

Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters to be Considered: The agenda will include discussions on (1) 2020 TB provisional surveillance data; (2) Tuberculosis Trials Consortium Update; (3) COVID impact on TB programs; (4) Perceptions of non-U.S.-born persons on the link between country of birth and TB risk; (5) Using Big Data to Understand Latent Tuberculosis Care in the United States; and (6) Bacillus Calmette-Guerin Vaccine Guidance Development. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been

delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021-09006 Filed 4-30-21; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9130-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 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 January through March 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**.

Dated: April 16, 2021.

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: April 24, 2020 (85 FR 23030), August 12, 2020 (85 FR 48691), November 4, 2020 (85 FR 70168) and March 17, 2021 (86 FR 14629). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (January through March 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 Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits, use (CMS-Pub. 100-04) Transmittal No. 10564.

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)
	None
	Medicare Benefit Policy (CMS-Pub. 100-02)
10568	Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2021
	Medicare National Coverage Determination (CMS-Pub. 100-03)
	None
	Medicare Claims Processing (CMS-Pub. 100-04)
10550	Instructions for Retrieving the 2021 Pricing and Healthcare Common
10551	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10557	January 2021 Update of the Ambulatory Surgical Center (ASC) Payment System
10559	Modernization of the Electronic Files Transfer (EFT) Associated with the National Coordination of Benefits Agreement (COBA) Consolidated Claims Crossover Process Coordination of Benefits Agreement (COBA) Detailed Error Report

10624	or After January 1, 2021 International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)—July 2021
10631	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2021 Update
10634	User CR: VIPS Medicare System (VMS) - Update Interactive Correspondence Online Reporting (ICOR) Mail Date Calculation
10635	Claims Processing Instructions for National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)
10638	Modernization of the Electronic Files Transfer (EFT) Associated with the National Coordination of Benefits Agreement (COBA) Crossover Process
10639	Update to the Manual for Telephone Services, Physician Assistant (PA) Supervision, and Medical Record Documentation for Part B Services
10641	Updates to Chapter 4 of Publication (Pub.) 100-08
10646	Primary Care First (PCF) and Serious Illness Patient (SIP) Models: Part 3: IURs and Edits for Non-Sequential Claims
10650	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
10651	July 2021 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
10655	Mobile Personal Identity Verification (PIV) Station Installation
10656	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10657	Combined Common Edits/Enhancements Modules (CEEM) Code Set Update
10658	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2021
10660	The Intravenous Immune Globulin (IVIG) Demonstration: Demonstration is ending on December 31, 2023
10663	Revisions to Medicare Administrative Contractor (MAC) Standardized Monthly Status Report (MSR) Narrative Template
10665	Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opipid Treatment Programs (Manual Updates Only)
10666	Annual 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10667	April 2021 Integrated Outpatient Code Editor (IOCE) Specifications Version 22.1
Medicare Secondary Payer (CMS-Pub. 100-05)	
	None
Medicare Financial Management (CMS-Pub. 100-06)	
10548	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
10561	Notice of New Interest Rate for Medicare Overpayments and Underpayments -2nd Qtr Notification for FY 2021
Medicare State Operations Manual (CMS-Pub. 100-07)	
	None
Medicare Program Integrity (CMS-Pub. 100-08)	
10553	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10560	Second Update to Policies on the Enrollment of Opioid Treatment Programs (OTPs)
10567	Opioid Treatment Programs Update to Chapter 12 (The Comprehensive Error Rate Testing (CERT) Program) of Publication (Pub.) 100-08 The Comprehensive Error Rate Testing (CERT) Program MAC Communication with the CERT Program

10562	Notification Process Coordination of Benefits Agreement (COBA) Eligibility File Claims Recovery Process Crossover Process
10563	April 2021 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10564	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
10565	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - April 2021
10569	Updates to Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM) Claims Patient Readmitted Within 30 Days After Discharge Total and Noncovered Charges
10571	Fiscal Year (FY) 2021 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
10572	April 2021 Update to the Fiscal Year (FY) 2021 Inpatient Prospective Payment System (IPPS)
10574	Shared System Support Hours for Application Programming Interfaces (APIs)
10575	Calendar Year (CY) 2021 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
10579	Special Provisions for Radiology Additional Documentation Requests
10582	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
10592	Fiscal Intermediary Shared System (FISS) - Eliminate Multiple Common Working File (CWF) Replies Received in the Same Cycle
10593	Modernization of the Electronic Files Transfer (EFT) Processes Associated with Medicare Integrated Systems Testing (MIST) Contractor Testing and Fiscal Intermediary Shared System (FISS) Alpha Testing with the Coordination of Benefits and Recovery (COB and R) System on Behalf of the Benefits Coordination and Recovery Center (BCRC)
10596	Correction to Period Sequence Edits on Home Health Claims
10597	Submission of Condition Codes to the Inpatient Prospective Payment System (IPPS) Prior to Report Services Provided as Part of an Expanded Access Approval or Emergency Use Authorization
10599	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for July 2021
10601	Modifications to the National Coordination of Benefits Agreement (COBA) Claims Crossover Process
10611	Completion of Removal/Moving of Instructions from Chapter 15 of Publication (Pub.) 100-08 to Chapter 10 of Pub. 100-08
10613	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
10614	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
10615	Clinical Laboratory Fee Schedule - Medicare Travel Allowance Fees for Collection of Specimens
10616	User Change Request (CR): Multi-Carrier System (MCS) - Correct Coding Initiative (CCI) Related Procedure Codes
10618	Common Working File (CWF) Edits for Medicare Telehealth Services and Manual Update
10621	Updated Billing Requirements for Home Infusion Therapy (HIT) Services on

	None	Medicare Prescription Drug Benefit (CMS-Pub. 100-18)
	None	Demonstrations (CMS-Pub. 100-19)
10555	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
10556	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
	One Time Notification (CMS-Pub. 100-20)	
10549	Shared System Enhancement 2018: Rewrite Fiscal Intermediary Shared System (FIS) module FSSB6001, Common Working File (CWF) Unsolicited Response Function	
10551	Send Electronic Funds Transfer (EFT) Information from Provider Enrollment Chain and Ownership System (PECOS) to Multi-Carrier System (MCS) Phase 2	
10552	Modification to Existing Common Working File (CWF) Edits for Osteoporosis Drug Codes Billable on Home Health Claims	
10566	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)—April 2021	
10576	Changes to the End Stage Renal Disease (ESRD) PRICER to Accept the New Outpatient Provider Specific File Supplemental Wage Index Fields, the Network Reduction Calculation and New Value Code for Time on Machine	
10587	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10595	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
10603	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
10634	User CR: VIPS Medicare System (VMS) - Update Interactive Correspondence Online Reporting (ICOR) Mail Date Calculation	
10655	Mobile Personal Identity Verification (PIV) Station Installation	
10663	Revisions to Medicare Administrative Contractor (MAC) Standardized Monthly Status Report (MSR) Narrative Template	
10670	Modification to Existing Common Working File (CWF) Edits for Osteoporosis Drug Codes Billable on Home Health Claims	
10673	Send Electronic Funds Transfer (EFT) Information from Provider Enrollment Chain and Ownership System (PECOS) to Multi-Carrier System (MCS) Phase 2	
10694	Create a New Media Preference Indicator Custom Format and New eMedicare Correspondence Preference Indicator	
10712	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
	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 (January through March 2021)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal**

	Overview of the CERT Process Providing Sample Information to the CERT Review Contractor Disputing a CERT Decision Handling Overpayments and Underpayments Resulting from the CERT Findings Handling Appeals Resulting from CERT-Initiated Denials CERT Appeal Results	
10570	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10581	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10585	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10591	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10608	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10609	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10612	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10619	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10642	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10649	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10653	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10664	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10675	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10676	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
10680	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10699	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10700	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
10701	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
	Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None	
	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)	

Register, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

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

This information is available on our website at: <https://www.cms.gov/files/document/regs1q21qpu.pdf>

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

Addendum III: CMS Rulings (January through March 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 (January through March 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
Claims Processing Instructions for National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)	NCD 20.4	10635	03/23/2021	02/15/2018

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

Addendum VI: Approval Numbers for Collections of Information (January through March 2021)

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

Addendum VII: Medicare-Approved Carotid Stent Facilities (January through March 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	Effective Date	State
The following facilities are new listings for this quarter.			
Mercy Health West 3300 Mercy West Boulevard Cincinnati, OH 45211	360234	02/12/2021	OH
Sentara Williamsburg Regional Medical Center 100 Sentara Circle Williamsburg, VA 23188	1780694372	01/11/2021	VA
Kootenai Hospital District dba Kootenai Health 2300 Kootenai Health Way Coeur d' Alene, ID 83814	1992798409	01/19/2021	ID
Scripps Memorial Hospital Encinitas 354 Santa Fe Drive P O Box 230817 Encinitas, CA 92024	050503	01/26/2021	CA
Belleuve Hospital 462 First Avenue New York, NY 10016	1487812624	02/09/2021	NY
Prime Healthcare Services-Monroe LLC 4011 S Monroe Medical Park Boulevard Bloomington, IN 47403 Other information: dba Monroe Hospital	150183	03/02/2021	IN
Orlando Health South Lake Hospital 1900 Don Wickham Drive Clermont FL 34711	1336221019	03/02/2021	FL
Orlando Health Dr. P. Phillips Hospital 9400 Turkey Lane Orlando, FL 32819	1184709057	03/02/2021	FL
Affinity Hospital LLC d/b/a Grandview Medical Center 3690 Grandview Parkway Birmingham, AL 35243	010104	03/02/2021	AL
Memorial Hermann Katy 23900 Katy Freeway Katy, TX 77494	1932152337	03/16/2021	TX
Legacy Salmon Creek Medical Center 2211 NE 139th Street Vancouver, WA 98686	500150	03/16/2021	WA
Emanate Health Medical Center 210 W. San Bernardino Road Covina, CA 91723	050382	03/16/2021	CA
Legacy Good Samaritan Medical Center 1015 NW 22nd Avenue Portland, OR 97211	380017	03/16/2021	OR
The following facilities have editorial changes (in bold).			
FROM: J D Archbold Memorial Hospital TO: John D. Archbold Memorial 915 Gordon Avenue Thomasville, GA 31792-6614	110038	06/22/2006	GA

Facility	Provider Number	Effective Date	State
FROM: Memorial Hospital TO: UPMC Memorial 1701 Innovation Drive York PA 17408	39-0101	01/11/2012	PA
FROM: Orange Regional Medical Center TO: Garnet Health Medical Center 707 East Main Street Middletown, NY 10940	330126	05/02/2011	NY

Addendum VIII:**American College of Cardiology's National Cardiovascular Data Registry Sites (January through March 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 (January through March 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 (January through March 2021)**

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
The following facilities have editorial changes (in bold).				
Barnes-Jewish Hospital 1 Barnes Jewish Plaza Saint Louis, MO 63110 Albuquerque, NM 87102 Other information: Joint Commission ID # 8387 Previous Re-certification Dates: 03/06/2007; 02/13/2009; 08/19/2011; 08/30/2013; 10/02/2015; 11/10/2017	260032	03/26/2007	10/22/2020	NM
The Johns Hopkins Hospital 600 N. Wolfe Street Baltimore, MD 21287 Other information: DNV-GL # 492949-2020-VAD Previous Re-certification Dates: 2018-11-14; 2014-10-21; 2016-11-22	210009	12/11/2007	10/24/2020	MD
Penn State Milton S. Hershey Medical Center 500 University Drive Hershey, PA 17033 Other information: Joint Commission ID # 6075 Previous Re-certification Dates: 04/01/2008; 03/24/2010; 03/16/2012; 04/08/2014; 06/07/2016; 05/22/2018	390256	04/01/2008	09/11/2020	PA
University of Texas Medical Branch 301 University Boulevard Galveston, TX 77555-0518 Other information: Joint Commission ID # 9058 Previous Re-certification Dates: 01/31/2012; 01/28/2014; 02/23/2016; 01/30/2018	450018	01/31/2012	10/08/2020	TX

available at <http://www.cms.gov>. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (January through March 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/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 (January through March 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/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
UPMC Presbyterian Shadyside 200 Lothrop Street Pittsburgh, PA 15213 Other information: Joint Commission ID # 390164 Previous Re-certification Dates: 06/10/2008; 05/21/2010; 04/12/2012; 03/25/2014; 04/13/2016; 03/20/2018	6169	06/10/2008	12/09/2020	PA
Hillcrest Medical Center 1120 S Utica Tulsa, OK 74104 Other information: DNV GL Certificate # 457367- 2020-VAD Previous Re-certification Dates: 12/4/2017	370001	12/04/2017	11/25/2020	OK
University of Minnesota Medical Center, Fairview 2450 Riverside Avenue Minneapolis, MN 55454 Other information: Joint Commission ID # 2908 Previous Re-certification Dates: 03/26/2009; 08/26/2011; 10/10/2013; 11/03/2015; 12/05/2017	240080	03/26/2009	09/11/2020	MN
Chippendale Hospital, a campus of CJW Medical Center 7101 Jahnke Road Richmond, VA 23225 Other information: Joint Commission ID # 519792-2020-VAD Previous Re-certification Dates: 12/19/2017	490112	12/19/2017	12/21/2020	VA
University of Michigan Health System 1500 E Medical Center Drive, SPC 5474 Ann Arbor, MI 48109 Other information: Joint Commission ID # 7457	230046	03/27/2008	12/03/2020	MI
Previous Re-certification Dates: 03/27/2008; 03/18/2010; 03/07/2012; 02/04/2014; 03/15/2016; 04/24/2018 FROM: Allegheny General Hospital; TO: West Penn Allegheny Health System, Inc. 320 East North Avenue Pittsburgh, PA 15212 Other information: Joint Commission ID # 6158 Previous Re-certification Dates: 03/07/2008; 04/02/2010; 03/13/2012; 02/11/2014; 03/15/2016; 03/30/2018	390050	03/07/2008	01/09/2021	PA
University of California, Davis Medical Center 2315 Stockton Boulevard Sacramento, CA 95817 Other information: Joint Commission ID # 10055 Previous Re-certification Dates: 10/06/2015; 02/06/2018	050599	10/06/2016	12/10/2020	CA
Carolinas Medical Center 1000 Blythe Boulevard Charlotte, NC 28232 Other information: Joint Commission ID # 6480 Previous Re-certification Dates: 05/11/2010; 05/11/2012; 04/22/2014; 04/12/2016; 04/24/2018	340113	05/11/2010	12/17/2020	NC
MedStar Washington Hospital Center 110 Irving St, NW Washington, DC 20010 Other information: Joint Commission ID # 6308 Previous Re-certification Dates:	090011	04/22/2008	12/17/2020	DC

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)
(January through March 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/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities
(January through March 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).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
04/22/2008; 04/06/2010; 03/23/2012; 03/04/2014; 05/03/2016; 05/22/2018 Scripps Memorial Hospital La Jolla 9888 Genesee Avenue La Jolla, CA 92037 Other information: Joint Commission ID # 9880 Previous Re-certification Dates: 11/14/2012; 09/09/2014; 10/18/2016	050324	11/14/2012	12/16/2020	CA
Newark Beth Israel Medical Center 201 Lyons Avenue Newark, NJ 07112 Other information: Joint Commission ID #: 5965 Previous Re-certification Dates: 02/06/2009; 09/20/2011; 10/01/2013; 12/15/2015; 02/06/2018	310002	02/06/2009	11/26/2020	NJ
MultiCare Tacoma General Hospital 315 Martin Luther King Jr. Way Tacoma, WA 98338 Other information: Joint Commission ID # 568395-2021-VAD Previous Re-certification Dates: 11/03/2010; 11/14/2012; 11/18/2014; 12/06/2016	500129	11/03/2010	02/09/2021	WA
Saint Luke's Hospital of Kansas City 4401 Wornall Road Kansas City, MO 64111 Other information: Joint Commission ID # 8351 Previous Re-certification Dates: 2010-06-16; 2012-06-06; 2014-05-06; 2016-06-21; 2018-05-09	260138	06/16/2010	02/06/2021	MO

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMB in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (January through March 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/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10450 and CMS-10249]

Agency Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 2, 2021.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development,

Attention: Document Identifier/OMB Control Number: CMS-P-0015A, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10450 Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey for Merit-based Incentive Payment Systems (MIPS)

CMS-10249 Administrative Requirements for Section 6071 of the Deficit Reduction Act

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA 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 Information Collection; *Title of Information Collection:* Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey for Merit-based Incentive Payment Systems (MIPS); *Use:* CMS is submitting updates to one information collection request associated with the CAHPS for MIPS survey. The CAHPS for MIPS survey is

used in the Quality Payment Program (QPP) to collect data on fee-for-service Medicare beneficiaries' experiences of care with eligible clinicians participating in MIPS and is designed to gather only the necessary data that CMS needs for assessing physician quality performance, and related public reporting on physician performance, and should complement other data collection efforts. The survey consists of the core Agency for Healthcare Research and Quality (AHRQ) CAHPS Clinician & Group Survey, version 3.0, plus additional survey questions to meet CMS's information and program needs. The survey information is used for quality reporting, the Care Compare website, and annual statistical experience reports describing MIPS data for all MIPS eligible clinicians.

This 2021 information collection request addresses changes to the CAHPS for MIPS Survey associated with the CY 2021 Physician Fee Schedule (PFS) final rule. In order to address the increased use of telehealth care due to the Public Health Emergency (PHE) for COVID-19, an additional question is added to the CAHPS for MIPS survey to integrate one telehealth item to assess the patient-reported usage of telehealth services. In addition, the cover page of the CAHPS for MIPS Survey is revised to include a reference to care in telehealth settings. The CAHPS for MIPS survey results in burden to three different types of entities: Groups and virtual groups, vendors, and beneficiaries associated with administering the survey. Virtual groups are subject to the same requirements as groups; therefore, we will refer only to groups as an inclusive term for both unless otherwise noted. The estimated time to administer the 2021 CAHPS for MIPS survey has increased from 12.9 minutes to 13.1 minutes; however, there was an overall decrease in burden as the number of respondents decreased. *Form Number:* CMS-10450 (OMB control number: 0938-1222); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions and Individuals and Households; *Number of Respondents:* 30,249; *Total Annual Responses:* 30,249; *Total Annual Hours:* 6,902 (For policy questions regarding this collection contact Alesia Hovatter at 410-786-6861.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Administrative Requirements for Section 6071 of the Deficit Reduction Act; *Use:* State Operational Protocols should provide enough information such that: The CMS