



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9111-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July through September 2018

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2018, 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 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	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan	(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	Stuart Caplan, RN, MAS	(410) 786-8564
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>.

Dated: October 22, 2018.

Kathleen Cantwell,

Director,

Office of Strategic Operations and Regulatory Affairs.

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: October 27, 2017 (82 FR 49819), January 26, 2018 (83 FR 3716), May 4, 2018 (83 FR 19769) and August 13, 2018 (83 FR 40043). 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 2018)

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 Electronic Correspondence Referral System (ECRS) Enhanced Functionality, use (CMS-Pub. 100-05) Transmittal No. 122.

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. 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)	
117	Analysis to Expand All Monetary Amount Fields related to Billing and Payment to Accommodate 10 Digits in Length (\$99,999,999.99)
Medicare Benefit Policy (CMS-Pub. 100-02)	
244	Internet Only Manual (IOM) Update to Publication 100-02, Chapter End Stage Renal Disease (ESRD), Section 100
245	System Changes to Implement Epoetin Alfa Biosimilar, Retacrit for End Stage Renal Disease (ESRD) and Acute Kidney Injury (AKI) Claims
246	Manual Updates Related to Payment Policy Changes Affecting the Hospice Aggregate Cap Calculation and the Designation of Hospice Attending Physicians
Medicare National Coverage Determination (CMS-Pub. 100-03)	
	None
Medicare Claims Processing (CMS-Pub. 100-04)	
4083	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2018 Update
4084	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2019

4085	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2019
4086	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4087	New Physician Specialty Code for Undersea and Hyperbaric Medicine Physician Specialty Codes
4088	Update to the Internet Only Manual (IOM) Publication 100-04 - Medicare Claims Processing Manual, Chapter 27 - Contractor Instructions for Common Working File (CWF) Change Control Procedures Processing Disposition and Error Codes
4089	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4090	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
4091	New Waived Tests
4092	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2018
4093	October Quarterly Update to 2018 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement
4094	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
4095	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
4096	Update to the Medicare Claims Processing Manual, Chapter 24, Section 90
4097	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4098	Update to the Fiscal Intermediary Shared Systems (FISS) Outpatient Provider Specific File (OPSF) for Outpatient Prospective Payment System (OPPS) Hospitals and OPPS Pricer Interface
4099	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4100	Quarterly Influenza Virus Vaccine Code Update - January 2019
4101	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2019
4102	Updates to the Medicare Claims Processing Manual, Chapter 24, ASCA Waiver Review Form of Letters, Exhibits A-H
4103	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4104	Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2019
4105	System Changes to Implement Epoetin Alfa Biosimilar, Retacrit for End Stage Renal Disease (ESRD) and Acute Kidney Injury (AKI) Claims
4106	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4107	October 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
4108	October Quarterly Update for 2018 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule

4109	October Quarterly Update for 2018 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
4110	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4111	Revisions to Medicare Claims Processing Manual for Foreign, Emergency and Shipboard Claims
4112	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4113	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4114	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - October 2018 Update
4115	Claim Status Category and Claim Status Codes Update
4116	Healthcare Provider Taxonomy Codes (HPTCs) October 2018 Code Set Update
4117	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
4118	Combined Common Edits/Enhancements Modules (CEEM) Code Set Update
4119	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4120	Instructions for Downloading the Medicare ZIP Code File for January 2019
4121	2019 Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
4122	October 2018 Integrated Outpatient Code Editor (I/OCE) Specifications Version 19.3
4123	October 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)
4124	Influenza Vaccine Payment Allowances - Annual Update for 2018-2019 Season
4125	October 2018 Update of the Ambulatory Surgical Center (ASC) Payment System
4126	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4127	Quarterly Influenza Virus Vaccine Code Update - January 2019
4128	Annual Clotting Factor Furnishing Fee Update 2019
4129	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4130	Update to the Medicare Claims Processing Manual, Chapter 23, Section 60.3
4131	Updates to Chapter 23 Fee File Instructions
4132	Instructions for Retrieving the January 2019 Medicare Physician Fee Schedule Database (MPFSDB) Files Through the CMS Mainframe Telecommunications System
4133	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4134	Quarterly Healthcare Common Procedure Coding System (HCPCS)

	Drug/Biological Code Changes - October 2018 Update
4135	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4136	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4137	New Waived Tests
4138	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - October 2018
4139	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2019
4140	Updates to Chapter 1 Payer Only Codes in the Medicare Claims Processing Manual
4141	Quarterly Influenza Virus Vaccine Code Update - January 2019
4142	2019 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
Medicare Secondary Payer (CMS-Pub. 100-05)	
122	Electronic Correspondence Referral System (ECRS) Enhanced Functionality
123	Updating Language to Clarify for Providers Chapter 3, Section 20 and Chapter 5, Section 70 of the Medicare Secondary Payer Manual
124	Updates to Chapters 5 and 6 of Publication 100-05 to Further Clarify Medicare Secondary Payer (MSP) Processes that Include Electronic Correspondence Referral System (ECRS) Requests Submissions and Timely Submission of MSP I Records, General Inquiries and Hospital Reviews
Medicare Financial Management (CMS-Pub. 100-06)	
305	Notice of New Interest Rate for Medicare Overpayments and Underpayments - 4th Qtr Notification for FY 2018
306	New Physician Specialty Code for Undersea and Hyperbaric Medicine
Medicare State Operations Manual (CMS-Pub. 100-07)	
179	Revisions to the State Operations Manual (SOM) Chapter Two for Organ Procurement Organizations (OPOs)
180	Revisions to the State Operations Manual (SOM) Appendix Y, Organ Procurement Organization (OPO) Interpretive Guidance
181	Revisions to State Operations Manual, Chapter 2, Certification Process
182	Revisions to State Operation Manual (SOM), Appendix B - Guidance to Surveyors for Home Health Agencies
Medicare Program Integrity (CMS-Pub. 100-08)	
805	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
806	Clarify Detailed Written Orders For Durable Medical Equipment, Prosthetics, Orthotics, And Supplies (DMEPOS)
807	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
808	Medical Review of Evaluation and Management (E/M) Documentation
809	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
810	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
811	Issued to a specific audience, not posted to Internet/Intranet due to

	Confidentiality of Instructions
812	Clarify Detailed Written Orders For Durable Medical Equipment, Prosthetics, Orthotics, And Supplies (DMEPOS)
813	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
814	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
815	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
816	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
817	New Instructions for Home Health Agency Misuse of Requests for Anticipated Payments (RAPs)
818	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
819	Adding a Targeted Probe and Educate (TPE) Sub-Section Into Section 3.2 of Chapter 3 in Publication (Pub.) 100-08
820	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
821	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
822	Update to Chapter 15 of Publication (Pub.) 100-08, Certification Statement Policies
823	Update to Exhibit 16 - Model Payment Suspension Letters in Publication (Pub.) 100-08
824	Update to Chapter 15 of Publication (Pub.) 100-08, Certification Statement Policies
825	Credentials of Reviewers (This Change Request (CR) Rescinds and Fully Replaces CR 10157.)
826	Update to Chapter 4, Section 4.18.1.4 and Exhibit 16 in Publication (Pub.) 100-08
827	Updates to Chapter 4 of Publication (Pub.) 100-08
828	Guidance Regarding the Use of Statistical Sampling for Overpayment Estimation
829	None
830	
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
Medicare Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None

Demonstrations (CMS-Pub. 100-19)	
200	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
201	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
202	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
203	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
204	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
205	Next Generation Accountable Care Organization (ACO) Model 2019 Benefit Enhancement
206	Next Generation Accountable Care Organization (ACO) Model 2019 Benefit Enhancement
One Time Notification (CMS-Pub. 100-20)	
2098	Implementation of Automating First Claim Review in Serial Claims for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
2099	Client Letter Code Removal and Decommission in the ViPS Medicare System (VMS)
2100	Analysis for First Coast Service Options (FCSO) and Novitas for the Security Assertion Markup Language 2.0 (SAML 2.0) Migration
2101	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete On-Request Jobs - Phase 4
2102	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete On-Request Jobs - Phase 3
2103	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2104	Analysis of the Structured Data Elements for Sending Additional Documentation Request (ADR) Decision Letters and Prior Authorization/Pre-Claim Review (PA/PCR) Decision Letters Electronically via the Electronic Submission of Medical Documentation (esMD) System
2105	User CR: MCS - Analysis to Expand Narrative File Message Number Range
2106	Procedures for Shared Systems to Handle Foreign (non US) Addresses
2107	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2108	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects within the Fiscal Intermediary Shared System - (Removing /Archiving demonstration codes 44 and 47)
2109	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2110	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2111	Modifications Within Common Working File (CWF) to Adjustment Claims Exceeding Annual Therapy Threshold
2112	User CR: FISS to Add Additional Search Features to Provider Direct Data Entry (DDE) Screen
2113	Combined Common Edits/Enhancements Module (CCEM) Updates for

	JAVA (version 6) to JAVA (version 7)
2114	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2115	Correct the CWF Handling of Beneficiaries with 14+ MSP Occurrences for HETS
2116	Modifications to the National Coordination of Benefits Agreement (COBA) Medicare Crossover Process
2117	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2118	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2119	Process Improvement for Recovery Audit Contractor (RAC) Mass Adjustment Input File – Underpayment Adjustment Enhancement
2120	New CWF Edit for Part A Outpatient Medicare Advantage (MA), Health Maintenance Organization (HMO)
2121	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2122	International Code of Diseases, Tenth Revision (ICD-10) and Other Coding
2123	Not Issued--Revisions to National Coverage Determinations (NCDs)
2124	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2125	Medicare Diabetes Prevention Program (MDPP) Service Period Change from 3 Years to 2 Years
2126	User CR: FISS to Add Location/Statuses to the 6H File Fix
2127	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2128	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2129	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2130	Enhancement for Undeliverable Pay Medicare Summary Notices (MSNs) for Multi-Carrier System (MCS) Users
2131	Ensuring Home Health Standardized Amounts Are Reflected in the National Claims History
2132	User CR: MCS - Enhance H9 Screen to Hold Information After Claim Finalizes
2133	Clarification of Policies Related to Reasonable Cost Payment for Nursing and Allied Health Education Programs
2134	Shared System Enhancement 2015: Resolve Operating Report (ORPT) Issues – Development and Implementation
2135	Medicare Appeals System (MAS) Part B and Durable Medical Equipment (DME) Data Collection Web Services Pilot
2136	Standardization of Case File Transmittal and Provider Information Processes, Bankruptcy, Payment Hold, and Cancellation Reporting Between the Medicare Administrative Contractors (MAC) and the Recovery Audit Contractor (RAC)
2137	National Correct Coding Initiative (NCCI) Add-on Codes for Non-Outpatient Prospective Payment System (OPPS) Institutional Providers Implementation
2138	International Classification of Diseases, Tenth Revision (ICD-10) and Other

	Coding Revisions to National Coverage Determinations (NCDs)
2139	Monthly Status Report (MSR) Excel Data Template Updates and Implementation of Medicare Administrative Contractor (MAC)/Centers for Medicare & Medicaid Services (CMS) Data Exchange (MDX) Portal System - This CR Rescinds and Fully Replaces CR 10399.
2140	Redesign of Flu Vaccines in Fiscal Intermediary Shared System (FISS)
2141	Implementing the Insertion of a Sheet of Paper Promoting the Electronic Medicare Summary Notices (eMSNs) into Mailed Medicare Summary Notices (MSNs)
2142	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
2143	Implementation of the Award for the Jurisdiction F (J-F) Part A and Part B Medicare Administrative Contractor (JF A/B MAC)
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
77	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
78	Payments to Home Health Agencies That Do Not Submit Required Quality Data - This CR Rescinds and Fully Replaces CR 9651
79	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (July through September 2018)

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. 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: <http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-3Q18QPU.pdf>

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

Addendum III: CMS Rulings (July through September 2018)

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 2018)

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 that have occurred in the 3-month period. There were no 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).

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2018)
(Inclusion of this addenda is under discussion internally.)

**Addendum VI: Approval Numbers for Collections of Information
(July through September 2018)**

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

**Addendum VII: Medicare-Approved Carotid Stent Facilities,
(July through September 2018)**

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.			
Maine General Medical Center 35 Medical Center Parkway Augusta, ME 04330	1669423380	07/01/2018	ME
West Florida Regional Hospital 8383 North Davis Highway Pensacola, FL 32514	1639116726	07/20/2018	FL
The following facilities have editorial changes (in bold).			
Methodist Hospital 1701 N. Senate Boulevard Indianapolis, IN 46202-1239	150056	05/23/2005	IN
Florida Medical Center - A Campus	FROM:	02/06/2006	FL

Facility	Provider Number	Effective Date	State
of North Shore 5000 West Oakland Park Boulevard Ft. Lauderdale, FL 33313	10002900 TO: 002900		

**Addendum VIII:
American College of Cardiology's National Cardiovascular Data
Registry Sites (July through September 2018)**

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 2018)**

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 2018)**

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

available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

**Addendum XI: National Oncologic PET Registry (NOPR)
(July through September 2018)**

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

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies.

Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2018)

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

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is

available at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, JD, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
The following facilities are new listings for this quarter.				
West Virginia University Hospitals 1 Medical Center Drive Morgantown, WV 26506 Other information: Joint Commission ID #6444	510001	07/26/2018		WV
The following facilities have editorial changes (in bold).				
FROM: Saint Thomas Hospital/ Saint Thomas Health Services TO: Saint Thomas West Hospital 4220 Harding Rd. Nashville, TN Other information: Joint Commission ID #7891 Previous Re-certification Dates: 2012-06-22; 2014-05-20; 2016-07-13	440082	08/05/2010	06/23/2018	TN
Robert Wood Johnson University Hospital 1 Robert Wood Johnson Place New Brunswick, NJ 08903 Other information: Joint Commission ID #5969 Previous Re-certification Dates: 2012-07-20; 2014-06-17; 2016-07-19	310038	07/23/2010	06/27/2018	NJ

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
<p>Carolinas Medical Center 1000 Blythe Boulevard Charlotte, NC 28232</p> <p>Other Information: Joint Commission 6480</p> <p>Previous Re-certification Dates: 2012-05-11; 2014-04-22; 2016-04-12</p>	340113	05/12/2010	04/25/2018	NC
<p>FROM: Saint Luke's Hospital TO: Saint Luke's Hospital of Kansas City 4401 Wornall Road Kansas City, MO 64111</p> <p>Other information: Joint Commission ID #8351</p> <p>Previous Re-certification Dates: 2012-06-06; 2014-05-06; 2016-06-21</p>	440039	04/21/2012	05/09/2018	MO
<p>FROM: Vanderbilt University Hospital and the Vanderbilt Clinic TO: Vanderbilt University Medical Center 1211 Medical Center Drive Nashville, TN 37232</p> <p>Other information: Joint Commission ID #7892</p> <p>Previous Re-certification Dates: 2014-03-11; 2016-04-05</p>	440039	04/21/2012	05/09/2018	TN

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
<p>University of Colorado Hospital Authority 12401 E. 17th Ave. Aurora, CO 80045</p> <p>Other information: Joint Commission ID #9384</p> <p>Previous Re-certification Dates: 2008-07-23; 2010-08-17; 2012-08-10; 2014-07-22; 2016-07-26</p>	060024	11/06/2003	07/18/2018	CO
<p>FROM: Washington Hospital Center TO: MedStar Washington Hospital Center 110 Irving St., NW Washington, DC 20010</p> <p>Other information: Joint Commission ID #6308</p> <p>Previous Re-certification Dates: 2010-04-06; 2012-03-23; 2014-03-04; 2016-05-03</p>	090011	04/23/2008	05/23/2018	DC
<p>Strong Memorial Hospital 601 Elmwood Avenue Rochester, NY 14642</p> <p>Other information: Joint Commission ID #5856</p> <p>Previous Re-certification Dates: 2008-06-17; 2010-07-02; 2012-06-06; 2014-05-13; 2016-07-26</p>	330285	10/20/2003	07/25/2018	NY
<p>Abington Memorial Hospital 1200 Old York Road Abington, PA 19001</p> <p>Other information: Joint Commission ID #6013</p> <p>Previous Re-certification Dates: 2014-06-03; 2016-06-28</p>	390231	07/10/2012	05/23/2018	PA
Penn State Milton S. Hershey	390256	10/29/2003	05/23/2018	PA

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
Medical Center 500 University Drive Hershey, PA 17033 Other information: Joint Commission ID #6075 Previous Re-certification Dates: 2008-04-01; 2010-03-24; 2012-03-16; 2014-04-08; 2016-06-07				
Mission Hospital 509 Biltmore Avenue Asheville, NC 28801 Other information: Joint Commission ID #6468	340002	06/09/2016	06/27/2018	NC
FROM: University of Michigan Hospitals and Health Centers, The TO: University of Michigan Health System 1500 E Medical Center Drive Ann Arbor, MI 48109 Other information: Joint Commission ID #7457 Previous Re-certification Dates: 2008-03-27; 2010-03-18; 2012-03-07; 2014-02-04; 2016-03-15	230046	10/27/2003	04/25/2018	MI
FROM: University of Virginia Health System TO: University of Virginia Medical Center 1215 Lee Street Charlottesville, VA 22908 Other information: Joint Commission ID #6329 Previous Re-certification Dates: 2012-03-21; 2014-05-06; 2016-06-07	490009	02/12/2010	06/06/2018	VA

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
FROM: Columbia Hospital at Medical City Dallas TO: Medical City Dallas 7777 Forest Lane Dallas, TX 75230 Other information: Joint Commission ID #9008 Previous Re-certification Dates: 2008-10-02; 2010-08-10; 2012-07-17; 2014-06-27; 2016-07-12	450647	12/03/2003	06/06/2018	TX
FROM: Vanderbilt University Hospital and the Vanderbilt Clinic TO: Vanderbilt University Medical Center 1211 Medical Center Drive Nashville, TN 37232 Other information: Joint Commission ID #7892 Previous Decertification Date: 2007-08-13 Previous Re-certification Dates: 2012-04-21; 2014-03-11; 2016-04-05	440039	10/28/2003	05/09/2018	TN
FROM: Saint Joseph's Hospital of Atlanta TO: Emory Saint Joseph's Hospital 5665 Peachtree Dunwoody Rd. Atlanta, GA 30342 Other information: Joint Commission ID #6652 Previous Re-certification Dates: 2012-07-11; 2014-06-03; 2016-07-12	110082	07/14/2010	06/06/2018	GA
The following facilities are decertifications for this quarter.				
The University of Toledo Medical Center 3000 Arlington Avenue	360048	04/20/2012		OH

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
Toledo, OH 43614 Other information: Joint Commission De-certified: 2018-05-18				
Geisinger Wyoming Valley Medical Center 1000 East Mountain Drive Wilkes Barre, PA 18711 Other information: Joint Commission De-certified: 2018-05-28	390270	02/26/2014	04/13/2016	PA
Delray Medical Center, Inc. 5352 Linton Boulevard Delray Beach, FL 33484 Other information: Joint Commission De-certified: 2018-06-01	100258	08/11/2015	08/17/2017	FL

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)
(July through September 2018)**

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 editorial updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at [FR Doc. 2018-23924 Filed: 11/1/2018 8:45 am; Publication Date: 11/2/2018]

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

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities
(July through September 2018)**

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's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2018)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).