

ID and password validation. The states are asked to provide information on issuers in their state and various Web sites maintained for consumers. The issuers are also tasked with providing information on their major medical insurance products and plans. They are ultimately given the choice to download a basic information template to enter data then upload into the web portal; to manually enter data within the web portal itself; or to submit .xml files containing their information. Once the states and issuers submit their data, they will receive an email notifying them of any errors, and that their submission was received.

CMS is mandates that issuers verify and update their information on a quarterly basis and requests that States verify State-submitted information on an annual basis. In the event that an issuer enhances its existing plans, proposes new plans, or deactivates plans, the organization would be required to update the information in the web portal. Changes occurring during the three month quarterly periods will be allowed utilizing effective dates for both the plans and rates associated with the plans. *Form Number:* CMS-10320 (OMB control number: 0938-1086); *Frequency:* Annually, Quarterly; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 305; *Total Annual Responses:* 5,500; *Total Annual*

*Hours:* 89,725. (For policy questions regarding this collection contact Kim Heckstall at 410-786-1647.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare/Medicaid Psychiatric Hospital Survey Data and Supporting Regulations; *Use:* The CMS-724 form is used to collect data that assists us in program planning and evaluation and in maintaining an accurate database on providers participating in the psychiatric hospital program. Specifically, we use the information collected on this form in evaluating the Medicare psychiatric hospital program. The form is also used for audit purposes; determining patient population and characteristics of the hospital; and survey term composition. *Form Number:* CMS-724 (OMB control number: 0938-0378); *Frequency:* Annually; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 150; *Total Annual Responses:* 150; *Total Annual Hours:* 75. (For policy questions regarding this collection contact Stephanie Hursey at 410-786-4349.)

Dated: May 2, 2017.  
**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2017-09170 Filed 5-4-17; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS-9103-N]

**Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 2017**

**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 2017, relating to the Medicare and Medicaid programs and other programs administered by CMS.

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

Addenda	Contact	Phone number
I CMS Manual Instructions .....	Ismael Torres .....	(410) 786-1864
II Regulation Documents Published in the <b>Federal Register</b> .....	Terri Plumb .....	(410) 786-4481
III CMS Rulings .....	Tiffany Lafferty .....	(410)786-7548
IV Medicare National Coverage Determinations .....	Wanda Belle, MPA .....	(410) 786-7491
V FDA—Approved Category B IDEs .....	John Manlove .....	(410) 786-6877
VI Collections of Information .....	William Parham .....	(410) 786-4669
VII Medicare—Approved Carotid Stent Facilities .....	Sarah Fulton, MHS .....	(410) 786-2749
VIII American College of Cardiology—National Cardiovascular Data Registry Sites .....	Sarah Fulton, MHS .....	(410) 786-2749
IX Medicare’s Active Coverage—Related Guidance Documents .....	JoAnna Baldwin, MS .....	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions .....	JoAnna Baldwin, MS .....	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites .....	Stuart Caplan, RN, MAS .....	(410) 786-8564
XII Medicare—Approved Ventricular Assist Device (Destination Therapy) Facilities .....	Linda Gousis, JD .....	(410) 786-8616
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

**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 Web site 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 Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site 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 Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of updates is automatic and sent to the subscriber as they occur. If

assessing a Web site 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: May 1, 2017.

**Kathleen Cantwell**

*Director, Office of Strategic Operations and Regulatory Affairs.*

**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: May 9, 2016 (81 FR 28072), August 5, 2016 (81 FR 51901), November 2016 (81 FR 79489 and February 23, 2017 (82 FR 11456). 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 2017)

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 Gender Dysphoria and Gender Reassignment Surgery use (CMS-Pub. 100-03) Transmittal No. 194.

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](http://www.cms.gov/Manuals).

Transmittal Number	Manual/Subject/Publication Number
<b>Medicare General Information (CMS-Pub. 100-01)</b>	
	None
<b>Medicare Benefit Policy (CMS-Pub. 100-02)</b>	
233	Clarification of Payment Policy Changes for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device and the Outlier Payment Methodology for Home Health Services National 60-Day Episode Rate Outlier Payments Consolidated Billing Patient Confined to the Home Sequence of Qualifying Services and Other Medicare Covered Home Health Services Needs Skilled Nursing Care on an Intermittent Basis (Other than Solely Venipuncture for the Purposes of Obtaining a Blood Sample), Physical Therapy, Speech-Language Pathology Services, or Has Continued Need for Occupational Therapy Physician Certification Supporting Documentation Requirements Wound Care Medical Supplies (Except for Drugs and Biologicals Other Than Covered Osteoporosis Drugs), the Use of Durable Medical Equipment

	and Furnishing Negative Pressure Wound Therapy Using a Disposable Device Negative Pressure Wound Therapy Using a Disposable Device Coinsurance, Copayments, and Deductibles
234	Clarification of Admission Order and Medical Review Requirements Covered Inpatient Hospital Services Covered Under Part A Hospital Inpatient Admission Order and Certification
<b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b>	
194	Gender Dysphoria and Gender Reassignment Surgery
<b>Medicare Claims Processing (CMS-Pub. 100-04)</b>	
3688	Update to the Federally Qualified Health Centers (FQHC) Prospective Payment System (PPS) - Recurring File Updates
3689	Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List
3690	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3691	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for April 2017
3692	April 2017 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3693	Medicare Physician Fee Schedule Database (MPFSDB) 2017 File Layout Manual Addendum
3694	Issued to a specific audience, not posted to Internet/ Intranet to Confidentiality of Instruction
3695	Medicare Outpatient Observation Notice (MOON) Instructions Part A Medicare Outpatient Observation Notice
3696	New Waived Tests
3697	Issued to a specific audience, not posted to Internet/ Intranet to Confidentiality of Instruction
3698	Medicare Outpatient Observation Notice (MOON) Instructions Part A Medicare Outpatient Observation Notice Statutory Authority Scope Medicare Outpatient Observation Notice Alterations to the MOON Completing the MOON Hospital Delivery of the MOON Required Delivery Timeframes Refusal to Sign the MOON MOON Delivery to Representatives Ensuring Beneficiary Comprehension Completing the Additional Information Field of the MOON Notice Retention for the MOON Intersection with State Observation Notices
3699	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3700	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3701	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to

	and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
3702	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - April 2017
3703	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3704	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3705	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3706	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3707	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3708	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) Edits, Version 23.1, Effective April 1, 2017
3709	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) Edits, Version 23.1, Effective April 1, 2017
3710	New "K" Code for Continuous Positive Airway Pressure Device Bundle
3711	Implementation of New Influenza Virus Vaccine Code Table of Preventive and Screening Services Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes Payment for Pneumococcal Pneumonia Virus, Influenza Virus, and Hepatitis B Virus and Their Administration on Institutional Claims Procedures for Renal Dialysis Facilities (RDF) CWF Edits on AB MAC (A) Claims CWF Edits on AB MAC (B) Claims CWF Crossover Edits for AB MAC (B) Claims
3712	New Fields in the Fiscal Intermediary Shared System (FISS) Inpatient and Outpatient Provider Specific Files (PSF) Addendum A- Provider Specific File Outpatient Provider Specific File
3713	Addendum A- Provider Specific File Outpatient Provider Specific File
3714	Changes to the National Coordination of Benefits Agreement (COBA) Crossover Process as a Result of the Social Security Number Removal Initiative (SSNRI) Beneficiary Insurance Assignment Selection Consolidation of the Claims Crossover Process Coordination of Benefits Agreement (COBA) Detailed Error Report Notification Process Coordination of Benefits Agreement (COBA) ASC X12 837 5010 Coordination of Benefits (COB) Flat File Errors Coordination of Benefits Agreement (COBA) ASC X12 837 Coordination of Benefits (COB) Mapping Requirements as of July 2012 National Council for Prescription Drug Programs (NCPDP) New Version Coordination of Benefits (COB) Requirements
3715	Qualified Medicare Beneficiary Indicator in the Medicare Fee-For-Service Claims Processing System

3716	Extension of the Transition to the Fully Adjusted Durable Medical Equipment, Prosthetics, Orthotics and Supplies Payment Rates under Section 16007 of the 21st Century Cures Act Phase-In for Competitive Bidding Rates in Areas Not in a Competitive Bid Area
3717	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens
3718	Instructions to Process Services Not Authorized by the Veterans Administration (VA) in a Non-VA Facility Reported With Value Code (VC) 42
3719	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April CY 2017 Update
3720	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
3721	Updates to Pub. 100-04, Chapters 12, 17 and 23 to Correct Remittance Advice Messages
3722	Instructions for Downloading the Medicare ZIP Code File for July 2017
3723	Healthcare Provider Taxonomy Codes (HPTCs) April 2017 Code Set Update
3724	Common Edits and Enhancements Modules (CEM) Code Set Update
3725	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
3726	April 2017 Update of the Ambulatory Surgical Center (ASC) Payment System
3727	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3728	April 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3729	April Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3730	Payment for Oxygen Volume Adjustments and Portable Oxygen Equipment Billing for Oxygen and Oxygen Equipment
3731	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3732	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2017
3733	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - July 2017
3734	Federally Qualified Health Centers (FQHC) Prospective Payment System (PPS) - Recurring File Updates
3735	April 2017 Integrated Outpatient Code Editor (I/OCE) Specifications Version 18.1
3736	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3737	Quarterly Updates to ESRD PRICER
3738	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2017
3739	Billing for Advance Care Planning (ACP) Claims
3740	FISS Implementation of the Restructured Clinical Lab Fee Schedule
3741	New Waived Tests

3742	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
<b>Medicare Secondary Payer (CMS-Pub. 100-05)</b>	
117	Remote Identity Proofing (RIDP) and Multi-Factor Authentication (MFA) for Electronic Correspondence Referral System (ECRS) Web Users Electronic Correspondence Referral System for the Web (ECRS Web) Quick Reference Card
118	Individuals Not Subject to the Limitation on Medicare Secondary Payment (MSP) Individuals Not Subject to the Limitation on Payment
<b>Medicare Financial Management (CMS-Pub. 100-06)</b>	
280	Notice of New Interest Rate for Medicare Overpayments and Underpayments -2nd Qtr Notification for FY 2017
281	Innovation Payment Contractor (IPC) for D1 D4 File Exchange
<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b>	
167	Revision to State Operations Manual (SOM) Appendix PP - Incorporate revised Requirements of Participation for Medicare and Medicaid certified nursing facilities
168	Revision to State Operations Manual (SOM) Appendix PP - Incorporate revised Requirements of Participation for Medicare and Medicaid certified nursing facilities.
<b>Medicare Program Integrity (CMS-Pub. 100-08)</b>	
702	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
703	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
704	Home Health (HH) Language in Pub. 100-8 of Instruction Certification Requirements The Use of the Patient's Medical Record Documentation to Support Home Health Certification
705	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Order Requirements for Changing Suppliers Requirement of New Orders
706	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
707	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
708	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
709	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
<b>Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)</b>	
	None
<b>Medicare Quality Improvement Organization (CMS- Pub. 100-10)</b>	
	None
<b>Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)</b>	
	None
<b>Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)</b>	
	None
<b>Medicare Managed Care (CMS-Pub. 100-16)</b>	
	None

<b>Medicare Business Partners Systems Security (CMS-Pub. 100-17)</b>	
	None
<b>Demonstrations (CMS-Pub. 100-19)</b>	
170	Affordable Care Act Bundled Payments for Care Improvement Initiative
171	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
<b>One Time Notification (CMS-Pub. 100-20)</b>	
1767	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for July 2017
1768	Common Working File (CWF) Reorganization of Daily Beneficiary Extract Files Shared System Enhancement 2015: Resolve Operating Report (ORPT) Issues - Development and Implementation
1769	eMSN and Alternate Format MSN Service Improvements
1770	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1771	Fraud Prevention System (FPS) 2 Edit Migration Testing
1772	Common Working File (CWF) Reorganization of Daily Beneficiary Extract Files
1773	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1774	Shared System Enhancement 2014 – Identification of Fiscal Intermediary Standard System (FISS) Obsolete Reports - Analysis Only
1775	Updated Editing of Professional Therapy Services
1776	Instructions to Hospitals on the Election of a Medicare-Supplemental Security Income (SSI) Component of the Disproportionate Share (DSH) Payment Adjustment for Cost Reports that Involve SSI Ratios for Fiscal Year (FY) 2004 and earlier, or SSI Ratios for Hospital Cost-reporting Periods for Patient Discharges Occurring before October 1, 2004
1777	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1778	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1779	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1780	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1781	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1782	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1783	Innovation Payment Contractor (IPC) for D1 D4 File Exchange
1784	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1785	Payment for Oxygen Volume Adjustments and Portable Oxygen Equipment-FISS
1786	Update for Additional International Classification of Diseases (ICD)-10 Codes for the System Changes to Implement Section 231 of the Consolidated Appropriations Act, 2016, Temporary Exception for Certain Severe Wound Discharges From Certain Long-Term Care Hospitals (LTCHs)

1787	New Common Working File (CWF) Medicare Secondary Payer (MSP) Type for Liability Medicare Set-Aside Arrangements (LMSAs) and No-Fault Medicare Set-Aside Arrangements (NFMSAs)
1788	Combined Common Edits/Enhancements (CCEM) Proxool and Apache Software Upgrades
1789	Shared System Enhancement 2016: Common Working File (CWF) to Show Date for Informational Unsolicited Response (IUR) Indicator on Claim History
1790	Shared System Enhancement 2016: Complete Disablement of Health Maintenance Organization (HMO) Inquiry Transaction, HIHO, and Related Vestige within Common Working File (CWF)
1791	Change to Beneficiary Liability and Cost Report Days for Subclause (II) Long Term Care Hospitals (LTCHs)
1792	ICD-10 Coding Revisions to National Coverage Determination (NCDs)
1793	Analysis Only - Modification of Process for Handling the Provider Enrollment Chain Ownership System (PECOS) Extract File
1794	Provider Enrollment, Chain and Ownership System (PECOS) Extract File – Analysis
1795	Advance Care Planning (ACP) Implementation for Outpatient Prospective Payment System (OPPS) Claims
1796	Processing Updates for VMS From Provider Enrollment, Chain and Ownership System (PECOS) Extract File
1797	Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)
1798	ICD-10 Coding Revisions to National Coverage Determinations (NCDs)
1799	Preventing Hospice Notices of Election with Future Dates
1800	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1801	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1802	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1803	Innovation Payment Contractor (IPC) for D1 D4 File Exchange
1804	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1805	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1806	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for July 2017
1807	Intern and Resident Information System (IRIS) Data Upload into STAR
1808	Advanced Provider Screening (APS) Phase 1 Go-Live
1809	Client Letter v5.2 Upgrade - DME MAC Training and Testing
1810	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
1811	Shared System Enhancement 2014 – Identification of Fiscal Intermediary Shared System (FISS) Obsolete On-Request Jobs - Analysis Only
1812	HIGLAS Connectivity Updates and Testing
1813	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects Within the Common Working File (CWF)

1814	Shared System Enhancement 2014 – Identification of Fiscal Intermediary Standard System (FISS) Obsolete Reports - Analysis Only
<b>Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)</b>	
66	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)</b>	
	None

**Addendum II: Regulation Documents Published  
in the Federal Register (January through March 2017)**

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:  
<http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-3Q16QPU.pdf>

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

**Addendum III: CMS Rulings  
(January through March 2017)**

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

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

**Addendum IV: Medicare National Coverage Determinations  
(January through March 2017)**

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. 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
Gender Dysphoria and Gender Reassignment Surgery	NCD 140.9	194	03/03/2017	08/30/2016

**Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January through March 2017)**

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization

process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
BB17214	Transpose RT System	02/09/2017
BB17240	CliniMACS CD34 Reagent System	02/03/2017
BB17374	Magnetic- Activated Cell Sorter (CliniMACS, Miltenyi) for TCR <sup>++</sup> /CD19 <sup>+</sup> Depletion of G-CSF or GM-CSF Mobilized Allogeneic Unrelated or Partially Matched Related Peripheral Stem Cells; Chemotherapy	03/23/2017
BB17376	Amicus Separator System - Extracorporeal Photopheresis (ECP)	03/23/2017
G160152	ACCUSYTE 3-D FIDUCIAL MARKER	01/12/2017
G160163	Abre Venous Self-expanding Stent System	01/19/2017
G160225	ORBERA INTRAGASTRIC BALLOON	03/29/2017
G160255	Prostate Artery Embolization	03/30/2017
G160266	Insightec Exablate	01/06/2017
G160270	Prostate Artery Embolization for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hyperplasia	01/13/2017
G160273	Arrow StimuCath Continuous Nerve Block Set	01/19/2017
G160276	Olympus PK Morcellator and Pneumoliner	01/19/2017
G160277	CELCUITY CELX HER2 SIGNALING FUNCTION TEST	01/20/2017
G160278	PV-001 Pulmonary Valved Conduit	01/26/2017
G170001	VM110 and Olympus NIR Laparoscopic System	02/03/2017
G170002	TULA System	02/03/2017
G170003	NEUROPORT ARRAY, PN 6248, NEUROPORT BIOPOTENTIAL SIGNAL PROCESSOR SYSTEM, PN 5416	02/03/2017
G170004	smART System	02/02/2017
G170006	FENIX™ Continence Restoration System	02/02/2017
G170007	SAPPHIRE II PRO CORONARY DILATION CATHETER	02/08/2017
G170010	Bidirectional Cortical Neuroprosthetic System (BiCNS)	02/10/2017
G170011	Treatment of Severe Lower Urinary Tract Obstruction (LUTO)	02/10/2017
G170014	Aquadex FlexFlow Aquapheresis System	02/22/2017
G170017	Senza Spinal Cord Stimulation (SCS) System	02/22/2017
G170018	ExAblate MR guided focused ultrasound system	02/24/2017
G170019	MAGE-A3/A6 Screening Test	02/21/2017
G170020	Attain Stability Quad MRI SureScan 4798 Lead	02/24/2017
G170024	TAAA Debranching Stent Graft System	02/23/2017
G170026	Cochlear Reponse Telemetry Research Tool	02/28/2017
G170028	Subcutaneous Tibial Nerve Stimulation for Urgency Urinary Incontinence	03/02/2017
G170031	Vivistim System for Stroke	03/10/2017
G170035	Activa RC Rechargeable Neurostimulator Model37612,	03/09/2017

IDE	Device	Start Date
	Activa RC Recharger Model37651, DBS leads Models 3387S and 3389S, DBS extension Model37086, Patient Programmer Model #37642, External Neurostimulator Model37022, Clinician Programmer Model 8840,	
G170036	Medtronic Valiant Thoracoabdominal Stent Graft System	03/09/2017
G170037	Neocis Guidance System (NGS)	03/15/2017
G170043	Side Positioner	03/23/2017
G170044	VITARIA System	03/17/2017
G170048	Valiant Thoracoabdominal Stent Graft System	03/21/2017
G170050	Restylane; Restylane-L; Perlane; Restylane Lyft; Restylane Silk	03/30/2017
G170053	Edwards Alterra Adaptive Prestent System	03/29/2017
G170054	HAC-Coil (H7) Deep Transcranial Magnetic Stimulation (DTMS) Device for the Treatment of Major Depression Disorder (MDD)	03/29/2017
G170055	TECNIS Next-Generation Intraocular Lens	03/30/2017
G170056	Unity Subcutaneous Infusion System	03/31/2017

#### **Addendum VI: Approval Numbers for Collections of Information (January through March 2017)**

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

#### **Addendum VII: Medicare-Approved Carotid Stent Facilities, (January through March 2017)**

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

Facility	Provider Number	Effective Date	State
<b>The following facilities are new listings for this quarter.</b>			
Redlands Community Hospital 350 Terracina Boulevard Redlands, CA 92373	050272	01/10/2017	CA
Dignity Health Dominican Hospital 1555 Soquel Drive Santa Cruz, CA 95065	050242	01/26/2017	CA
Advocate BroMenn Medical Center 1304 Franklin Avenue Normal, IL 61761	140127	03/15/2017	IL
White River Medical Center 1710 Harrison Street Batesville, AR 72501	040119	03/30/2017	AR
<b>The following facilities have editorial changes (in bold).</b>			
<b>FROM: Fletcher Allen Health Care</b> <b>TO: University of Vermont Medical Center</b> 1111 Colchester Avenue Burlington, VT 05401-1473	470003	05/26/2005	VT
Baxter Regional Medical Center 624 Hospital Drive Mountain Home, AR 72653	<b>1881788933</b>	10/26/2016	AR
Silver Cross Hospital <b>1900 Silver Cross Boulevard</b> <b>New Lenox, IL 60453</b>	140213	01/23/2006	IL
<b>FROM: Midwest Regional Medical Center</b> <b>TO: Alliance Health Midwest</b> 2825 Parklawn Drive Midwest City, OK 73110	370094	06/08/2005	OK
Memorial Hospital at Gulfport 4500 13th Street Gulfport, MS 39501	<b>1073606901</b>	06/05/2013	MS
<b>FROM: Central Mississippi Medical Center</b> <b>TO: Jackson HMA, LLC d/b/a Merit Health Central</b> 1850 Chadwick Drive Jackson, MS 39204	250072	05/06/2010	MS
<b>FROM: St. Mary's Health System</b> <b>TO: Tennova Healthcare – Physicians Regional Medical Center</b> 900 E. Oak Hill Avenue Knoxville, TN 37917	440120	10/11/2005	TN
<b>FROM: Providence Hospital</b> <b>TO: Providence-Providence Park Hospital</b> 16001 West Nine Mile Road Southfield, MI 48075	230019	06/27/2005	MI
<b>FROM: St. Elizabeth Health Center</b> <b>TO: St. Elizabeth Youngstown Hospital</b> 1044 Belmont Avenue Youngstown, OH 44501-1790	360064	11/16/2006	OH
Arizona Heart Hospital	<b>030094</b>	04/18/2005	AZ

Facility	Provider Number	Effective Date	State
1930 E. Thomas Road Phoenix, AZ 85016			
<b>The following facilities are terminations for this quarter.</b>			
Palm West Hospital 13001 Southern Boulevard Loxahatchee, FL 33470-1150 P.O. Box 1150	100269	01/26/2017	FL
Scripps Memorial Hospital Encinitas 354 Santa Fe Drive ENC01 Encinitas, CA 92024	050503	04/16/2010	CA

**Addendum VIII:  
 American College of Cardiology's National Cardiovascular Data  
 Registry Sites (January through March 2017)**

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961>

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD

registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at [www.ncdr.com/webncdr/common](http://www.ncdr.com/webncdr/common)

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 by accessing our website and clicking on the link for the

American College of Cardiology's National Cardiovascular Data Registry at: [www.ncdr.com/webncdr/common](http://www.ncdr.com/webncdr/common). For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	City	State
<b>The following facilities are new listings for this quarter.</b>		
Rancho Spring Medical Center	Murrieta	CA
Carolina Pines Regional Medical Center	Hartsville	SC
Protestant Memorial Medical Center	Belleville	IL
Fairbanks Memorial Hospital	Fairbanks	AK
Tennova- Dyersburg Regional Medical Center	Dyersburg	TN
Baptist Health Richmond, Inc.	Richmond	KY
The Hospitals of Providence Transmountain Campus	El Paso	TX
CMSC LLC Dba Great Falls Clinic Hospital	Great Falls	MT
Centegra Hospital - Huntley	McHenry	IL
Sacramento Heart Ambulatory Surgery Center, Inc.	Sacramento	CA
Piedmont Fayette Hospital	Fayetteville	GA
Integrus Miami Hospital	Miami	OK
Doctor's Same Day Surgery Center	Sarasota	FL
Largo Ambulatory Surgery Center	Upper Marlboro	MD
South Baltimore Ambulatory Surgery Center	Rockville	MD
Tysons Corner Ambulatory Surgery Center	Tysons Corner	VA
Surgical Hospital of Oklahoma	Oklahoma City	OK
Beaumont ASC, LP	Beaumont	TX
Collin County ASP, LP	Plano	TX
Conroe ASC, LP	The Woodlands	TX
Katy ASC, LP	Houston	TX
Lake Charles Ambulatory Surgery Center, LP	Lake Charles	LA
Mid-Cities ASC, LP	Bedford	TX
Phoenix ASC, LP	Phoenix	AZ
Kaiser Permanente Orange County - Anaheim Medical	Irvine	CA
Memorial Hermann Cypress Hospital	Cypress	TX

#### **Addendum IX: Active CMS Coverage-Related Guidance Documents (January through March 2017)**

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with

Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

#### **Addendum X:**

#### **List of Special One-Time Notices Regarding National Coverage Provisions (January through March 2017)**

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

#### **Addendum XI: National Oncologic PET Registry (NOPR) (January through March 2017)**

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 (January through March 2017)**

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.

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 Linda Gousis, JD, (410-786-8616).

Facility	Provider Number	Date Approved	State
<b>There are no new listings for this quarter.</b>			
<b>The following facilities have editorial changes (in bold).</b>			
Spectrum Health - Butterworth Campus 100 Michigan Street Northeast Grand Rapids, MI 49503	<b>230028</b>	06/17/2011	MI
<b>Piedmont Hospital, Inc.</b> 1968 Peachtree Road, NW Atlanta, GA 30309	110083	<b>02/08/2017</b>	GA

**Addendum XIII: Lung Volume Reduction Surgery (LVRS) (January through March 2017)**

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):

**Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (January through March 2017)**

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

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);

- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and

- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at [www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage](http://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 (January through March 2017)**

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

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