

there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to submit comments during the 60-day comment period beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under section 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.308(e) and (f).

## II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A-95-11) detailing the waiver process and discussing the information hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a

final determination on the waiver request and notify the hospital and the designated and requested OPOs.

## III. Hospital Waiver Request

As permitted by § 486.308(e), the following hospital has requested a waiver to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located:

North Carolina Baptist Hospital, Winston-Salem, North Carolina, is requesting a waiver to work with: LifeShare Carolinas, 5000 D Airport Center Parkway, Charlotte, North Carolina 28208.

The Hospital's Designated OPO is: HonorBridge, 1430 WestBrook Plaza Drive, Winston-Salem, North Carolina 27103.

## IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

## V. Response to Comments

We will consider all comments we receive by the date specified in the **DATES** section of this preamble.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for

purposes of publication in the **Federal Register**.

Dated: November 8, 2022.

**Lynette Wilson,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2022-24715 Filed 11-10-22; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-9138-N]

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2022

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

**ACTION:** Notice.

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2022, relating to the Medicare and Medicaid programs and other programs administered by CMS.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone number
I CMS Manual Instructions .....	Ismael Torres .....	(410) 786-1864
II Regulation Documents Published in the <b>Federal Register</b> .....	Terri Plumb .....	(410) 786-4481
III CMS Rulings .....	Tiffany Lafferty .....	(410) 786-7548
IV Medicare National Coverage Determinations .....	Wanda Belle, MPA .....	(410) 786-7491
V FDA-Approved Category B IDEs .....	John Manlove .....	(410) 786-6877
VI Collections of Information .....	William Parham .....	(410) 786-4669
VII Medicare-Approved Carotid Stent Facilities .....	Sarah Fulton, MHS .....	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites .....	Sarah Fulton, MHS .....	(410) 786-2749
IX Medicare's Active Coverage-Related Guidance Documents .....	JoAnna Baldwin, MS .....	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions .....	JoAnna Baldwin, MS .....	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites .....	David Dolan, MBA .....	(410) 786-3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities .....	David Dolan, MBA .....	(410) 786-3365
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities .....	Sarah Fulton, MHS .....	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities .....	Sarah Fulton, MHS .....	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials .....	David Dolan, MBA .....	(410) 786-3365
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: November 4, 2022.

**Trenesha Fultz-Mimms,**

*Federal Register Liaison, Department of Health and Human Services.*

**BILLING CODE 4120-01-P**

**Publication Dates for the Previous Four Quarterly Notices**

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 18, 2021 (86 FR 64492), February 9, 2022 (87 FR 7458), May 13, 2022 (87 FR 29327) and August 4, 2022 (87 FR 47751). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

**Addendum I: Medicare and Medicaid Manual Instructions (July through September 2022)**

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

**How to Obtain Manuals**

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

**How to Review Transmittals or Program Memoranda**

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government

publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Revision to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) to Align to 1834(a)(5)(E) of the Social Security Act (CMS-Pub. 100-03) Transmittal No. 11587.

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

**Fee-For Service Transmittal Numbers**

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

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

Transmittal Number	Manual/Subject/Publication Number
<b>Medicare General Information (CMS-Pub. 100-01)</b>	
11520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11438	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>Medicare Benefit Policy (CMS-Pub. 100-02)</b>	
11501	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
<b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b>	
11587	Revision to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) to Align to 1834(a)(5)(E) of the Social Security Act
<b>Medicare Claims Processing (CMS-Pub. 100-04)</b>	
11484	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11486	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

11487	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11490	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11493	Claim Status Category and Claim Status Codes Update
11494	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11496	October 2022 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
11497	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11498	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11500	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11502	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11504	Modification of Existing Common Working File (CWF) Editing for Preventive Services
11507	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11508	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11509	Cessation of Use of MyMedicare.gov Web Address
11510	Masking the Medicare Beneficiary Identifier (MBI) on the Medicare Summary Notice (MSN)
11511	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11514	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11518	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11519	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11523	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11527	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11531	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11532	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11540	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2023
11541	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update Fiscal Year (FY) 2023
11542	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for Fiscal Year (FY) 2023
11543	Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2023
11544	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2022 Update
11547	New Waived Tests

11548	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11549	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
11551	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
11552	Claim Status Category and Claim Status Codes Update
11555	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11558	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
11559	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11560	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
11561	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
11564	Influenza Vaccine Payment Allowances - Annual Update for 2022-2023 Season
11565	2023 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
11566	January 2023 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
11567	Annual Clotting Factor Furnishing Fee Update 2023 Updates are Being Made to Chapter 1 of the Medicare Claims Processing Manual to Include Newly Created and Utilized Payer Only Codes
11571	Updates are Being Made to Chapter 1 of the Medicare Claims Processing Manual to Include Newly Created and Utilized Payer Only Codes
11572	Exceptions to Average Sales Price (ASP) Payment Methodology – Claims Processing Manual Changes
11573	2023 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update
11581	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11583	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2023
11589	Billing for Hospital Part B Inpatient Services Editing Of Hospital Part B Inpatient Services: Reasonable and Necessary Part A Hospital Inpatient Denials Editing Of Hospital Part B Inpatient Services: Other Circumstances in Which Payment Cannot Be Made under Part A
11590	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 3, Section 20.1.2.7 to Correct the Device Reductions Data Element in the FISS Extract File Procedure for Medicare Contractors to Perform and Record Outlier
11591	Instructions for Retrieving the January 2023 Medicare Physician Fee Schedule Database (MPFSDB) Files Through the CMS Mainframe Telecommunications System
11592	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11593	October 2022 Integrated Outpatient Code Editor (IOCE) Specifications Version 23.3
11594	October 2022 Update of the Hospital Outpatient Prospective Payment System

	(OPPS)
11595	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
11596	Annual Clotting Factor Furnishing Fee Update 2023
11599	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 29.0, Effective January 2023
11600	Instructions for Retrieving the January 2023 Opioid Treatment Program (OTP) Payment Rates Through the CMS Mainframe Telecommunications System
11601	Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes Used for Home Health Consolidated Billing Enforcement
11602	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11603	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11604	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
11605	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11610	October 2022 Update of the Ambulatory Surgical Center (ASC) Payment System
11611	January 2023 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
11612	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January 2023
11617	Instructions for Retrieving the January 2023 Home Infusion Therapy (HIT) Services Payment Rates Through the CMS Mainframe Telecommunications System
11618	Instructions for Downloading the Medicare ZIP Code File for January 2023
11619	October Quarterly Update for 2022 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
11620	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11621	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>Medicare Secondary Payer (CMS Pub. 100-05)</b>	
11512	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11513	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11550	Significant Updates to Internet Only Manual (IOM) Publication (Pub.) 100-05 Medicare Secondary Payer (MSP) Manual, Chapter 5
11557	Automation of the Medicare Duplicate Primary Payment (DPP) Process
<b>Medicare Financial Management (CMS-Pub. 100-06)</b>	
11495	Automation of the Duplicate Primary Payer (DPP) Process
11499	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
11562	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b>	
207	Revisions to State Operation Manual (SOM), Appendix PP Guidance to Surveyors for Long Term Care Facilities
<b>Medicare Program Integrity (CMS-Pub. 100-08)</b>	
11480	Issued to a specific audience, not posted to Internet/Intranet due to a

	Confidentiality of Instruction
11483	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11528	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11529	Update of Chapter 3 in Publication (Pub.) 100-08, Including Update to Medicare Program Integrity Contractor Post-Payment Review Process, and Update of Chapter 8 Pub. 100-08, Including Revision to When Contractor Suspects Additional Improper Claims Medical Record Review Contractor Suspects Additional Improper Claims
11530	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11536	Provider/Supplier Enrollment Adverse Legal Actions
11537	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11556	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11563	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11574	Sixth General Update to Provider Enrollment Instructions in Chapter 10 of Publication (Pub.) 100-08, Program Integrity Manual (PIM)
11575	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11576	Final Round of Transition of Enrollment and Certification Activities for Various Certified Provider and Supplier Types and Transactions
11580	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11588	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11597	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11598	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11606	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11608	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11609	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11613	Final Round of Transition of Enrollment and Certification Activities for Various Certified Provider and Supplier Types and Transactions
<b>Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)</b>	
11579	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11616	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Years (FYs) 2019 and 2020 for Inpatient Prospective Payment System (IPPS) Hospitals with Updated Data for Hospitals in the 9th Circuit
<b>Medicare Quality Improvement Organization (CMS- Pub. 100-10)</b>	
	None
<b>Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)</b>	
	None
<b>Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)</b>	
	None
<b>Medicare Managed Care (CMS-Pub. 100-16)</b>	
	None

<b>Medicare Business Partners Systems Security (CMS-Pub. 100-17)</b>	
11570	Pub 100-17 Medicare Business Partners Systems Security Manual Update
<b>Medicare Prescription Drug Benefit (CMS-Pub. 100-18)</b>	
	None
<b>Demonstrations (CMS-Pub. 100-19)</b>	
11489	ESRD Treatment Choices (ETC) Model Performance Payment Adjustment (PPA) - Facility Component (Implementation CR)
11505	Concatenation of Multiple Separate Comma-Separated Values Files to One File - Update to CR 12492 – Implementation
11506	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11515	Federally Qualified Health Center (FQHC) Participation in and Payment Under the Maryland Primary Care Program (MDPCP) - Implementation Change Request (CR) to correct Business Requirement (BR) 12326.7.2.
11516	Monthly Report of Performance Payment Adjustment (PPA) Claims - Addition to Change Request (CR) 12404 - Implementation CR
11517	Remove Beneficiaries Below 18 Years Old From Model Adjustments – Correction for CR11390
11534	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11553	Automatic Reprocessing of Claims for Kidney Care Choices (KCC) Model-Implementation
11554	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
<b>One Time Notification (CMS-Pub. 100-20)</b>	
11481	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11482	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11485	Instructions to the Fiscal Intermediary Shared System [FISS] Edit to Expand the Existing MA Bypass Reusable Solution PARMCC78 and Modify the Existing Logic to Read the New PARMS
11488	New Edit for Prospective Payment System (PPS) Outpatient and Inpatient Bill Types Receiving an Outlier Payment When a Device Credit is Reported
11491	Interns and Residents Information System (IRIS) XML Format
11492	User CR: MCS - HIMR Functions Menu Additional Fields
11503	Corrections to Processing of Canceled Home Health Notices of Admission and of Period Sequence Edits
11521	Multi-Carrier System (MCS) Removal of the Physician Pay for Reporting (P4R), Physician Quality Reporting System (PQRS) and Electronic Prescribing (ERx) Incentive Payments Financial Logic from the Claims Processing System
11522	Remove Hard Coded Logic for Edits 004H and 005H - Remove the Edits from Displaying on the H99RBEA1 and H99RBEA2 Reports
11524	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11525	User Enhancement Change Request (CR) - Update the Multi-Carrier System (MCS) Desk Top Tool (MCSDT) Editing for Same Day Adjustments
11526	User Enhancement Change Request (CR)- Update the Model Participant Provider (M1) Screen and Model Participant Provider Report (H99RVMPP) in the Multi-Carrier System (MCS)
11533	Implementation of the Capital Related Assets Adjustment (CRA) for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Under the End Stage Renal Disease Prospective Payment System (ESRD PPS)

11535	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front-End Updates for January 2023
11538	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11539	Implementation of the Award for the Jurisdiction N (J-N) Part A and Part B Medicare Administrative Contractor (JN A/B MAC)
11545	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--January 2023 Update
11546	The purpose of this Change Request (CR) is to provide a maintenance update of ICD-10 conversions and other coding updates specific to NCDs. These NCD coding changes are the result of newly available codes, coding revisions to NCDs released separately, or coding feedback received. Previous NCD coding changes appear in ICD-10 quarterly updates that can be found at: <a href="https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html">https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html</a> , along with other CRs implementing new policy NCDs
11568	User CR: MCS - HIMR Functions Menu Additional Fields
11569	Medicare Summary Notice (MSN) Created with Wrong Beneficiary Data - Update Beneficiary Data Streamlining Logic
11577	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11578	Updated Merit-based Incentive Payment System (MIPS)/MIPS Value Pathways (MVP) Healthcare Common Procedure Coding System (HCPCS) Codes
11582	Mobile Personal Identity Verification (PIV) Station
11584	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--January 2023 Update
11585	User Enhancement Change Request (CR) - Update the Multi-Carrier System (MCS) Desk Top Tool (MCSDT) Editing for Same Day Adjustments
11586	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11607	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11614	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11622	Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter As Certain Colorectal Cancer Screening Tests
11623	Updates to the Common Working File (CWF) for Editing and Claims Processing to Allow Medicare Fee-For-Service (FFS) Coverage of Kidney Acquisition Costs for Medicare Advantage (MA) Beneficiaries Provided by Maryland Waiver (MW) Hospitals
<b>Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)</b>	
	None
<b>State Payment of Medicare Premiums (CMS-Pub.100-24)</b>	
	None
<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)</b>	
	None

**Addendum II: Regulation Documents Published  
in the Federal Register (July through September 2022)  
Regulations and Notices**

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys). When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

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

This information is available on our website at: <https://www.cms.gov/files/document/regs3q22qpu.pdf>

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

#### **Addendum III: CMS Rulings (July through September 2022)**

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

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

#### **Addendum IV: Medicare National Coverage Determinations (July through September 2022)**

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in

some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. There are no updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: [www.cms.gov/medicare-coverage-database/](http://www.cms.gov/medicare-coverage-database/). For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

#### **Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2022)** (Inclusion of this addenda is under discussion internally.)

#### **Addendum VI: Approval Numbers for Collections of Information (July through September 2022)**

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

#### **Addendum VII: Medicare-Approved Carotid Stent Facilities (July through September 2022)**

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Date Approved	State
<b>The following facilities are new listings for this quarter.</b>			
Medical City Alliance 3101 N. Tarrant Parkway	670103	05/01/2022	TX

Facility	Provider Number	Date Approved	State
Fort Worth, TX 76177			
South Baldwin Regional Medical 1613 N. McKenzie Street Foley, AL 36535	010083	07/07/2022	AL
Ogden Regional Medical Center 5475 South 500 Ogden, UT 844505	1720031636	07/15/2022	UT
Cleveland Clinic Tradition Hospital 10000 SW Innovation Way Port St. Lucie, FL 34987	100044	07/26/2022	FL
Cleveland Clinic Martin North II Hospital 200 SE Hospital Avenue Stuart, FL 34994	100044	07/26/2022	FL
Aurora St. Luke's Medical Center 2900 West Oklahoma Avenue Milwaukee, WI 53215	520138	07/09/2022	WI
HCA Florida Gulf Coast Hospital 449 W. 23rd Street Panama City, FL 32405	1548392475	08/16/2022	FL
Decatur Morgan Hospital 1201 7th Street Decatur, AL 35601	010085	09/20/2022	AL
Centennial Hills Hospital Medical Center 6900 N. Durango Drive Las Vegas, NV 89149	290054	09/27/2022	NV
Indiana Regional Medical Center 835 Hospital Road Indiana, PA 15701	390173	10/25/2022	PA
Stillwater Medical Center Authority 1323 W. 6th Avenue Stillwater, OK 74074	370049	10/25/2022	OK
Memorial Hermann Sugar Land Hospital 17500 W Grand Parkway S Sugar Land, TX 77479	1295788735	10/25/2022	TX
Hilo Medical Center 1190 Waianuenue Avenue Hilo, HI 96720	120005	10/25/2022	HI
<b>The following facilities have editorial changes (in bold).</b>			
<b>FROM: Blake Medical Center</b> <b>TO: HCA Florida Blake Hospital</b> 2020 59 <sup>th</sup> Street W Bradenton, FL 34209	114964244	11/06/2008	FL
<b>FROM: Orlando Health</b> <b>TO: OH Orlando Regional Medical Center</b> <b>1414 Kuhl Avenue</b> Orlando FL 32806	100006	05/23/2005	FL
<b>FROM: St. Francis Hospital and Health Centers – Indianapolis</b> <b>TO: Franciscan Health Indianapolis</b> 8111 South Emerson Avenue Indianapolis, IN 46237	150162	08/28/2006	IN

Facility	Provider Number	Date Approved	State
<b>FROM: Great River Medical Center</b> <b>TO: Southeast Iowa Regional Medical Center</b> 1221 S. Gear Avenue West Burlington, IA 52655-1681	420680407	04/16/2010	IA
<b>The following facility is being removed.</b>			
Franciscan St. Francis Health – Indianapolis 1600 Albany Street Beech Grove, IN 46107	150033	04/01/2005	IN

**Addendum VIII:****American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2022)**

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

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

**Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2022)**

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the 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 (July through September 2022)**

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

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

**Addendum XI: National Oncologic PET Registry (NOPR)  
(July through September 2022)**

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilities/NOPR/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, MBA (410-786-3365).

**Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2022)**

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

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilities/VAD/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
<b>The following facilities have editorial changes (in bold).</b>				
Westchester Health Care Corporation 100 Woods Road Valhalla, NY 10595  Other information: Joint Commission ID # 2518  Previous Re-certification Dates: 11/19/2009; 11/15/2011; 12/03/2013; 12/08/2015; 12/19/2017; 03/07/2020	330234	11/29/2009	<b>06/30/2022</b>	NY
Ronald Reagan UCLA Medical Center 757 Westwood Plaza Los Angeles, CA 90095  Other information: Joint Commission ID # 9944  Previous Re-certification Dates: 02/06/2009; 08/09/2011; 08/13/2013; 09/15/2015; 10/06/2017; 12/04/2019	050262	02/06/2009	<b>04/09/2022</b>	CA
St. Vincent Infirmary Medical Center dba CHI St. Vincent 2 St. Vincent Circle Little Rock, AR 72205  Other information: Joint Commission ID # 8661  Previous Re-certification Dates: 11/21/2017; 02/05/2020	040007	11/21/2017	<b>05/04/2022</b>	AR
Lancaster General Hospital 555 North Duke Street Lancaster, PA 17602  Other information: Joint Commission ID # 6086  Previous Re-certification Dates: 05/19/2009; 09/23/2011; 09/06/2013; 09/22/2015; 10/03/2017; 02/05/2020	390100	05/19/2009	<b>05/04/2022</b>	PA
University of Kentucky Hospital/ UK Albert B. Chandler Hospital 800 Rose Street Lexington, KY 40536-0293	180067	02/10/2009	<b>05/12/2022</b>	KY

<p>Other information: Joint Commission ID # 7760</p> <p>Previous Re-certification Dates: 02/10/2009; 09/20/2011; 09/18/2013; 11/03/2015; 12/05/2017; 02/26/2020</p>				
<p>Lehigh Valley Hospital 1200 S. Cedar Crest Boulevard Allentown, PA 18105</p> <p>Other information: Joint Commission ID # 4880</p> <p>Previous Re-certification Dates: 10/29/2013; 11/10/2015; 12/12/2017; 03/04/2020</p>	390133	10/29/2013	<b>05/28/2022</b>	PA
<p>UMC Health System 602 Indiana Avenue Lubbock, TX 79415</p> <p>DNV Healthcare Certificate #: C558801</p> <p>Previous Re-certification Dates: 06/17/2017; 06/09/2019</p>	450686	06/17/2017	<b>07/26/2022</b>	TX
<p>West Penn Allegheny Health System, Inc. 320 East North Avenue Pittsburgh, PA 15212</p> <p>Other information: Joint Commission ID # 6158</p> <p>Previous Re-certification Dates: 03/07/2008; 04/02/2010; 03/13/2012; 02/11/2014; 03/15/2016; 03/30/2018; 01/09/2021</p>	390050	03/07/2008	<b>07/27/2022</b>	PA
<p>University of Michigan Health System 1500 E Medical Center Drive, SPC 5474 Ann Arbor, MI 48109</p> <p>Other information: Joint Commission ID # 7457</p> <p>Previous Re-certification Dates: 03/27/2008; 03/18/2010; 03/07/2012; 02/04/2014; 03/15/2016; 04/24/2018; 12/03/2020</p>	230046	03/27/2008	<b>06/03/2022</b>	MI

<p>Baptist Health Medical Center - Little Rock 9601 Baptist Health Drive Little Rock, AR 72205-7299</p> <p>Other information: Joint Commission ID # 8656</p> <p>Previous Re-certification Dates: 11/10/2009; 11/08/2011; 12/11/2013; 01/12/2016; 12/15/2017; 02/12/2020</p>	040114	11/10/2009	<b>05/07/2022</b>	AR
<p>Sutter Medical Center 2825 Capitol Ave Sacramento, CA 95816</p> <p>Other information: Joint Commission ID # 2902</p> <p>Previous Re-certification Dates: 10/20/2009; 09/22/2011; 10/17/2013; 10/27/2015; 11/07/2017; 03/04/2020</p>	050108	10/20/2009	<b>06/16/2022</b>	CA
<p>WellSpan York Hospital 1001 South George Street York, PA 17405</p> <p>Other information: Joint Commission ID # 6228</p> <p>Previous Re-certification Dates: 11/19/2013; 12/15/2015; 01/23/2018; 03/14/2020</p>	390046	11/19/2012	<b>06/18/2022</b>	PA
<p>UPMC Presbyterian Shadyside 200 Lothrop Street Pittsburgh, PA 15213</p> <p>Other information: Joint Commission ID # 6169</p> <p>Previous Re-certification Dates: 06/10/2008; 05/21/2010; 04/12/2012; 03/25/2014; 04/13/2016; 03/20/2018; 12/09/2020</p>	390164	06/10/2008	<b>06/03/2022</b>	PA
<p>NYU Langone Hospitals 550 First Avenue New York, NY 10016</p> <p>Other information: Joint Commission ID # 5820</p> <p>Previous Re-certification Dates: 02/14/2012;</p>	330214	02/14/2012	<b>07/27/2022</b>	NY

01/14/2014; 03/08/2016; 03/27/2018; 8/26/2020				
The Johns Hopkins Hospital 600 N. Wolfe Street Baltimore, MD 21287  Other information: Joint Commission ID # 6252 Previous Re-certification Dates: 12/11/2007; 12/15/2009; 11/29/2011; 12/03/2013; 01/12/2016; 02/13/2018; 10/24/2020	210009	12/11/2007	<b>06/15/2022</b>	MD
<b>FROM: Jackson Memorial Hospital</b> <b>TO: Public Health Trust of Dade County Florida dba Jackson Memorial Hospital</b> 1611 Northwest 12th Avenue Miami, FL 33136-1094  Other information: Joint Commission ID # 6850  Previous Re-certification Dates: 10/22/2009; 10/21/2011; 11/06/2013; 12/08/2015; 12/08/2017; 3/3/2020	100022	10/22/2009	<b>06/22/2022</b>	FL
Christ Hospital 2139 Auburn Avenue Cincinnati, OH 45219  Other information: Joint commission ID #: 6987  Previous Re-certification Dates: 02/17/2012; 02/20/2014; 04/05/2016; 03/20/2018; 2/26/21	360163	02/17/2012	<b>07/09/2022</b>	OH
MedStar Washington Hospital Center 110 Irving St, NW Washington, DC 20010  Other information: Joint Commission ID # 6308  Previous Re-certification Dates: 04/22/2008; 04/06/2010; 03/23/2012; 03/04/2014; 05/03/2016; 05/22/2018; 12/17/2020	090011	04/22/2008	<b>07/08/2022</b>	DC
Penn State Milton S. Hershey Medical Center	390256	04/01/2008	<b>06/30/2022</b>	PA

500 University Drive Hershey, PA 17033 Joint Commission ID # 6075 Previous Re-certification Dates: 04/01/2008; 03/24/2010; 03/16/2012; 04/08/2014; 06/07/2016; 05/22/2018; 9/11/2020				
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; 10/08/2020	450018	01/31/2012	<b>06/08/2022</b>	TX
Abington Memorial Hospital 1200 Old York Road Abington, PA 19001  Other information: Joint commission ID #: 6013  Previous Re-certification Dates: 06/28/2012; 06/03/2014; 06/28/2016; 05/22/2018	390231	06/28/2012	<b>07/16/2022</b>	PA
West Virginia University Hospitals, Inc. One Medical Center Drive Morgantown, WV 26506  Other information: Joint Commission ID # 6444 Previous Re-certification Dates: 07-26-2018; 02-25-2021	510001	07/26/2018	<b>08/17/2022</b>	WV
Medical University of South Carolina Medical Center 169 Ashley Avenue Charleston, SC 29425  Other information: Joint Commission ID # 6584 Previous Re-certification Dates: 09/23/2010; 09/07/2012; 08/05/2014; 09/13/2016; 09/26/2018; 03/24/2021	420004	09/23/2010	<b>07/21/2022</b>	SC
Scott & White Memorial Hospital 2401 S 31st St Temple, TX 76508  Other information:	450054	12/07/2011	<b>07/02/2022</b>	TX

Joint commission ID #: 9241 Previous Re-certification Dates: 12/07/2011; 12/03/2013; 01/12/2016; 12/19/2017; 03/05/2020				
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; 12/17/2020	340113	05/11/2010	08/03/2022	NC
Saint Luke's Hospital of Kansas City 4401 Wornall Road Kansas City, MO 64111  Other information: Joint Commission ID # 8351  Previous Re-certification Dates: 06/15/2010; 06/06/2012; 05/06/2014; 06/21/2016; 05/08/2018; 02/06/2021	260138	06/15/2010	08/05/2022	MO
The University of Kansas Hospital Authority 4000 Cambridge Street Kansas City, KS 66160  Other information: Joint Commission ID # 8567 Previous Re-certification Dates: 03/08/2016; 03/06/2018	170040	03/08/2016	07/20/2022	KS

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)  
(July through September 2022)**

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. 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 [www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage). For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Date of Certification	State
Ohio State University Hospitals 410 West Tenth Avenue, DN 168 Columbus, OH 43210  Other information: Joint Commission ID # 7029  Recertification date: 08/28/2021 Previous Re-certification Dates: 12/15/2018  Tammie Hayes, Director, LVRS, 614-293-3629	36-0085	10/29/2016	OH

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities  
(July through September 2022)**

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMB in the 3-month period. This information is available at [www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage](http://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 (July through September 2022)**

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period. This information is available on our website at [www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage). For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2022-24670 Filed 11-10-22; 8:45 am]

BILLING CODE 4120-01-C

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-2683]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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

**DATES:** Submit written comments (including recommendations) on the collection of information by December 14, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to [https://](https://www.reginfo.gov/public/do/PRAMain)

[www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0847. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

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

**Data To Support Social and Behavioral Research as Used by the Food and Drug Administration**

*OMB Control Number 0910-0847—Extension*

This information collection is intended to support FDA-conducted research. Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decision-

making processes and communications that affect various stakeholders. FDA uses the following methods to achieve these goals: (1) individual indepth interviews, (2) general public focus group interviews, (3) intercept interviews, (4) self-administered surveys, (5) gatekeeper surveys, and (6) focus group interviews. These methods serve the narrowly defined need for direct and informal opinion on a specific topic and serve as a qualitative and quantitative research tool having two major purposes:

- Obtaining useful information for the development of variables and measures for formulating the basic objectives of social and behavioral research and
- successfully communicating and addressing behavioral changes with intended audiences to assess the potential effectiveness of FDA communications, behavioral interventions, and other materials.

While FDA will use these methods to test and refine its ideas and help develop communication and behavioral strategies research, the Agency will generally conduct further research before making important decisions (such as adopting new policies and allocating or redirecting significant resources to support these policies).

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the