

**DATES:** Information must be received by June 30, 2020.

**ADDRESSES:** Written comments should be submitted by email to: *Opioids\_OlderAdults@abtassoc.com*.

**FOR FURTHER INFORMATION CONTACT:** Parivash Nourjah, *Parivash.nourjah@ahrq.gov*, or 301-427-1106.

**SUPPLEMENTARY INFORMATION:**

The United States is in the midst of an unprecedented opioid epidemic that is affecting people from all walks of life. Regulators and policy makers have initiated many activities to curb the epidemic, but relatively little attention has been paid to the growing toll of opioid use, opioid misuse and opioid use disorder (OUD) among older adults.

The opioid crisis in older adults is strongly related to challenges in prescription opioid management in this population. Older adults have a high prevalence of chronic pain and are especially vulnerable to suffering adverse events from opioid use, making safe prescribing more challenging even when opioids are an appropriate therapeutic choice. Identifying adverse effects due to opioid use, misuse or abuse is complicated further by factors such as co-occurring medical disorders that can mimic the effects of opioid use. There is also a risk of attributing clinical findings in older adults (e.g. personality changes, falls/balance problems, difficulty sleeping, and heart problems) to other conditions that are also common with age. If adverse events due to opioid prescriptions are identified, finding appropriate alternatives for pain management can be challenging if other pharmacologic options (such as NSAIDs) are contraindicated or mobility issues limit access to other therapeutic options.

Diagnosis of substance use disorders is also more complicated in this population. Clinicians may not associate drug misuse or addiction with older adults or they may be inadequately trained in identification and treatment of opioid misuse and OUD among older adults, and hence may not monitor for the signs of opioid use disorder in this population.

Successfully optimizing the prescribing and use of opioids in older adults will require addressing the issue

at many points along the care continuum where older adults may need additional attention or a different approach. AHRQ wants to identify specific tools, strategies and approaches to opioid management in older adults throughout the breadth of the care delivery continuum, from avoiding opioid initiation to screening for opioid misuse and opioid use disorder, as well as approaches to opioid tapering in older adults.

AHRQ is interested in all innovative approaches that address the opioid management concerns in older adults listed above, but respondents are welcome to address as many or as few as they choose and to address additional areas of interest not listed.

Strategies and approaches could come from a variety of health care settings including, but not limited to, primary care and other ambulatory care clinics, emergency departments, home health care organizations, skilled nursing care settings, and inpatient care. Other sources of these strategies might include health care payers, accountable care organizations, and organizations that provide external quality improvement support. Some of the examples of the types of innovations we are looking for might be specific tools or workflows that support providers to assess the risk/benefit balance of opioids within a multidisciplinary approach in pain management; to optimize and monitor the opioid prescribing when appropriate, including tapering strategies; to screen and treat for opioid misuse or opioid use disorder; or to involve family or other caregivers of an older adult in conversations about opioid safety. Descriptions of strategies or approaches should include the setting where it is deployed and the type of patient population served.

This RFI is for planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the Government to provide support for any ideas in response to it. AHRQ will use the information submitted in response to this RFI at its discretion, and will not provide comments to any respondent's submission. However, responses to the RFI may be reflected in future solicitation(s) or policies. Respondents

are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. No proprietary, classified, confidential or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s). The contents of all submissions will be made available to the public upon request. Submitted materials must be publicly available or able to be made public.

Dated: April 21, 2020.

**Virginia L. Mackay-Smith,**

*Associate Director, Office of the Director, AHRQ.*

[FR Doc. 2020-08727 Filed 4-23-20; 8:45 am]

**BILLING CODE 4160-90-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-9124-N]

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 2020

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

**ACTION:** Notice.

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from January through March 2020, relating to the Medicare and Medicaid programs and other programs administered by CMS.

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

Addenda	Contact	Phone No.
I. CMS Manual Instructions .....	Ismael Torres .....	(410) 786-1864
II. Regulation Documents Published in the <b>Federal Register</b> .....	Terri Plumb .....	(410) 786-4481
III. CMS Rulings .....	Tiffany Lafferty .....	(410) 786-7548
IV. Medicare National Coverage Determinations .....	Wanda Belle, MPA .....	(410) 786-7491
V. FDA-Approved Category B IDEs .....	John Manlove .....	(410) 786-6877
VI. Collections of Information .....	William Parham .....	(410) 786-4669
VII. Medicare-Approved Carotid Stent Facilities .....	Sarah Fulton, MHS .....	(410) 786-2749

Addenda	Contact	Phone No.
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 Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 15, 2020.

**Evell J. Barco Holland,**  
Federal Register Liaison, Department of  
Health and Human Services.

**BILLING CODE 4120-01-P**

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

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: April 29, 2019 (84 FR 18040), August 9, 2019 (84 FR 39323), November 6, 2019 (84 FR 59815) and February 13, 2020 (85 FR 8282). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

**Addendum I: Medicare and Medicaid Manual Instructions (January through March 2020)**

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

**How to Obtain Manuals**

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

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

**How to Review Transmittals or Program Memoranda**

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have

arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Update to Medicare Benefit Policy Manual and Medicare Claims Processing Manual Adding New Chapters for Opioid Treatment Programs (Manual Updates Only), use (CMS-Pub. 100-02) Transmittal No. 268.

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
Medicare General Information (CMS-Pub. 100-01)	
130	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
These transmittal numbers reflect the change effective on March 20, 2020.	
10001	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

266	January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS) Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on January 1, 2010 through December 31, 2019 Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2020 - Changes to Supervision Requirements Non-Surgical Extended Duration Therapeutic Services
267	January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS) Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on January 1, 2010 through December 31, 2019 Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2020 - Changes to Supervision Requirements Non-Surgical Extended Duration Therapeutic Services
268	Update to Medicare Benefit Policy Manual and Medicare Claims Processing Manual Adding New Chapters for Opioid Treatment Programs (Manual Updates Only)
<b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b>	
None	
<b>Medicare Claims Processing (CMS-Pub. 100-04)</b>	
4487	CY 2020 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
4488	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
4489	Home Health (HH) Patient-Driven Groupings Model (PDGM) - Split Implementation Creation of HH PPS and Subsequent Refinements The HH PPS Unit of Payment Number, Duration, and Claims Submission of HH PPS Episodes More Than One Agency Furnished Home Health Services Effect of Election of Medicare Advantage (MA) Organization and Eligibility Changes Split Percentage Payment Basis of Medicare Prospective Payment Systems and Case-Mix Coding of HH PPS Case-Mix Groups on HH PPS Claims: HHRGs and HIPPS Code Composition of HIPPS Codes for HH Grouper Links Assessment and Payment Health Insurance Beneficiary Eligibility Inquiry for Home Health Agencies Submission of Request for Anticipated Payment (RAP) Claim Submission and Processing Payment, Claim Adjustments and Cancellations Request for Anticipated Payment (RAP) Transfer Situation - Payment Effects Discharge and Readmission Situation Under HH PPS - Payment Effects Adjustments of Payment - Partial Episode Payment (PEP) Payment When Death Occurs During an HH PPS Episode/Period Adjustments of Payment - Low Utilization Payment Adjustments (LUPAs) Adjustments of Payment - Special Submission Case: "No-RAP" LUPAs

10010	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>	
265	Manual Updates Related to Calendar Year (CY) 2020 Home Health Payment Policy Changes, Maintenance Therapy, and Remote Patient Monitoring Home Health Prospective Payment System (HH PPS) National 30-Day Period Payment Rate Adjustments to the 30-Day Period Payment Rates Continuous 60-Day Recertifications Split Percentage Payment Approach to the 30-Day Period Unit of Payment Physician Signature Requirements for the Split Percentage Payments Low Utilization Payment Adjustment (LUPA) Partial Payment Adjustment Outlier Payments Discharge Issues Consolidated Billing Change of Ownership Relationship to Periods Under HH PPS Patient Confined to the Home Patient's Place of Residence Specificity of Orders Timeliness of Signature Use of Oral (Verbal) Orders Termination of the Plan of Care-Qualifying Services Sequence of Qualifying Services and Other Medicare Covered Home Health Services Physician Certification Physician Recertification General Principles Governing Reasonable and Necessary Skilled Nursing Care Observation and Assessment of the Patient's Condition When Only the Specialized Skills of a Medical Professional Can Determine Patient's Status Management and Evaluation of a Patient Care Plan Venipuncture General Principles Governing Reasonable and Necessary Physical Therapy, Speech-Language Pathology Services, and Occupational Therapy Medical Supplies The Law, Routine and Nonroutine Medical Supplies, and the Patient's Plan of Care Negative Pressure Wound Therapy Using a Disposable Device Counting Visits Under the Hospital and Medical Plans Respiratory Care Services Remote Patient Monitoring Use of Telehealth in the Delivery of Home Health Services

	Adjustments of Payment - Confirming OASIS Assessment Items Adjustments of Episode Payment - Therapy Thresholds Adjustments of Episode Payment - Early or Later Episodes Adjustments of Payment - Validation of HIPPS Codes Adjustments of Payment - Outlier Payments Multiple Adjustments to Payments Request for Anticipated Payment (RAP) HH PPS Claims Input/Output Record Layout		Table of Preventive and Screening Services Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes CWF Edits on A/B MAC (A) Claims CWF Edits on A/B MAC (B) Claims CWF Crossover Edits for A/B MAC (B) Claims Confidentiality of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions 2020 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS) Payment Adjustment for Certain Cancer Hospitals Beginning CY 2019 Payment Adjustment for Certain Cancer Hospitals Beginning CY 2020 Use of HCPCS Modifier - CG Devices Eligible for Transitional Pass-Through Payments Bypass Edit Modifier "CG" for Claims on Which Specified Procedures are to be Reported With Device Codes Inpatient-only Services Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions Update to Medicare Benefit Policy Manual and Medicare Claims Processing Manual Adding New Chapters for Opioid Treatment Programs (Manual Updates Only) Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2020 Update
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	Adjustments of Payment - Confirming OASIS Assessment Items Adjustments of Episode Payment - Therapy Thresholds Adjustments of Episode Payment - Early or Later Episodes Adjustments of Payment - Validation of HIPPS Codes Adjustments of Payment - Outlier Payments Multiple Adjustments to Payments Request for Anticipated Payment (RAP) HH PPS Claims Input/Output Record Layout		Adjustments of Payment - Confirming OASIS Assessment Items Adjustments of Episode Payment - Therapy Thresholds Adjustments of Episode Payment - Early or Later Episodes Adjustments of Payment - Validation of HIPPS Codes Adjustments of Payment - Outlier Payments Multiple Adjustments to Payments Request for Anticipated Payment (RAP) HH PPS Claims Input/Output Record Layout
4490	Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for Vaping Related Disorder		Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for Vaping Related Disorder
4491	Updates to CR 11152 Implementation of the Skilled Nursing Facility (SNF) Patient Payment Model (PDPMP)		Updates to CR 11152 Implementation of the Skilled Nursing Facility (SNF) Patient Payment Model (PDPMP)
4492	Billing SNF PPS Services Billing in Benefits Exhaust and No-Payment Situations Medicare Billing Requirements for Beneficiaries Enrolled in MA Plans Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions		Billing SNF PPS Services Billing in Benefits Exhaust and No-Payment Situations Medicare Billing Requirements for Beneficiaries Enrolled in MA Plans Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4493	January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)		January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
4494	January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)		January 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
4495	Clinical Laboratory Fee Schedule - Medicare Travel Allowance Fees for Collection of Specimens		Clinical Laboratory Fee Schedule - Medicare Travel Allowance Fees for Collection of Specimens
4496	2020 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List		2020 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List
4497	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 26.1, Effective April 1, 2020 Calendar Year (CY) 2020 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment		Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 26.1, Effective April 1, 2020 Calendar Year (CY) 2020 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
4499	Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for Vaping Related Disorder Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions		Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for Vaping Related Disorder Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4500	Confidentiality of Instructions		Confidentiality of Instructions
4501	2020 Annual Update to the Therapy Code List		2020 Annual Update to the Therapy Code List
4502	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions		Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4503	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions		Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4504	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions		Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4505	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions		Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4506	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions		Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4507	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions		Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4508	Quarterly Influenza Virus Vaccine Code Update - July 2020		Quarterly Influenza Virus Vaccine Code Update - July 2020

4546	System NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR) Transcatheter Aortic Valve Replacement (TAVR) Coding Requirements for TAVR Furnished on or After May 1, 2012, through December 31, 2012 Coding Requirements for TAVR Services Furnished on or After January 1, 2013 Claims Processing Requirements for TAVR Services on Professional Claim Instructions for Downloading the Medicare ZIP Code Files for July 2020
4547	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4548	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4549	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4550	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4551	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
<b>These transmittal numbers reflect the change effective on March 20, 2020.</b>	
10000	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10002	Update to the Internet Only Manual (IOM) Publication (Pub.) 100-04, Chapter 3, Section 90.4.2
10003	April 2020 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
10004	April Quarterly Update for 2020 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
10005	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10006	Quarterly Update for the Temporary Gap Period of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - July 2020
10007	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10008	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10009	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
10013	April 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
10015	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 26.1, Effective April 1, 2020
10026	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10027	April 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.
10028	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10030	Issued to a specific audience, not posted to Internet/Intranet due to

4526	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4527	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4528	January 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.0
4529	Implementation of the Long Term Care Hospital (LTCH) Discharge Payment Percentage (DPP) Payment Adjustment Payment Provisions Under LTCH PPS Payment Rate Short-Slay Outliers Payment Policy for Co-located Providers High Cost Outlier Cases Discharge Payment Percentage (DPP) Payment Adjustment Procedure for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments Provider Specific File
4530	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4531	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4532	Quarterly Update for the Temporary Gap Period of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) - April 2020
4533	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
4534	July 2020 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
4535	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
4536	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
4537	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4538	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4539	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4540	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2020 Update
4541	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
4542	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
4543	April 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.1
4544	April 2020 Update of the Hospital Outpatient Prospective Payment System (OPPS)
4545	April 2020 Update of the Ambulatory Surgical Center (ASC) Payment

933	Update to Chapter 3, Section 3.2.3.1 Additional Documentation Requests (ADR) of Publication (Pub) 100-08
934	Updates to Chapter 4 and Exhibit 8 in Publication (Pub.) 100-08 Investigations Conducting Investigations Disposition of Cases Referred to Law Enforcement UCM Outages UPIC Hospice Cap Liability Process—Coordination with the MAC Immediate Advisements to the OIG/OI Identity Theft Investigations and Victimized Provider Process Victimized Provider Process Letter Templates Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
935	Provider Enrollment Appeals Procedure Model Approval Letter Model Denial Letter Model Revocation Letter for Part B Suppliers and Certified Providers and Suppliers Model Revocation Letter for National Supplier Clearinghouse (NSC) Reserved for Future Use CAP Withdrawn Acknowledgement Template to RCAP Receipt Acknowledgement Template to Provider/Supplier Representative RCAP Decision Email Template to Provider/Supplier Representative RCAP Not Actionable (Moot) Model Letter Untimely CAP Dismissal Model Letter Improperly Signed CAP Dismissal Model Letter No CAP Rights Dismissal Model Letter Not Eligible to Submit CAP Dismissal Model Letter CAP Signature Development Model Letter Favorable CAP Model Letter in Response to an Enrollment Denial Unfavorable CAP Model Letter for Revocation Determination Unfavorable CAP Model Letter for Revocation Determination CAP Further Information Required for Development Model Letter Reserved for Future Use Reconsideration Request Withdrawn Acknowledgement Template Reconsideration Request Receipt Acknowledgement Template to Provider/Supplier Representative Reconsideration Request Decision Email Template to Provider/Supplier Representative Reconsideration Request Not Actionable (Moot) Model Letter Untimely Reconsideration Request Dismissal Model Letter Improperly Signed Reconsideration Request Dismissal Model Letter Not Eligible to Submit Reconsideration Request Dismissal Model Letter Reconsideration Request Signature Development Model Letter Favorable Reconsideration Request Model Letter in Response to an Enrollment Denial Favorable Reconsideration Request Model Letter in Response to a Reactivation Effective Date Determination

	Confidentiality of Instructions
129	<b>Medicare Secondary Payer (CMS-Pub. 100-05)</b> Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
334	<b>Medicare Financial Management (CMS-Pub. 100-06)</b> Notice of New Interest Rate for Medicare Overpayments and Underpayments -2nd Qtr Notification for FY 2020
335	Updates to Medicare Financial Management Manual Chapter 3, Section 140.1 Bankruptcy Forms
336	Pub. 100-06, Chapter 4, Section 110 (Confirmed Identity Theft) Revision Confirmed Identity Theft
196	<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b> Revisions to State Operations Manual (SOM) Appendix G, Guidance for Surveyors: Rural Health Clinics
197	Revisions to the State Operating Manual (SOM) Chapter 2: Community Mental Health Center (CMHC) Citations and Definitions Citations and Definitions Special Requirements Partial Hospitalization Services Provided by CMHCs or by Others Under Arrangements with the CMHC Request to Participate Processing CMHC Initial Certification Request, SA Role Processing CMHC Initial Certification Request, RO Role Facility Allages it is Provider-Based Voluntary Termination
198	Revisions to the State Operations Manual (SOM) Chapter 2 and Chapter 3
199	Revisions to State Operations Manual (SOM) Chapter 6 - Special Procedures for Laboratories and Chapter 9 Exhibits
200	Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA - Psychiatric Hospitals, Appendix B - Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H - End Stage Renal Disease Facilities (ESRD), Appendix K - Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M - Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X - Organ Transplant Program and Appendix Z - Emergency Preparedness
930	<b>Medicare Program Integrity (CMS-Pub. 100-08)</b> Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
931	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
932	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

	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>	
	None	
	<b>Medicare Prescription Drug Benefit (CMS-Pub. 100-18)</b>	
	None	
	<b>Demonstrations (CMS-Pub. 100-19)</b>	
235	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
236	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
	<b>One Time Notification (CMS-Pub. 100-20)</b>	
2413	New State Codes for California, Kentucky and West Virginia	
2414	SUBJECT: VIPS Medicare System (VMS) Online and Print Reporting of Automated Claims Examination System (ACES) Statistics	
2415	Updates to Bills Pending Report for the Fiscal Intermediary Shared System (FISS)	
2416	User CR: VIPS Medicare System (VMS) - Increase Edit Code Maximum	
2417	Implementation to Send Post-Pay Electronic Medical Documentation Requests (eMDR) to Participating Providers via the Electronic Submission of Medical Documentation (esMD) System	
2418	Implementation to Accept Document Codes and Include Appropriate Document Code(s) in the Pre-Pay Electronic Medical Documentation Requests (eMDR) to Participating Providers, via the Electronic Submission of Medical Documentation (esMD) System	
2419	Implementation to Send Pre-Pay Electronic Medical Documentation Requests (eMDR) to Participating Providers via the Electronic Submission of Medical Documentation (esMD) System	
2420	Implementation to Adopt the Document Codes into the Post-Pay Electronic Medical Documentation Requests (eMDR) to Participating Providers via the Electronic Submission of Medical Documentation (esMD) System	
2421	User Change Request (CR) - Adjustment Reason Code to Identify Office of the Inspector General (OIG) Initiated Overpayments and Healthcare Integrated General Ledger Accounting System (HIGLAS) Demand Letter Verbiage	
2422	Add Dates of Service (DOS) for Pneumococcal Pneumonia Vaccination (PPV) Health Care Procedure Code System (HCPCS) Codes (90670, 90732), and remove Next eligible dates for PPV HCPCS	
2423	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions	
2424	Analysis of the Combined Common Edits Module (CCEM) for Compatibility with JAVA Software Version 1.8 (also known as JAVA 8)	
2425	Implementation of Usage of the K3 Segment for Reporting Line Level Ordering Provider on Institutional Claims for Advanced Diagnostic Imaging	

	Favorable Reconsideration Request Model Letter in Response to an Effective Date of Participation Determination (Non-Revalidation)	
	Favorable Reconsideration Request Model Letter for Revocation Determination	
	Unfavorable Reconsideration Request Model Letter in Response to an Enrollment Denial	
	Unfavorable Reconsideration Request Model Letter in Response to a Reactivation Effective Date Determination	
	Unfavorable Reconsideration Request Model Letter in Response to an Effective Date of Participation Determination (Non-Revalidation)	
	Unfavorable Reconsideration Request Model Letter for Revocation Determination	
	Reconsideration Further Information Required for Development Model Letter	
	Review Procedures for Determinations that Affect Participation in the Medicare Program	
	Corrective Action Plans (CAPs)	
	Further Appeal Rights for Reconsidered Determinations	
	External Reporting Requirements for CAPs and Reconsideration Requests	
	External Reporting Requirements	
937	Updates to the Prior Authorization (PA) Guidance Within Publication (Pub.) 100-08	
	Prior Authorization Program for Certain DMEPOS	
	Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services	
938	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
939	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
940	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
941	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
942	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
943	Updates to Chapter 4 and Exhibit 8 in Publication (Pub.) 100-08	
	Investigations	
	Conducting Investigations	
	Disposition of Cases Referred to Law Enforcement	
	LCM Outages	
	Hospice Cap Liability Process - Coordination with the MAC	
	Immediate Advisements to the OIG/OI	
	Identity Theft Investigations and Victimized Provider Process	
944	Section 4.26.2 in Chapter 4 of Publication (Pub.) 100-08	
945	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
	<b>Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)</b>	
44	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions	
	<b>Medicare Quality Improvement Organization (CMS-Pub. 100-10)</b>	



10029	Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for Vaping Related Disorder and 2019 Novel Coronavirus (COVID-19)
	<b>Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)</b>
	None
	<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)</b>
	None

## **Addendum II: Regulation Documents Published in the Federal Register (January through March 2020)**

### **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/regs1q20qpu.pdf>

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

## **Addendum III: CMS Rulings (January through March 2020)**

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).

2426	Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for Vaping Related Disorder
2427	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs) – April 2020 Update
2428	Multi-Carrier System (MCS) Financial Changes for Combining Pay Alone Payments in the Healthcare General Ledger Accounting System (HIGLAS) Payment Sets
2429	Updates to Ensure the Original 1-Day and 3-Day Payment Window Edits are Consistent with Current Policy
2430	Update to the Fiscal Intermediary Shared System (FISS) Integrated Outpatient Code Editor (IOCE) Claim Return Buffer
2431	Second Update to CR 11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPDM)
2432	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
2433	Update to the Home Health Grouper for New Diagnosis Code for Vaping Related Disorder
2434	Implementation for First Coast Service Options (FCSO) and Novitas for the CMS Enterprise Identity Management OKTA/Savvynt Migration
2435	User CR: ViPS Medicare System (VMS) Analysis and Redesign of SuperOp Claim Counter Functionality
2436	User CR: ViPS Medicare System (VMS) Analysis and Design to Create Auto-Inactivation Utility for SuperOp
2437	User CR: ViPS Medicare System (VMS) Report Daily Edit Receipts
2438	Multi-Carrier System (MCS) Financial Changes for Combining Pay Alone Payments in the Healthcare General Ledger Accounting System (HIGLAS) Payment Sets
2439	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs) – July 2020 Update
2440	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
2441	Provider Education for Required Prior Authorization (PA) of Hospital Outpatient Department (OPD) Services
2443	Schedule and Policies for Termination of the Rural Community Hospital Demonstration
2444	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2018 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long-Term Care Hospitals (LTCs)
<b>These transmittal numbers reflect the change effective on March 20, 2020.</b>	
10018	Shared System Enhancement 2018: Rewrite Fiscal Intermediary Shared System (FISS) module FSSB6001, Common Working File (CWF) Unsolicited Response Function
10024	Second Update to CR 11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPDM)
10025	Update to the Home Health Grouper for New Diagnosis Codes for Vaping Related Disorder and COVID-19.

[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, (January through March 2020)**

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.			
St Francis Hospital, Inc. d/b/a St Francis Downtown 1 St Francis Drive Greenville, SC 29601	420023	01/20/2020	SC
Kaiser Foundation Hospital Oakland/Richmond 275 West MacArthur Boulevard Oakland, CA 94611	050075	02/03/2020	CA
HCA Houston Healthcare Conroe 504 Medical Center Boulevard Conroe, TX 77304	1962455816	02/10/2020	TX
Javon Bea Hospital "Riverside Hospital" 8201 E. Riverside Boulevard Rockford, IL 61114	140239	02/10/2020	IL
Knox Community Hospital 1330 Coshocton Avenue Mount Vernon, OH 43050	360040	02/17/2020	OH
Medical City Weatherford	450203	03/31/2020	TX

**Addendum IV: Medicare National Coverage Determinations (January through March 2020)**

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

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

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Transcatheter Aortic Valve Replacement (TAVR)	NCD (20.32)	217	03/13/2020	06/21/2019

**Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January through March 2020)**  
(Inclusion of this addenda is under discussion internally.)

**Addendum VI: Approval Numbers for Collections of Information (January through March 2020)**

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

Facility	Provider Number	Effective Date	State
TO: UPMC Hamot 201 State Street Erie, PA 16550-0002 Other information: NPI #1487647590			

### Addendum VIII:

#### American College of Cardiology's National Cardiovascular Data Registry Sites (January through March 2020)

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

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

#### Addendum IX: Active CMS Coverage-Related Guidance Documents (January through March 2020)

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).

Facility	Provider Number	Effective Date	State
713 E. Anderson Street Weatherford, TX 76086			
<b>The following facilities have editorial changes (in bold).</b>			
FROM: Frankford Hospital TO: Aria Health D/B/A Jefferson Health – Northeast 800 Knights Road Philadelphia, PA 19114	390115	10/11/2005	PA
FROM: Providence Everett Medical Center TO: Providence Regional Medical Center Everett 1321 Colby Avenue Everett, WA 98201	500014	12/19/2005	MI
FROM: Mount Diablo Medical Center TO: John Muir Medical Center, Concord Campus 2540 East Street Concord, CA 94524-4110	050496	05/10/2005	CA
Cape Cod Hospital 27 Park Street Hyannis, MA 02601 P.O. Box 640	220012	11/01/2005	MA
FROM: California Pacific Medical Center – Pacific Campus TO: California Pacific Medical Center – Van Ness Campus 1101 Van Ness Avenue San Francisco, CA 94109	050047	01/23/2006	CA
FROM: Rockford Memorial Hospital TO: Javon Bea Hospital 2400 N Rockton Avenue Rockford IL 61103	140239	06/14/2005	IL
FROM: Luther Hospital TO: Mayo Clinic Health System Eau Claire 1221 Whipple Street Eau Claire, WI 54703	520070	09/08/2005	WI
FROM: St. Elizabeth Hospital TO: Ascension NE Wisconsin, Inc 1506 South Oneida Street Appleton, WI 54915	520009	11/01/2005	WI
Cookeville Regional Medical Center FROM: 142 West Fifth Street TO: 1 Medical Center Boulevard Cookeville, TN 38501	440059	05/03/2007	TN
FROM: Hamot Medical Center	390063	05/05/2005	PA

**Addendum X:****List of Special One-Time Notices Regarding National Coverage Provisions (January through March 2020)**

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) (January through March 2020)**

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

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

**Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (January through March 2020)**

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

our standards in order to receive coverage for VADs implanted as destination therapy.

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

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

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
<b>The following facilities are new for this quarter.</b>				
Carilion Roanoke Memorial Hospital (CRMH) 1906 Bellevue Avenue Roanoke, VA 24014	490024	12/30/2019		VA
Other information: DNV certificate #: 176238-2019-VAD				
UCI Medical Center 101 The City Drive South Orange, CA 92868	050348	12/17/2019		CA
Other information: DNVGL #: 175702-2019-VAD Previous Re-certification Dates: n/a				
<b>The following facilities have editorial changes (in bold).</b>				
<b>FROM: Houston Methodist Hospital</b> <b>TO: The Methodist Hospital</b> d/b/a Houston Methodist Hospital 6565 Fannin Street Houston, TX 77030	450358	11/03/2003	11/06/2019	TX
Other information: DNV Certification #: 306213-2019-VAD				
Previous Re-Certification Dates: <b>DNV certified 12/6/16;</b>				

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Newark, DE 19713  Other information: <b>Joint Commission ID #: 6237</b> <b>Previous re-Certification dates: 07/25/2013;</b> <b>07/21/2015; 10/24/2017</b>				
North Carolina Baptist Hospital d/b/a Wake Forest Baptist Health Medical Center Boulevard Winston Salem, NC 27157  Other information: <b>Joint Commission ID #: 6571</b> <b>Previous recertification dates:</b> <b>06/28/2011; 08/13/2013;</b> <b>08/04/2015; 08/18/2017</b>	340047	06/28/2011	10/09/2019	NC
Einstein Medical Center Philadelphia 5501 Old York Road Philadelphia, PA 19141  Other information: <b>Joint Commission ID #: 6118</b> <b>Previous certification dates:</b> <b>08/24/2011; 08/20/2013;</b> <b>08/04/2015; 09/19/2017</b>	390142	08/24/2011	10/23/2019	PA
Hackensack University Medical Center 30 Prospect Avenue Hackensack, NJ 07601  Other information: <b>Joint Commission ID #: 5934</b> <b>Previous recertification dates: 10/20/2015; 09/19/2017</b>	310001	10/20/2015	10/05/2019	NJ

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
<b>JCAHO certified 10/29/08</b> Northwestern Memorial Hospital 251 E. Huron Street Chicago, IL 60611  Other information: <b>Joint Commission ID # 7267</b> <b>Previous Re-Certification Dates: 01/30/2009;</b> <b>06/17/2011; 05/31/2013;</b> <b>06/09/2015; 08/18/2017</b>	140281	01/30/2009	11/06/2019	IL
Riverside Methodist Hospital 3535 Olenlangy River Road Columbus, OH 43214-3998  Other information: <b>Joint Commission ID # Joint Commission ID #: 7030</b> <b>Previous Re-certification Dates: Initial 2015-08-11;</b> <b>2017-08-30</b>	360006	08/11/2015	10/23/2019	OH
Methodist Hospital 7700 Floyd Curl Drive San Antonio, TX 78229  Other information: <b>Joint Commission ID # 9219</b> <b>Previous Re-Certification Dates: 01/27/2009;</b> <b>07/12/2011; 07/09/2013;</b> <b>07/07/2015; 08/08/2017</b>	450388	01/27/2009	10/23/2019	TX
UT Southwestern William P. Clements Jr. University Hospital 6201 Harry Hines Boulevard Dallas, TX 75390-9262  Other information: <b>Joint Commission ID # 9013</b> <b>Previous Re-Certification Dates: 12/17/2008;</b> <b>06/07/2011; 06/04/2013;</b> <b>06/23/2015; 08/08/2017</b>	450044	12/10/2003	10/12/2019	TX
<b>FROM: Christiana Hospital</b> <b>TO: Christiana Care Health Services, Inc.</b> 4755 Ogletown-Stanton Road	080001	07/25/2013	12/21/2019	DE

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
<b>FROM: Inova Fairfax Medical Campus</b> <b>TO: Inova Fairfax Hospital</b> 3300 Gallows Road Falls Church, VA 22042  Other information: <b>Joint Commission ID #: 6351</b> <b>Previous recertification dates: 12/09/2008; 03/22/2011; 05/01/2013; 06/09/2015; 07/25/2017</b>	490063	12/09/2008	09/25/2019	VA
Emory University Hospital 1364 Clifton Rd NE Atlanta, GA 30322  Other information: <b>Joint Commission ID #: 6689</b> <b>Previous recertification: 08/18/2009; 09/09/2011; 08/29/2013; 08/11/2015; 09/26/2017</b>	110010	08/18/2009	11/20/2019	GA
Mayo Clinic Florida 4500 San Pablo Road Jacksonville, FL 32224  Other information: <b>Joint Commission ID #: 369946</b> <b>Previous recertifications: 03/17/2009; 10/19/2011; 09/24/2013; 09/15/2015; 10/03/2017</b>	100151	03/17/2009	11/06/2019	FL
<b>FROM: Sacred Heart Medical Center</b> <b>TO: Providence Sacred Heart Medical Center &amp; Children's Hospital</b> 101 West 8th Avenue Spokane, WA 99204  Other information: <b>Joint Commission ID #: 9638</b> <b>Previous recertifications: 03/10/2009; 08/17/2011; 08/06/2013; 07/14/2015; 09/12/2017</b>	500054	01/12/2004	11/06/2019	WA
<b>FROM: Inova Fairfax Medical Center Austin</b> <b>TO: Ascension Seton</b> 1201 West 38th Street Austin, TX 78705-1056  Other information: <b>Joint Commission ID #: 8939</b> <b>Recertification dates: 03/06/2009; 07/15/2011; 09/04/2013; 10/20/2015; 10/03/2017</b>				
<b>FROM: Strong Memorial Hospital; TO: University of Rochester/Strong Memorial Hospital</b> 601 Elmwood Ave Rochester, NY 14642-0002  Other information: <b>Joint Commission ID # 5856</b> <b>Recertification dates: 06/17/2008; 07/02/2010; 06/06/2012; 05/13/2014; 07/26/2016</b>	330285	10/29/2003	07/25/2018	NY
<b>New York-Presbyterian Hospital</b> 525 East 68th Street New York, NY 10065  Other information: <b>Joint Commission ID # 5838</b> <b>Recertification dates: 03/03/2009; 07/14/2011; 08/21/2013; 09/23/2015; 10/25/2017</b>	330101	03/03/2009	01/24/2020	NY
Pitt County Memorial Hospital, Inc. DBA Vidant Medical Center 2100 Stattonsburg Road Greenville, NC 27835-6028  Other information: <b>Joint Commission ID #: 6506</b> <b>Previous recertification: 9/26/17</b>	340040	09/26/2017	12/18/2019	NC
<b>FROM: Baylor University Medical Center at Dallas</b>	450021	08/21/2007	12/18/2019	TX

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Previous Re-certification Dates: 03/31/2009; 11/16/2011; 10/22/2013; 10/20/2015; 11/14/2017				
Keck Hospital of USC 1500 San Pablo Street Los Angeles, CA 90033  Other information: Joint Commission ID #: 5033 Previous Recertification dates: 03/13/2009; 08/16/2011; 09/10/2013; 10/06/2015; 10/20/2017	050696	03/13/2009	12/04/2019	CA
University of Chicago Medical Center 5841 South Maryland Avenue Chicago, IL 60637  Other information: Joint Commission ID # 7315 Previous Re-certification Dates: 02/24/2009; 08/17/2011; 09/04/2013; 09/15/2015; 10/24/2017	140088	02/24/2009	12/20/2019	IL
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	050262	02/06/2009	12/04/2019	CA
University of California San Diego Medical Center 200 West Arbor Drive San Diego, CA 92103-8949  Other information: Joint Commission ID # 10071 Previous Re-Certification Dates: 11/17/2011; 11/15/2013; 11/03/2015; 10/17/2017	050025	11/17/2017	12/18/2019	CA

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
TO: Baylor University Medical Center 3500 Gaston Avenue Dallas, TX 75246  Other information: Joint Commission ID #: 8993 Previous recertification: 08/21/2007; 08/27/2009; 10/07/2011; 11/20/2013; 11/10/2015; 10/31/2017				
Thomas Jefferson University Hospitals, Inc. 111 South 11th Street Philadelphia, PA 19107  Other information: Joint Commission ID #: 6132 Previous recertifications: 07/09/2009; 09/13/2011; 10/17/2013; 09/22/2015; 09/20/2017	390174	07/09/2009	11/06/2019	PA
University of Washington Medical Center 1959 Northeast Pacific Street, Box 356151 Seattle, WA 98195-6151  Other information: Joint Commission ID #: 9626 Recertification dates: 02/10/2009; 10/18/2011; 11/22/2013; 12/08/2015; 12/05/2017	500008	01/10/2009	11/20/2019	WA
WellStar Kennestone Hospital 677 Church Street Marietta, GA 30060  Other information: Joint Commission ID # 6711 Previous Re-certification Dates: 11-07-2017	110035	11/07/2017	11/23/2019	GA
Hartford Hospital 80 Seymour Street Hartford, CT 06102-5037  Other information: Joint Commission ID # 2649	070025	03/31/2009	12/11/2019	CT

**Addendum XIII: Lung Volume Reduction Surgery (LVRS) (January through March 2020)**

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

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

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at [www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage). For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (January through March 2020)**

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21,

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

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASBMS in the 3-month period. This information is available at [www.cms.gov/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 (January through March 2020)**

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).



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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3390-FN]

#### Medicare Program; Approval of Application by the Accreditation Commission for Healthcare for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Final notice.

**SUMMARY:** This final notice announces our decision to approve the Accreditation Commission for Healthcare for initial recognition as a national accrediting organization for home infusion therapy suppliers that wish to participate in the Medicare program. A home infusion therapy supplier that participates must meet the Medicare conditions for coverage (CfCs).

**DATES:** The approval announced in this final notice is effective April 23, 2020 through April 23, 2024.

**FOR FURTHER INFORMATION CONTACT:** Christina Mister-Ward, (410) 786-2441. Lillian Williams, (410) 786-8636.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Home Infusion therapy (HIT) is a treatment option for Medicare beneficiaries with a wide range of acute and chronic conditions. Section 5012 of the 21st Century Cures Act (Pub. L. 114-255, enacted December 13, 2016) added section 1861(iii) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines HIT as professional services, including nursing services; training and education not otherwise covered under the Durable Medical Equipment (DME) benefit; remote monitoring; and other monitoring services. Home infusion therapy must be furnished by a qualified HIT supplier and furnished in the individual's home. The individual must:

- Be under the care of an applicable provider (that is, physician, nurse practitioner, or physician assistant); and
- Have a plan of care established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs under Part B, that prescribes the type, amount, and duration of infusion therapy services that are to be furnished.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that a qualified HIT supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and in reviewing and modifying the list of designated AOs. These statutory factors are as follows:

- The ability of the organization to conduct timely reviews of accreditation applications.
- The ability of the organization take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).
- Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.
- Such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit HIT suppliers furnishing HIT not later than January 1, 2021. Section 1861(iii)(3)(D) of the Act defines "qualified home infusion therapy suppliers" as being accredited by a CMS-approved AO.

In the March 1, 2019 **Federal Register**, we published a solicitation notice entitled, "Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Home Infusion Therapy Supplier Accreditation Program" (84 FR 7057). This notice informed national AOs that accredit HIT suppliers of an opportunity to submit applications to participate in the HIT supplier accreditation program. Complete applications will be considered for the January 1, 2021 designation deadline if received by February 1, 2020.

Regulations for the approval and oversight of AOs for HIT organizations are located at 42 CFR part 488, subpart L. The requirements for HIT suppliers are located at 42 CFR part 486, subpart I.

##### II. Approval of Accreditation Organizations

Section 1834(u)(5) of the Act and the regulations at § 488.1010 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and

ability to provide CMS with the necessary data.

Section 488.1020(a) requires that we publish, after receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. In accordance with § 488.1010(d), we have 210 days from the receipt of a complete application to approve or deny the application.

##### III. Provisions of the Proposed Notice

In the November 25, 2019 **Federal Register** (84 FR 64904), we published a proposed notice announcing Accreditation Commission for Health Care's (ACHC's) request for initial approval of its Medicare HIT accreditation program. In the November 25, 2019 proposed notice, we detailed our evaluation criteria. Under section 1834(u)(5) the Act and in our regulations at § 488.1010, we conducted a review of ACHC Medicare home infusion accreditation application in accordance with the criteria specified by our regulations, which included, but are not limited to the following:

- An onsite administrative review of ACHC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its home infusion therapy surveyors; (4) ability to investigate and respond appropriately to complaints against accredited home infusion therapies; and (5) survey review and decision-making process for accreditation.

- The ability for an ACHC to conduct timely review of accreditation applications.

- The ability of an ACHC to take into account the capacities of suppliers located in a rural area.

- The comparison of an ACHC's Medicare home infusion therapy accreditation program standards to our current Medicare home infusion therapy conditions for coverage (CfCs).

- ACHC's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and ACHC's ability to provide continuing surveyor training.

++ ACHC's processes, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited home infusion therapies.

++ Evaluate ACHC's procedures for monitoring home infusion therapies it has found to be out of compliance with ACHC's program requirements.