2 Years to 1 Year
11134	Medicare Administrative Contractor (MAC) Educational Requirements for the Expansion of the Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior Authorization (PA) Model
11141	User Change Request (UCR) - Fiscal Intermediary Shared System (FISS) Implement New Search Functionality for Reason Codes, Expert Claims Processing System (ECPS) and Medical Policy Parameters (MPP)
11144	Implementation of Medicare Administrative Contractor (MAC) Appeals Upload Process Changes for the Recovery Audit Contractor (RAC) Data Warehouse (RACDW) and Addition of Disposition Category "U" to RACDW Appeals Layout File
11155	Correct Processing of Home Health Claims if the Request for Anticipated Payment (RAP) or Notice of Admission (NOA) Was More Than 30 Days Late and Correct Identification Critical Access Hospital Sub-Unit Discharges as Institutional Periods of Care
11156	Addition of the QW modifier to Healthcare Common Procedure Coding System (HCPCS) Code 86328
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
	None
State Payment of Medicare Premiums (CMS-Pub.100-24)	
	None
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

**Addendum II: Regulation Documents Published
in the Federal Register (October through December 2021)**
Regulations and Notices

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This information is available on our website at:
<https://www.cms.gov/files/document/regs4q21qpu.pdf>

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

**Addendum III: CMS Rulings
(October through December 2021)**

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

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

**Addendum IV: Medicare National Coverage Determinations
(October through December 2021)**

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

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Transvenous Pulmonary Embolectomy (TPE) 240.6	NCD 240.6	IU9875	12/16/2021	10/28/2021
National Coverage Determination (NCD) 220.6.19, Positron Emission Tomography NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer- Manual Update Only	NCD 220.6.19	11158	12/17/2021	01/19/2021

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October through December 2021)
(Inclusion of this addenda is under discussion internally.)

**Addendum VI: Approval Numbers for Collections of Information
(October through December 2021)**

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

**Addendum VII: Medicare-Approved Carotid Stent Facilities
(October through December 2021)**

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
The following facilities are new listings for this quarter.			
Berkeley Medical Center 2500 Hospital Drive Martinsburg, WV 25401	510008	10/12/2021	WV
CGH Medical Center 100 E LeFevre Road Sterling, IL 61081	140043	10/12/2021	IL
Lee's Summit Medical Center 2100 SE Blue Parkway Lee's Summit, MO 64043	260190	09/27/2021	MO
McKenzie Willamette Medical Center 1460 G Street Provider Springfield, OR 97477	380020	10/15/2021	OR
Raleigh General Hospital 1710 Harper Road Beckley, WV 25801	510070	12/07/2021	WV
Faith Regional Health Services 2700 W. Norfolk Avenue Norfolk, NE 68701	280125	12/14/2021	NE
The following facilities have editorial changes (in bold).			
FROM: St. Joseph Hospital TO: PeaceHealth St. Joseph Medical Center 2901 Squalicum Parkway Bellingham, WA 98264	500030	09/28/2005	WA
FROM: Sacred Heart Medical Center at RiverBend TO: PeaceHealth Sacred Heart Riverbend Medical Center 3311 RiverBend Drive Springfield, OR 97477	380102	02/19/2009	OR
FROM: Western Baptist Hospital TO: Baptist Health Paducah 2501 Kentucky Avenue Paducah, KY 42003	180104	05/05/2005	KY
FROM: St. John Hospital and Medical Center TO: Ascension St. John Hospital 22101 Moross Road Detroit MI 48236	230165	04/27/2005	MI
FROM: Huntsville Health System – Marshall, LLC	010005	09/21/2021	AL

Facility	Provider Number	Date Approved	State
TO: HH Health System – Marshall, LLC 2505 431 Highway North Boaz, AL 35957			
FROM: North Hills TO: Medical City North Hills 4401 Booth Calloway Road North Richland Hills, TX 76180	450087	01/24/2006	TX
FROM: Carilion Roanoke Memorial Hospital TO: Roanoke Memorial Hospital 1906 Belleview Avenue Roanoke, VA 24014	490024	09/06/2005	VA

Addendum VIII:

American College of Cardiology's National Cardiovascular Data Registry Sites (October through December 2021)

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

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

Addendum IX: Active CMS Coverage-Related Guidance Documents (October through December 2021)

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 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 (October through December 2021)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at <http://www.cms.gov>. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (October through December 2021)

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/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (October through December 2021)

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

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>.

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

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
The following are new facilities.				
Summa Health 525 E. Market Street Akron, OH 44309 Other information: DNV Certificate #: 10000496174-MSC-DNV-USA Previous Re-certification Dates: n/a	360020	11/16/2021		OH
The following facilities have editorial changes (in bold).				
Abbott Northwestern Hospital 800 East 28th Street Minneapolis, MN 55407 Other information: Joint Commission ID # 8149 Previous Re-certification Dates: 11/16/2010; 11/29/2012; 11/18/2014; 12/06/2016; 2/13/2019	240057	11/16/2010	07/28/2021	MN
Bon Secours St. Mary's Hospital 5801 Breomo Road Richmond, VA 23226 Joint Commission ID # 6387 Previous Re-certification Dates: 12/15/2011; 12/17/2013; 01/26/2016; 02/21/2018	490059	12/15/2011	06/11/2021	VA
Presbyterian Medical Center of the UPHS 51 North 39th Street Philadelphia, PA 19104 Other information: Joint Commission ID # 6145 Previous Re-certification Dates: 07/22/2010; 07/20/2012; 06/17/2014; 07/19/2016	390223	10/05/2010	07/29/2021	PA
The George Washington University Hospital 900 23rd Street, NW	090001	09/12/2018	07/10/2021	DC

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Washington, DC 20037 Other information: Joint Commission ID # 6310 Previous Re-certification Dates: 9/12/2018				
Robert Wood Johnson University Hospital One Robert Wood Johnson Place New Brunswick, NJ 08903- 2601 Joint Commission ID # 5969 Previous Re-certification Dates: 07/22/2010; 07/20/2012; 06/17/2014; 07/19/2016	310038	07/22/2010	07/08/2021	NJ
TriStar Centennial Medical Center 2300 Patterson Street Nashville, TN 37203 Joint Commission ID # 7888 Previous Re-certification Dates: 12/12/2018	440161	12/12/2018	08/19/2021	TN
University of Maryland Medical Center 22 South Greene Street Baltimore, MD 21201-1595 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	210002	09/16/2008	07/03/2021	MD
NorthShore University Health System 1301 Central Street, Suite 300 Evanston, IL 60201 Other information: Joint Commission ID # 7343 Previous Re-certification Dates: 10/25/2016;11/15/2018	140010	10/25/2016	08/06/2021	IL
Ohio State University Hospitals	360085	11/12/2003	08/04/2021	OH

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
410 West Tenth Avenue, DN 168 Columbus, OH 43210 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				
Cleveland Clinic 9500 Euclid Avenue NA-4 Cleveland, OH 44195 Other information: Joint Commission ID # 7001 Previous Re-certification Dates: 10/28/2008; 11/23/2010; 12/11/2012; 12/02/2014; 11/08/2016; 12/12/2018	360180	12/03/2003	08/05/2021	OH
Virginia Commonwealth University Health System 1250 East Marshall Street Richmond, VA 23298-0510 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; 4/10/2019	490032	04/08/2004	08/07/2021	VA
Strong Memorial Hospital 601 Elmwood Avenue Rochester, NY 14642 Other information: Joint Commission ID # 5856 Previous Re-certification Dates: 10/29/2003; 06/17/2008; 07/02/2010; 06/06/2012; 05/13/2014; 07/26/2016; 7/25/2018	330285	10/29/2003	07/21/2021	NY
Jersey Shore University Medical Center 1945 Route 33 Neptune City, NJ 07753	310073	10/16/2018	10/14/2021	NJ

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Other information: DNV GL Certificate # 10000502976-MSC-DNV- USA				
Advocate Christ Medical Center 4440 W. 95th Street Oak Lawn, IL 60453 Other information: DNV GL Certificate # 10000504196-MSC-DNV- USA Previous re-certification dates: 10/01/2018	140208	09/08/2015	10/21/2021	IL
Bryan Medical Center 1600 South 48th Street Lincoln, NE 68506 Other information: Joint Commission ID # 244330 Previous Re-certification Dates: 03/05/2013; 02/12/2015; 04/18/2017; 07/17/2019	280003	03/05/2013	09/22/2021	NE
Beth Israel Deaconess Medical Center 330 Brookline Avenue Boston, MA 02215 Other information: Joint Commission ID # 5501 Previous Re-certification Dates: 04/25/2017; 05/22/2019	220086	04/25/2017	11/04/2021	MA
FROM: Kaiser Sunnyside Medical Center TO: Kaiser Foundation Hospital - Sunnyside 10180 SE Sunnyside Road Clackamas, OR 97015-9303 Other information: Joint Commission ID # 4858 Previous Re-certification Dates: 09/13/2016; 09/19/2018	380091	09/13/2016	10/27/2021	OR
Maimonides Medical Center 4802 Tenth Avenue	330194	08/23/2012	10/27/2021	NY

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Brooklyn, NY 11219-2916 Other information: Joint Commission ID # 5734 Previous Re-certification Dates: 08/23/2012; 07/29/2014; 09/13/2016; 10/11/2018				
University of Alabama at Birmingham 619 19th S. South Birmingham, AL 35249-1900 Other information: Joint Commission ID # 2814 Previous Re-certification Dates: 12/09/2008; 04/22/2011; 04/09/2013; 04/07/2015; 05/16/2017; 7/3/2019	010033	12/09/2008	08/21/2021	AL
Dignity Health 350 West Thomas Road Phoenix, AZ 85013 Other information: Joint Commission ID # 9494 Previous Re-certification Dates: 5/8/2019	030024	05/08/2019	08/19/2021	AZ
Fresno Community Hospital and Medical Center 2823 Fresno St. Fresno, CA 93721 Other information: Joint Commission ID # 9832 Previous Re-certification Dates: 11/04/2014; 12/13/2016; 2/13/2019	050060	11/04/2014	08/11/2021	CA
FROM: Henry Ford Hospital TO: Henry Ford Health System 2799 West Grand Boulevard Detroit, MI 48202 Other information: Joint Commission ID # 7485	230053	10/30/2008	07/29/2021	MI

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Previous Re-certification Dates: 10/30/2008; 10/21/2010; 11/06/2012; 10/28/2014; 12/20/2016; 3/13/2019				
The General Hospital Corporation 55 Fruit Street Boston, MA 02114 Other information: Joint Commission ID # 5513 Previous Re-certification Dates: 12/02/2008; 01/19/2011; 02/13/2013; 01/06/2015; 02/28/2017; 5/22/2019	220071	12/02/2008	10/14/2021	MA
Rochester General Hospital 1425 Portland Ave Rochester, NY 14621 Other information: DNV certificate #: 10000504804-MSC-DNV-USA Previous Re-certification Dates: 10/29/2018	330125	10/29/2018	10/28/2021	NY
University Hospital (Stony Brook) Health Sciences Center Stony Brook Stony Brook, NY 11794-8503 Other information: Joint Commission ID # 5188 Previous Re-certification Dates: 01/30/2013; 01/15/2015; 03/14/2017; 05/08/2019	330393	03/02/2011	09/17/2021	NY
FROM: Duke University Hospital TO: 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; 06/04/2013;	340030	10/31/2003	09/22/2021	NC

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
05/05/2015; 06/13/2017; 08/21/2019				
Nebraska Medical Center 4350 Dewey Avenue Omaha, NE 68198-7400 Other information: Joint Commission ID # 186313 Previous Re-certification Dates: 01/20/2011; 01/29/2013; 02/24/2015; 02/14/2017; 4/17/2019	280013	01/20/2011	09/09/2021	NE
FROM: Palmetto Health TO: Prisma Health Richland 5 Richland Medical Park Drive Columbia, SC 29203 Other information: Joint Commission ID # 6588 Previous Re-certification Dates: 03/06/2013; 04/21/2015; 06/06/2017; 6/28/2019	420018	03/06/2013	10/08/2021	SC

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)
(October through December 2021)**

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/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October through December 2021)

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 ASBMS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (October through December 2021)

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/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

[F.R. Doc. 2022-02677 Filed 2-8-22; 8:45 am]
BILLING CODE 4120-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1774-PN]

Medicare Program: Announcement of Request for an Exception to the Prohibition on Expansion of Facility Capacity Under the Hospital Ownership and the Rural Provider Exceptions to the Physician Self-Referral Prohibition

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

ACTION: Notice with request for comment.

SUMMARY: The Social Security Act prohibits a physician-owned hospital from expanding its facility capacity unless the Secretary of the Department of Health and Human Services grants the hospital's request for an exception to that prohibition after considering input on the request from individuals and entities in the community where the hospital is located. The Centers for Medicare & Medicaid Services has received a request from a physician-

owned hospital for an exception to the prohibition on expansion of facility capacity. This notice solicits comments on the request from individuals and entities in the community in which the hospital is located. Community input may inform our determination regarding whether the requesting hospital qualifies for an exception to the prohibition on expansion of facility capacity.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by March 11, 2022.

ADDRESSES: In commenting, refer to file code CMS-1774-PN.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1774-PN, P.O. Box 8010, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1774-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *POH-ExceptionRequests@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique

individuals or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique