

panel meeting and the transition to one meeting of the panel per year (81 FR 31941).

## II. Request for Nominations; Criteria for Nominees

The Panel shall consist of a chair and up to 15 members who are full-time employees of hospitals, hospital systems, or other Medicare providers that are subject to the OPPTS. For supervision deliberations, the Panel shall also include members that represent the interests of Critical Access Hospitals (CAHs), who advise the Centers for Medicare & Medicaid Services (CMS) only regarding the level of supervision for hospital outpatient therapeutic services. (For purposes of the Panel, consultants or independent contractors are not considered to be full-time employees in these organizations.)

The HOP Panel currently consists of 13 panel members. Two additional vacancies will occur in CY 2018. The list of HOP Panel members is located in the FACA database, Advisory Panel on Hospital Outpatient Payment Committee page, on the FACA database website at: <https://www.facadatabase.gov/committee/committee.aspx?cid=1791&aid=76>.

Panel members serve on a voluntary basis, without compensation, according to an advance written agreement; however, for the meetings, CMS reimburses travel, meals, lodging, and related expenses in accordance with standard Government travel regulations. CMS has a special interest in ensuring, while taking into account the nominee pool, that the Panel is diverse in all respects of the following: Geography; rural or urban practice; race, ethnicity, sex, and disability; medical or technical specialty; and type of hospital, hospital health system, or other Medicare provider subject to the OPPTS. Appointment to the HOP Panel shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Based upon either self-nominations or nominations submitted by providers or interested organizations, the Secretary, or his or her designee, appoints new members to the Panel from among those candidates determined to have the required expertise. New appointments are made in a manner that ensures a balanced membership under the FACA guidelines. This notice requests nominations for HOP Panel members on a continuous basis. Nominations for a person not serving on the committee may be reconsidered as committee vacancies arise, but should be updated

and resubmitted no later than 3 years after the original nomination submittal to continue to be considered for committee vacancies. CMS will consider the nominations submitted in response to the notice published in the **Federal Register** on December 23, 2016, entitled "Medicare Program; Renewal of the Advisory Panel on Hospital Outpatient Payment and Solicitation of Nominations to the Advisory Panel on Hospital Outpatient Payment" (81 FR 94378), unless they are withdrawn or the nominees' qualifications have changed. Nominations will be considered as vacancies occur.

The Panel must be balanced in its membership in terms of the points of view represented and the functions to be performed. Each panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPTS (except for the CAH members, since CAHs are not paid under the OPPTS). All members must have technical expertise to enable them to participate fully in the Panel's work. Such expertise encompasses hospital payment systems; hospital medical care delivery systems; provider billing systems; APC groups; Current Procedural Terminology codes; and alpha-numeric Health Care Common Procedure Coding System codes; and the use of, and payment for, drugs, medical devices, and other services in the outpatient setting, as well as other forms of relevant expertise. For supervision deliberations, the Panel shall have members that represent the interests of CAHs, who advise CMS only regarding the level of supervision for hospital outpatient therapeutic services.

It is not necessary for a nominee to possess expertise in all of the areas listed, but each must have a minimum of 5 years of experience and currently have full-time employment in his or her area of expertise. Generally, members of the Panel serve overlapping terms up to 4 years, based on the needs of the Panel and contingent upon the rechartering of the Panel. A member may serve after the expiration of his or her term until a successor has been sworn in.

Any interested person or organization may nominate qualified individuals. Self-nominations will also be accepted. Each nomination must include the following:

- Letter of Nomination stating the reasons why the nominee should be considered.
- Curriculum vitae or resume of the nominee that includes an email address where the nominee can be contacted.
- Written and signed statement from the nominee that the nominee is willing

to serve on the Panel under the conditions described in this notice and further specified in the Charter.

- The hospital or hospital system name and address, or CAH name and address, as well as all Medicare hospital and or Medicare CAH billing numbers of the facility where the nominee is employed.

Future updates or changes to the panel nomination process may be published in the **Federal Register** or posted on the CMS Advisory Panel for Hospital Outpatient Payment website, referenced in section II, "Request for Nominations; Criteria for Nominees," of this notice.

## IV. Copies of the Charter

To obtain a copy of the Panel's Charter, we refer readers to our website at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

## V. Collection of Information Requirements

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

Dated: January 12, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2018-01474 Filed 1-25-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-9106-N]

### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October Through December 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 October through December 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 No.
I. CMS Manual Instructions .....	Ismael Torres .....	(410) 786-1864
II. Regulation Documents Published in the Federal Register .....	Terri Plumb .....	(410) 786-4481
III. CMS Rulings .....	Tiffany Lafferty .....	(410) 786-7548
IV. Medicare National Coverage Determinations .....	Wanda Belle, MPA .....	(410) 786-7491
V. FDA-Approved Category B IDEs .....	John Manlove .....	(410) 786-6877
VI. Collections of Information .....	William Parham .....	(410) 786-4669
VII. Medicare-Approved Carotid Stent Facilities .....	Sarah Fulton, MHS .....	(410) 786-2749
VIII. American College of Cardiology-National Cardiovascular Data Registry Sites .....	Sarah Fulton, MHS .....	(410) 786-2749
IX. Medicare's Active Coverage-Related Guidance Documents .....	JoAnna Baldwin, MS .....	(410) 786-7205
X. One-time Notices Regarding National Coverage Provisions .....	JoAnna Baldwin, MS .....	(410) 786-7205
XI. National Oncologic Positron Emission Tomography Registry Sites .....	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 website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time”

accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

**III. How to Use the Notice**

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

Dated: January 17, 2018.

**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: February 23, 2017 (82 FR 11456), May 5, 2017 (82 FR 21241), August 4, 2017 (82 FR 36404) and October 27, 2017 (82 FR 49819). 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 (October through December 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 January 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files use (CMS-Pub. 100-04) Transmittal No. 3878.

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>	
108	Transition Workload Handbook Fee-for-Service Contractor Workload Transitions Transition Handbooks
109	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
110	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 April 2018 Updates
111	Update to Medicare Deductible, Coinsurance and Premium Rates for 2018 Basis for Determining the Part A Coinsurance Amounts Part B Annual Deductible Part B Premium
<b>Medicare Benefit Policy (CMS-Pub. 100-02)</b>	
228	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (SNF Requirements - General Medicare SNF PPS Overview Medicare SNF Coverage Guidelines Under PPS Hospital Providers of Extended Care Services

	<p>Three-Day Prior Hospitalization</p> <p>Three-Day Prior Hospitalization - Foreign Hospital</p> <p>Effect on Spell of Illness</p> <p>Medical Service of an Intern or Resident-in-Training</p> <p>Medical and Other Health Services Furnished to SNF Patients</p> <p>Services Furnished Under Arrangements With Providers</p> <p>Definition of Durable Medical Equipment</p>
229	<p>Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2017</p>
230	<p>Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Updates</p> <p>Table of Contents</p> <p>Index of Acronyms</p> <p>RHC General Information</p> <p>FQHC General Information</p> <p>RHC Staffing Requirements</p> <p>RHC Temporary Staffing Waivers</p> <p>RHC and FQHC Visits</p> <p>Multiple Visits on Same Day</p> <p>3-Day Payment Window</p> <p>RHC Services</p> <p>FQHC Services</p> <p>Emergency Services</p> <p>Non RHC/FQHC Services</p> <p>Description of Non RHC/FQHC Services</p> <p>RHC Payment Rate</p> <p>RHC Payment Limit and Exceptions</p> <p>Payment Codes for FQHCs Billing Under the PPS</p> <p>FQHC PPS Payment Rate and Adjustments</p> <p>FQHC Payment Codes</p> <p>RHC and FQHC Cost Report Requirements</p> <p>RHC and FQHC Cost Report Forms</p> <p>RHC and FQHC Charges, Coinsurance, Deductible, and Waivers</p> <p>Comminglin</p> <p>Dental, Podiatry, Optometry, and Chiropractic Services</p> <p>Graduate Medical Education</p> <p>Transitional Care Management (TCM) Services</p> <p>Chronic Care Management (CCM) Services</p> <p>Services and Supplies Furnished "Incident to" Physician's Services</p> <p>Provision of Incident to Services and Supplies</p> <p>Incident to Services and Supplies Furnished in the Patient's Home or Location Other than the RHC or FQHC</p> <p>Payment to Physician Assistants</p> <p>Services and Supplies Furnished Incident to NP, PA, and CNM Services</p> <p>Services and Supplies Incident to CP Services</p> <p>Mental Health Visits</p> <p>Physical Therapy, Occupational Therapy, and Speech Language Pathology Service</p> <p>Requirements for Visiting Nursing Services</p>

	<p>Treatment Plans</p> <p>Hospice Services</p> <p>Hospice Attending Practitioner</p> <p>Provision of Services to Hospice Patients in a RHC or FQHC</p> <p>Preventive Health Services</p> <p>Preventive Health Services in RHCs</p> <p>Preventive Health Services in FQHCs</p> <p>Copayment for FQHC Preventive Health Services</p>
231	<p>Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2017</p>
232	<p>January 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS)</p> <p>Covered Inpatient Hospital Services Covered Under Part A</p>
233	<p>Clarification of Payment Policy Changes for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device and the Outlier Payment Methodology for Home Health Services</p> <p>Table of Contents</p> <p>National 60-Day Episode Rate</p> <p>Outlier Payments</p> <p>Consolidated Billing</p> <p>Patient Confined to the Home</p> <p>Sequence of Qualifying Services and Other Medicare Covered Home Health Services</p> <p>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</p> <p>Physician Certification</p> <p>Supporting Documentation Requirements</p> <p>Wound Care</p> <p>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</p> <p>Negative Pressure Wound Therapy Using a Disposable Device</p> <p>Coinsurance, Copayments, and Deductibles</p>
234	<p>Clarification of Admission Order and Medical Review Requirements</p> <p>Table of Contents</p> <p>Covered Inpatient Hospital Services Covered Under Part A</p> <p>Hospital Inpatient Admission Order and Certification</p>
235	<p>Removal of Contractor Requirement to Submit Opt Out Data into the Contractor Reporting of Operational and Workload Data (CROWD) System (Form 8)</p>
236	<p>Medicare Benefit Policy Manual - Chapter 10, Ambulance Locality and Advanced Life Support (ALS) Assessment Locality</p> <p>Ground Ambulance Services</p>
237	<p>Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2018</p>

238	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update Treatment Plans or Home Care Plans Graduate Medical Education Services and Supplies Furnished “Incident to” Physician’s Services Provision of Incident to Services and Supplies Incident to Services and Supplies Furnished in the Patient’s Home or Location Other than the RHC or FQHC Payment for Incident to Services and Supplies Nurse Practitioner, Physician Assistant, and Certified Nurse Midwife Services Payment to Physician Assistants Services and Supplies Furnished Incident to NP, PA, and CNM Services Clinical Psychologist and Clinical Social Worker Services Services and Supplies Incident to CP Services Mental Health Visits Physical Therapy, Occupational Therapy, and Speech Language Pathology Services Description of Visiting Nursing Services Requirements for Visiting Nursing Services Home Health Agency Shortage Area Treatment Plans Telehealth Services Hospice Attending Practitioner Provision of Services to Hospice Patients in an RHC or FQHC Preventive Health Services in RHCs Copayment and Deductible for RHC Preventive Health Services Preventive Health Services in FQHCs Copayment for FQHC Preventive Health Service Care Management Services Transitional Care Management Services General Care Management Services – Chronic Care Management and General Behavioral Health Integration Services Psychiatric Collaborative Care Model Services
<b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b>	
203	Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen) Hyperbaric Oxygen Therapy
<b>Medicare Claims Processing (CMS-Pub. 100-04)</b>	
3872	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2018
3873	Place of Service Codes
3874	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3875	Internet Only Manual Update to Pub. 100-04, Chapter 16, to Update Clinical Lab Fee Schedule Layout
3876	Decommission the MCS Maintained HBCRB081 Report (“Correct Coding Quarterly Savings Report”) Savings Report Savings Record Format

3877	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3878	January 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3879	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3880	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3881	Clinical Laboratory Fee Schedule Not Otherwise Classified, Not Otherwise Specified, or Unlisted Service or Procedure Code Data Collection
3882	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3883	Payment for Services Furnished by Qualified Nonphysician Anesthetists Qualified Nonphysician Anesthetist Services Entity or Individual to Whom Fee Schedule is Payable for Qualified Nonphysician Anesthetists Anesthesia Fee Schedule Payment for Qualified Nonphysician Anesthetists Conversion Factors Used for Qualified Nonphysician Anesthetists Conversion Factors for Anesthesia Services of Qualified Nonphysician Anesthetists Furnished on or After January 1, 1992.
3884	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3885	Fiscal Year (FY) 2018 Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) PPS Changes
3886	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3887	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3888	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3889	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3890	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3891	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3892	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3893	Ambulance Inflation Factor for CY 2018 and Productivity Adjustment Ambulance Inflation Factor (AIF)
3894	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
3895	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3896	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3897	Pulmonary Rehabilitation (PR) Services Addition to Chapter 19, Indian Health Services (IHS) Pulmonary Rehabilitation, Physical Therapy, Occupational Therapy,

	Speech-Language Pathology and Diagnostic Audiology Services - Payment Policy Pulmonary Rehabilitation Services - Claims Processing
3898	Correction to Prevent Payment on Inpatient Information Only Claims for Beneficiaries Enrolled in Medicare Advantage Plans Claims Processing Requirements for TAVR Services for Medicare Advantage (MA) Plan Participants Claims Processing Requirements for TMVR for MR Services for Medicare Advantage (MA) Plan Participants
3899	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3900	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3901	Update to Pub 100-04, Chapter 18 Preventive and Screening Services - Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)
3902	New Waived Tests
3903	Annual Medicare Physician Fee Schedule (MPFS) Files Delivery and Implementation and Medicare Physician Fee Schedule Database (MPFSDB) 2018 File Layout Manual Addendum
3904	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3905	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3906	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3907	October 2017 Integrated Outpatient Code Editor (IOCE) Specifications Version 18.3
3908	Influenza Vaccine Payment Allowances - Annual Update for 2017-2018 Season
3909	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January 2018
3910	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
3911	New Positron Emission Tomography (PET) Radiopharmaceutical/Tracer Unclassified Codes
3912	Off-Cycle Update to the Long Term Care Hospital (LTCH) Prospective Payment System (PPS) Fiscal Year (FY) 2018 Pricer
3913	Common Edits and Enhancements Modules (CEM) Code Set Update
3914	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3915	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE)
3916	Claim Status Category and Claim Status Codes Update
3917	Calendar Year (CY) 2018 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures

3918	Therapy Cap Values for Calendar Year (CY) 2018
3919	Update to Rural Health Clinic (RHC) All Inclusive Rate (AIR) Payment Limit for Calendar Year (CY) 2018
3920	Qualified Medicare Beneficiary Indicator in the Medicare Fee-For-Service Claims Processing System
3921	Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen)
3922	Update to the Federally Qualified Health Center (FQHC) Prospective Payment System (PPS) for Calendar Year (CY) 2018 - Recurring File Update
3923	Quarterly Update of HCPCS Codes Used for Home Health Consolidated Billing Enforcement
3924	2018 Annual Update to the Therapy Code List
3925	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2018
3926	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3927	Instructions for Downloading the Medicare ZIP Code File for April 2018
3928	Off-Cycle Update to the Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Fiscal Year (FY) 2018 Pricer
3929	Elimination of the GT Modifier for Telehealth Services
3930	Hospice Manual Update Only for Section 30.3 Data Required on the Institutional Claim to A/B MAC (HHH) Hospice Pricer Program Input/Output Record Layout
3931	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3932	Special Requirements for Immunosuppressive Drugs
<b>Medicare Secondary Payer (CMS-Pub. 100-05)</b>	
	None
<b>Medicare Financial Management (CMS-Pub. 100-06)</b>	
295	Notice of New Interest Rate for Medicare Overpayments and Underpayments -1st Qtr. Notification for FY 2018
<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b>	
171	Revisions to State Operations Manual (SOM), Appendix U - Survey Procedures and Interpretive Guidelines for Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions
172	Revision to State Operations Manual (SOM) Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
173	Revisions to State Operation Manual (SOM), Appendix PP Guidance to Surveyors for Long Term Care Facilities
174	Revisions to the State Operations Manual (SOM) Appendix P
175	Revisions to State Operations Manual (SOM) Appendix J, Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities
176	Revisions to State Operations Manual (SOM) Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

<b>Medicare Program Integrity (CMS-Pub. 100-08)</b>	
747	Update to Reporting Requirements Reconsideration Requests – Non-certified Providers/Suppliers External Reporting Requirements
748	Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings Election of Status Coordination of the ALJ Hearing Party in the ALJ Hearing The ALJ Hearing
749	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
750	Proof of Delivery Documentation Requirements Supplier Proof of Delivery Documentation Requirements Proof of Delivery and Delivery Methods Proof of Delivery Requirements for Recently Eligible Medicare FFS Beneficiaries Supplier Documentation
751	Clarifying Signature Requirements
752	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
753	Certificates of Medical Necessity (CMN) and Durable Medical Equipment (DME) Information Forms (DIF)
754	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
755	Tracking Medicare Contractors' Prepayment and Postpayment Reviews
<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>	
180	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
181	Next Generation ACO Model - Weekly AIPBP Reduction File Change
182	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
183	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
184	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
185	Demonstration: Payment Update for 2018

186	IVIG Demonstration: Payment Update for 2018
187	Next Generation Accountable Care Organization (NGACO) Year Three Benefit Enhancements
<b>One Time Notification (CMS-Pub. 100-20)</b>	
1928	Multi-Carrier System (MCS), Fiscal Intermediary Shared System (FISS) and VIPS Medicare Shared System (VMS) Automation of Prior Authorization (PA) Requests/Pre-Claim Reviews (PCR) and their Responses with Multiple Services (for programs like Home Health (HH)) via the Electronic Submission of Medical Documentation (esMD) System
1929	CMS Approved Review Topics for Durable Medical Equipment, Prosthetic, Orthotics, Supplies (DMEPOS)
1930	National Provider Identification Crosswalk System (NPICS) Retirement Analysis Only - Engage Shared Systems Maintainers (SSMs) and Medicare Administrative Contractors (MACs) in Meetings and Correspondence Related to the NPICS Retirement with the Integrated Data Repository (IDR) Team
1931	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1932	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects within the Fiscal Intermediary Shared System - Removing/Archiving demonstration codes 38, 42 and 43)
1933	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects within the Fiscal Intermediary Shared System - Removing/Archiving demonstration codes 38, 42 and 43)
1934	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1935	FISS Process Enhancements – Analysis Only
1936	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1937	Provider Education and Referral Reporting
1938	Archiving National Provider Identifier Crosswalk System (NPICS) System Logic in the Durable Medical Equipment (DME) Claims Processing System
1939	Fiscal Intermediary Shared Systems (FISS) Enhancements to the Mass Adjustment of Process Recovery Audit Contractor (RAC) Claims
1940	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1941	Transitional Drug Add-on Payment Adjustment (TDAPA) for patients with Acute Kidney Injury (AKI)
1942	Common Working File (CWF) to Medicare Beneficiary Database (MBD) Extract File Changes for Detailed Skilled Nursing Facility Data to Support HIPAA Eligibility Transaction System (HETS)
1943	Assign the Correct 935 Indicator on Adjustment Claims Submitted through the Provider Portal
1944	MCS Analysis Only: Undeliverable Medicare Summary Notices (UMSNs) – Beneficiary Do Not Forward Process
1945	Add Date of Receipt to the Beneficiary Data Streamlining (BDS) Part A Claims Layout
1946	Shared System Enhancement 2015: Removing/Archiving Obsolete Reports within the Multi-Carrier System (MCS)

1947	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for April 2018
1948	Archiving National Provider Identifier Crosswalk System (NPICS) System Logic in the Multi-Carrier System (MCS)
1949	Remove Obsolete Edits from the Fiscal Intermediary Shared Systems (FISS)
1950	Fiscal Intermediary Shared System (FISS) and VIPS Medicare Shared System (VMS) to Update Records Based on the Automation of Prior Authorization (PA) Requests/Pre-Claim Reviews (PCR) and their Responses with Multiple Services (for programs like Home Health (HH))
1951	Shared System Enhancement 2015: Removing/Archiving Obsolete On Request Jobs within the Multi-Carrier System (MCS)
1952	Calculating Interim Rates for Graduate Medical Education (GME) Payments to New Teaching Hospitals
1953	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete On-Request Jobs - Phase 1
1954	New Common Working File (CWF) Medicare Secondary Payer (MSP) Type for Ijability Medicare Set-Aside Arrangements (IMSAs) and No-Fault Medicare Set-Aside Arrangements (NFMSAs)
1955	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1956	Analysis and Design Working Sessions for the Development of a Pre-Payment Common Additional Documentation Request (ADR) Letter
1957	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects Within the Common Working File (CWF) - Removing/Archiving Demonstration codes 51 and 56
1958	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Financial and Expert Claims Processing System (ECPS) Reports - Phase 1
1959	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Financial and Expert Claims Processing System (ECPS) Reports - Phase 1
1960	Implementation of the Award for the Jurisdiction Part A and Part B Medicare Administrative Contractor (JJ A/B MAC)
1961	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1962	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Core Reports - Phase 1
1963	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1964	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Core Reports - Phase 1
1965	Shared System Enhancement 2015: Resolve Operating Report (ORPT) Issues – Development and Implementation
1966	Out-of-Jurisdiction Providers (OJP) and Qualified Chain Providers (QCP) Move to Correct A/B MAC Jurisdiction - Analysis CR Only
1967	CICS Region Merge(s) for A/B MACs - Analysis Only
1968	Tracking Status of Claims Adjustments
1969	Partial Settlement of 2-Midnight Policy Court Cases
1970	Establish an Automated Process For Creating Mass Adjustments Utilizing

	Expert Claims Processing System (ECPS) - Analysis Only
1971	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1972	Analysis Only: Develop Enhanced Claims Search Reporting in Fiscal Intermediary Shared System (FISS)
1973	Multi-Carrier System (MCS) Modernization Proof of Concept Number 8
1974	Revision of PWK (Paperwork) Fax/Mail Cover Sheets
1975	ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs)
1976	Common Working File (CWF) to Modify CWF Provider Queries to Only Accept National Provider Identifier (NPI) as valid Provider Number
1977	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
1978	Implementation of Changes to Certificate of Medical Necessity (CMN) and CMN DME Information Form (CMN DIF) as a result of the New Medicare Card Project
1979	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects Within the Common Working File (CWF)
1980	Shared System Enhancement 2015: Removing/Archiving Obsolete On Request Jobs within the Multi-Carrier System (MCS)
1981	Fiscal Year (FY) 2014 and 2015 Worksheet S-10 Revisions: Further Extension for All Inpatient Prospective Payment System (IPPS) Hospitals
1982	Line Level versus Claim Level Reporting – Analysis Only
1983	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects within the Fiscal Intermediary Shared System - Removing/Archiving demonstration codes 38, 42 and 43)
1984	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
<b>Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)</b>	
70	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
71	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
72	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 (October through December 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-4Q17QPU.pdf>

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

**Addendum III: CMS Rulings  
(October through December 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  
(October through December 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
Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen)	NCD 20.29	203	11/17/2017	04/03/2017

**Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October through December 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
G170177	Medtronic IN.PACT Admiral Drug-Coated Balloon	10/04/2017
G170229	Gel-Bead embolization spheres	10/04/2017
G170226	Strattice Reconstructive Tissue Matrix	10/05/2017
G170227	DiamondTemp Ablation System	10/06/2017
G170232	LC Bead LUMI	10/13/2017
G170237	Exablate Model 4000 Type 1	10/20/2017
G170051	Left Gastric Artery Embolization for Glycemic Control	10/24/2017
G170100	Axonics Sacral Neuromodulation System	10/27/2017
G170240	Doctormate Renqiao Remote Ischemic Conditioning Device Type IPC-906X	10/27/2017
G170242	A High-Performance ECoG-based Neural Interface for Communication and Neuroprosthetic Control	10/27/2017
G170247	HiResolution Bionic Ear System	11/02/2017
G160196	Neovase Reducer System	11/03/2017
G170248	ClonoSEQ in-vitro assay, laboratory developed test	11/07/2017
G170252	TraceIT Tissue Spacer	11/07/2017
G170251	Wingman Crossing Catheter	11/08/2017
G170179	SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System	11/09/2017
G170261	AXIOS Stent and Electrocautery Enhanced Delivery System 10mmx10mm; AXIOS Stent and Electrocautery Enhanced Delivery System 15mmx10mm; AXIOS Stent and Electrocautery Enhanced Delivery System 20mmx10mm	11/09/2017
G170189	Contour PVA, Embosphere and Embosphere	11/14/2017
G170254	Wallstent	11/16/2017
G170257	SPRINT PNS System for the Treatment of Back Pain	11/17/2017
G170258	CardioMEMS HF System	11/17/2017
G170083	PQ Bypass System	11/20/2017
G170219	Cardio Flow Orbital Atherectomy System	11/21/2017
G170205	Brown Glaucoma Implant	11/22/2017
G170268	Activa PC+S Neurostimulation System; Neurostimulation Systems for Deep Brain Stimulation	11/24/2017
G170270	SurgiMed Meshed Collagen Matrix	11/29/2017
G170273	Medtronic Arctic Front Advance Cardiac Cryoballoon catheter	11/30/2017
G170272	Study of Left Main Coronary Artery Healing after PCI with Boston Scientific Synergy Bioabsorbable Polymer Stent (SOLEMN)	12/01/2017
G170126	MMS MicroStent System	12/08/2017
G170279	Aries 2 Device	12/08/2017
G170282	SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System	12/13/2017
G170283	Cardioblate BP2, Cardioblate LP, Cardioblate Pen, Cardioblate XL Pen, Cardioblate MAPs; Cardioblate Generator; Cardioblate CryoFlex Probes and Clamp; Cardioblate CryoFlex Console	12/13/2017

IDE	Device	Start Date
G150231	Mayo Clinic Nerve Scaffold #1 (MCNS1)	12/14/2017
G160258	REZUM SYSTEM	12/15/2017
G170286	Transmural Transcaval Closure Device (Delivery System & Implant); Guidewire for use with Transcaval Closure Device	12/15/2017
G170287	Invisalign Palatal Expander	12/15/2017

#### Addendum VI: Approval Numbers for Collections of Information (October through December 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, (October through December 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>			
Good Samaritan Hospital Medical Center 1000 Montauk Highway West Islip, NY 11795	1902865355	10/20/2017	NY
Salt Lake Regional Medical Center 1050 E. South Temple Salt Lake City, UT 84102	1417988833	12/11/2017	UT
<b>The following facilities have editorial changes (in bold).</b>			
<b>FROM: SSM St. Mary's Health Center</b> <b>TO: SSM Health St Mary's Hospital - St. Louis</b> 6420 Clayton Road Richmond Heights, MO 63117	26-0091	01/12/2012	MO
<b>FROM: DePaul Health Center</b> <b>TO: SSM Health DePaul Hospital - St. Louis</b> 12303 DePaul Drive St. Louis, MO 63044-2588	26-0104	10/30/2009	MO
<b>FROM: SSM St. Clare Health Center</b> <b>TO: SSM Health St. Clare Hospital – Fenton</b> 1015 Bowles Avenue Fenton, MO 63026	26-0081	01/23/2006	MO
<b>FROM: SSM St. Joseph Health Center</b> <b>TO: SSM Health St. Joseph Hospital - St Charles</b> 300 First Capitol Drive St. Charles, MO 63301	26-0005	04/26/2005	MO
<b>FROM: Saint Louis University Hospital</b> <b>TO: SSM Health Saint Louis University Hospital</b> 3635 Vista at Grand Boulevard St. Louis, MO 63110 <b>P.O. Box 15250</b> <b>SSM-SLUH, INC</b>	26-0105	05/17/2005	MO
<b>FROM: St Mary's Medical Center</b> <b>TO: St. Vincent Evansville</b> 3700 Washington Avenue Evansville, IN 47740	15-0100	05/17/2005	IN
<b>FROM: Provena Mercy Medical Center</b> <b>TO: Presence Mercy Medical Center</b> 1325 North Highland Avenue	140174	07/15/2005	IL

Facility	Provider Number	Effective Date	State
Aurora, IL 60506			
<b>FROM: Resurrection Medical Center</b> <b>TO: Presence Resurrection Medical Center</b> 35 West Talcott Avenue Chicago, IL 60631	140117	04/12/2005	IL
<b>FROM: Provena Saint Joseph Hospital</b> <b>TO: Presence Saint Joseph Hospital</b> 77 North Airlite Street Elgin, IL 60123-4912	140217	05/11/2005	IL
<b>FROM: Provena Saint Joseph Medical Center</b> <b>TO: Presence Saint Joseph Medical Center</b> 333 North Madison Street Joliet, IL 60435-6595	140007	09/06/2005	IL
<b>FROM: Provena St. Mary's Hospital</b> <b>TO: Presence St. Mary's Hospital</b> 500 West Court Street Kankakee, IL 60901	140155	06/01/2005	IL
<b>FROM: Tenet Hospital Limited</b> <b>TO: Baylor Scott &amp; White Medical Center-White Rock</b> 9440 Poppy Drive Dallas, TX 75218	450678	09/07/2007	TX
<b>FROM: Foote Hospital</b> <b>TO: Henry Ford Allegiance Health</b> 205 North East Avenue Jackson, MI 49201	230092	11/03/2005	MI
<b>FROM: Rogue Valley Medical Center</b> <b>TO: Asante Rogue Regional Medical Center</b> 2825 East Barnett Road Medford, OR 97504	380018	05/05/2005	OR
<b>The following facilities have been removed.</b>			
Facility	Provider Number	Effective Date	State
Lee's Summit Medical Center 2100 SE Blue Parkway Lee's Summit, MO 64063	260190	05/17/2005	MO

**Addendum VIII:**

**American College of Cardiology’s National Cardiovascular Data Registry Sites (October through December 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>		
Our Lady of the Lake Ascension Community	Gonzales	LA

Facility	City	State
Hospital		
Newton Wellesley Hospital	Newton	MA
Gerald Champion Regional Medical	Alamogordo	NM
<b>The following facilities are terminations for this quarter.</b>		
Forest Hills Hospital Termination Requested	Forest Hills	NY
Central Maine Medical Center Termination Requested--Please see case 00325173. We have consolidated ICD to PID 288750.	Lewiston	ME
Forrest General Hospital Service/Facility Closed--This facility had duplicate accounts. The ICD Registry was merged with PID 266955. Access to the ICD Registry for PID 656089 will cease 12/31/17.	Hattiesburg	MS
Nicholas H. Noyes Memorial Hospital Termination Requested	Dansville	NY
University Campus of CHI Health CUMC- Bergan Mercy Termination Requested	Omaha	NE
St. Joseph Regional Medical Center - South Bend Termination Requested-- Please see case 00325200. We have consolidated the ICD registry to PID 663672.	Mishawaka	IN
Willis Knighton Pierremont Termination Requested	Shreveport	LA
Union Hospital Termination Requested	Elkton	MD
Melbourne Same Day Surgery Termination Requested	Melbourne	FL
Integris Grove Hospital Termination Requested--Please see case 00325232. We are consolidating the ICD Account to PID 334434 so all registries are under one account.	Grove	OK

**Addendum IX: Active CMS Coverage-Related Guidance Documents (October through December 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 (October through December 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) (October through December 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 (October through December 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.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>. For questions or additional information, contact Linda Gousis, JD, (410-786-8616).

Facility	Provider Number	Date Approved	State
<b>The following facilities are new listings for this quarter.</b>			
Lovelace Medical Center 601 Dr. Martin Luther King Jr. Ave. NE Albuquerque, NM 87102	320009	10/09/2017	NM
JFK Medical Center 5301 South Congress Avenue Atlantis, FL 33462	100080	01/25/2017	FL
Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center 2100 Stantonsburg Road Greenville, NC 27834	340040	09/27/2017	NC
CHI St. Vincent Heart Clinic 2 St. Vincent Circle Little Rock, AR 72205	040007	11/22/2017	AR
Hillcrest Medical Center 1120 S. Utica Tulsa, OK 74104	370001	12/04/2017	OK
<b>The following facilities have editorial changes (in bold).</b>			
<b>FROM: Inova Fairfax Hospital</b> <b>TO: Inova Fairfax Medical Campus</b> 3300 Gallows Road Falls Church, VA 22042 <b>Joint Commission # 6351</b>	<b>490063</b>	<b>07/26/2017</b>	VA
Delray Medical Center, Inc 5352 Linton Boulevard Delray Beach, FL 33484 <b>Joint Commission # 5215</b>	100258	<b>08/17/2017</b>	FL

Facility	Provider Number	Date Approved	State
UT Southwestern Medical Center/William P. Clements Jr. University Hospital 6201 Harry Hines Boulevard Dallas, TX 75390 <b>Joint Commission #9013. Hospital previously listed as St. Paul Medical Center.</b>	450044	08/09/2017	TX
<b>New York Presbyterian – Columbia University Medical Center</b> 622 West 168th Street New York, NY 10032 <b>Joint Commission # 5838</b>	330101	09/24/2015	NY
University of Utah Hospital 50 N Medical Drive Salt Lake City, UT 84132 <b>Joint Commission # 9544</b>	460009	08/09/2017	UT
Northwestern Memorial Hospital 251 E Huron Street Chicago, IL 60611 <b>Joint Commission # 7267</b>	140281	08/19/2017	IL
Texas Heart Hospital of the Southwest DBA The Heart Hospital Baylor Plano 1100 Allied Drive Plano, TX 75093 <b>Joint Commission # 440319</b>	670025	08/23/2017	TX
North Carolina Baptist Hospital DBA Wake Forest Baptist Medical Center Medical Center Boulevard Winston Salem, NC 27157 <b>Joint Commission # 6571</b>	340047	08/19/2017	NC
Mayo Clinic 4500 San Pablo Road Jacksonville, FL 32224 <b>Joint Commission # 369946</b>	100151	10/04/2017	FL
Baylor University Medical Center at Dallas 3500 Gaston Avenue Dallas, TX 75246 <b>Joint Commission # 8993</b>	450021	11/01/2017	TX
Seton Medical Center Austin 1201 W 38th Street Austin, TX 78705 <b>Joint Commission # 8939</b>	450056	10/04/2017	TX
Emory University Hospital 1364 Clifton Road Atlanta, GA 30322 <b>Joint Commission # 6689</b>	110010	09/27/2017	GA
Thomas Jefferson University Hospital 111 South 11th Street Philadelphia, PA 19107 <b>Joint Commission # 6132</b>	390174	09/21/2017	PA
<b>FROM: Albert Einstein Medical</b>	390142	09/20/2017	PA

Facility	Provider Number	Date Approved	State
<b>Center</b> <b>TO: Einstein Medical Center Philadelphia</b> 5501 Old York Road Philadelphia, PA 19141 <b>Joint Commission # 6118</b>			
Lancaster General Hospital 555 North Duke Street Lancaster, PA 17602 <b>Joint Commission # 6086</b>	390100	10/04/2017	PA

### Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October through December 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):

- 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 (October through December 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,

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).

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

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

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

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