of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Measuring Worker Well-being for Total Worker Health—New—National Institute for Occupational Safety and Health (NIOSH)—Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As described in the Occupational Safety and Health Act of 1970 (PL 91–596), the mission of NIOSH is to conduct research and investigations on work-related disease and injury and to disseminate information for preventing identified workplace hazards (Sections 20 (a) (1) and (d), Attachment 1). NIOSH is requesting a one-year approval for this data collection.

Measuring worker well-being is the first step towards improving workplace policies, programs, and practices to promote prevention of disease and injury.

The Total Worker Health® Program within NIOSH has made worker well-being a key aspect of its mission. The Total Worker Health (TWH) Program encompasses policies, programs, and practices that integrate protection from work-related safety and health hazards with promotion of injury and illness prevention efforts to advance worker well-being. The goal of TWH is not only to prevent disease or injury, but also to promote a culture of safety and health and an enhancement of overall well-being.

In order to promote and enhance worker well-being it is first necessary to develop and validate instruments aimed at measuring the concept. This study is intended to generate data that can be used to validate a worker well-being survey instrument through testing of its psychometric properties. The survey includes questions on five domains of worker well-being including: worker evaluation and experiences with work; workplace physical environment and safety climate; organizational policies and culture; worker health status; and experiences outside of work (external context).

For this study, the survey instrument will be programmed into a web-based survey that will be administered online to an existing nationwide survey panel of employed adults (KnowledgePanel®) hosted by our vendor, GfK. De-identified data will be transmitted securely to RAND, and RAND researchers will analyze the data as a CDC contractor.

The survey will be fielded to approximately 1,025 respondents in the GFK panel, and the expected burden per respondent for reading the email and completing the survey is 15 minutes or 0.25 hours of their time. This will be a one-time survey and panelists will not be asked to respond to this survey again in the future. The total estimated burden hours are 385 for reading the recruitment email and responding to the survey. There are no costs to the respondent other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
GFK Panelists	Recruitment email	1,540	1	5/60	128
GFK Panelists	Worker Well-being survey	1,025	1	15/60	257
Total					385

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–27261 Filed 11–10–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9099–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2016

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2016, relating to the Medicare and Medicaid programs and other programs administered by CMS.

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

Addenda	Contact	Phone number
I CMS Manual Instructions	Ismael Torres	(410) 786–1864
II Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786–4481
III CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI Collections of Information	William Parham	(410) 786–4669
VII Medicare-Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786–2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786–7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786–8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	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: November 7, 2016.

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: November 13, 2015 (80 FR 70218), February 4, 2016 (81 FR 6009), May 9, 2016 (81 FR 28072) and August 5, 2016 (81 FR 51901). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (July through September 2016)

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 Medicare Internet Only Manual Publication Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 22.3, Effective October 1, 2016 use (CMS-Pub. 100-04) Transmittal No. 3561.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
100	Medicare Fee-for-Service Change Request Correction and Rescind Process Change Management Process (Electronic Change Information Management Portal
101	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (SNF) Certification and Recertification by Physicians for Extended Care Services Admission of Medicare Patients for Care and Treatment
Medicare Benefit Policy (CMS-Pub. 100-02)	
225	Ambulance Staffing Requirements Vehicle Requirements for Basic Life Support and Advanced Life Support Definition of Ambulance Services Ground Ambulance Services
226	Ambulance Staffing Requirements Vehicle Requirements for Basic Life Support and Advanced Life Support Definition of Ambulance Services
227	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 Prior Hospitalization and Transfer Requirements Three-Day Prior Hospitalization Three-Day Prior Hospitalization - Foreign Hospital Effect on Spell of Illness Medical Service of an Intern or Resident-in-Training Medical and Other Health Services Furnished to SNF Patients Services Furnished Under Arrangements With Providers Definition of Durable Medical Equipment
Medicare National Coverage Determination (CMS-Pub. 100-03)	
	None
Medicare Claims Processing (CMS-Pub. 100-04)	
3556	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes Stem Cell Transplantation Billing for Stem Cell Transplantation Billing for Autologous Stem Cell Transplants Billing for Allogeneic Stem Cell Transplants Stem Cell Transplantation
3557	July 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3558	Implement Operating Rules - Phase III ERA 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 CAQH CORE
3559	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for FY 2017
3560	Correction of Remark Code Information Preparation of Denial Notices Processing Initial Denial
3561	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 22.3, Effective October 1, 2016
3562	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
3563	New Waived Tests
3564	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3565	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Additional Instructions for the Implementation of Round 2 Recompete of the DMEPOS CBP and National Mail Order (NMO) Recompete Payment of a Part of a DMEPOS Item Payment for Capped Rental Items Items Payment for Repair and Replacement of Beneficiary-Owned Equipment
3566	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3567	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3568	Reopenings Update - Changes to Chapter 34 Reopenings and Revisions of Claim Determinations and Decisions – General Authority to Conduct a Reopening Reopenings Based on Clerical or Minor Errors and Omissions Telephone Reopenings - Required for A/B MACs (B) Only Informing the Provider Communities About the Telephone Reopenings Process Conducting the Telephone Reopening Monitoring the Telephone Reopening Timeframes to Reopen Claim Determinations Timeframes for Contractor Initiated Reopenings Timeframes for Party Requested Reopenings Timeframes for Adjudicator to Reopen Timeframes When a Party Requests an Adjudicator Reopen Their Decision Good Cause for Reopening Change in Substantive Law or Interpretative Policy
3569	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3570	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3571	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3572	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3573	October 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
3574	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3575	Update-Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Fiscal Year (FY) 2016 Annual Update Electroconvulsive Therapy (ECT) Payment
3576	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2017
3577	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3578	Multiple Procedure Payment Reduction (MPPR) on the Professional Component (PC) of Certain Diagnostic Imaging Procedures
3579	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3580	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3581	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3582	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3583	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction

3584	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3585	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3586	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3587	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3588	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3589	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3590	Changes to the Fiscal Intermediary Shared System (FISS) Inpatient Provider Specific File (PSF) for Low-Volume Hospital Payment Adjustment Factor and New Inpatient Prospective Payment System (IPPS) Pricer Output Field for Islet Isolation Add-on Payment
3591	October 2016 Integrated Outpatient Code Editor (I/OCE) Specifications Version 17.3
3592	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3593	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP): Additional Instructions for the Implementation of Round 2 Recompete of the DMEPOS CBP and National Mail Order (NMO) Recompete
3594	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2016 Update
3595	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October CY 2016 Update
3596	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3597	Healthcare Provider Taxonomy Codes (HPTCs) October 2016 Code Set Update
3598	October Quarterly Update for 2016 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
3599	Claim Status Category and Claim Status Codes Update
3600	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)
3601	October 2016 Update of the Ambulatory Surgical Center (ASC) Payment System
3602	October 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3603	2017 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update Payer Only Codes Utilized by Medicare
3604	Common Edits and Enhancements Modules (CEM) Code Set Update
3605	Instructions for Downloading the Medicare ZIP Code File for January 2017
3606	2017 Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
3607	Annual Clotting Factor Furnishing Fee Update 2017 Clotting Factor Furnishing Fee
3608	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3609	Annual Medicare Physician Fee Schedule (MPFS) Files Delivery and Implementation
3610	2017 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
3611	Influenza Vaccine Payment Allowances - Annual Update for 2016-2017 Season
3612	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct Errors and Omissions (SNF) Furnishing Services that are Subject to SNF Consolidated Billing Under an "Arrangement" With an Outside Entity Under Arrangements" Relationships Physician's Services and Other Professional Services Excluded From Part A PPS Payment and the Consolidated Billing Requirement Other Excluded Services Beyond the Scope of a SNF Part A Benefit Outpatient Surgery and Related Procedures - INCLUSION Decision Logic Used by the Pricer on Claims
3613	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3614	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for January 2017
3615	Update to Hepatitis B Deductible and Coinsurance and Screening Pap Smears Claims Processing Information Pneumococcal Pneumonia, Influenza Virus, and Hepatitis B Vaccines MSN Messages Remittance Advice Codes
3616	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity Instruction
3617	Implementation of New Influenza Virus Vaccine Code Table of Preventive and Screening Services Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes CWF Edits on A/B MAC (A) Claims CWF Edits on A/B MAC (B) Claims CWF Crossover Edits on A/B MAC (B) Claims
Medicare Secondary Payer (CMS-Pub. 100-05)	
	None
Medicare Financial Management (CMS-Pub. 100-06)	
270	Notice of New Interest Rate for Medicare Overpayments and Underpayments –4th Qtr Notification for FY 2016
271	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
272	Issued to a specific audience, not posted to Internet/Intranet due to

	Confidentiality of Instruction
Medicare State Operations Manual (CMS-Pub. 100-07)	
157	Revisions to the State Operations Manual (SOM) - Appendix PP – Guidance to Surveyors for Long Term Care Facilities
158	Revisions to the State Operations Manual (SOM) –Chapter 5 Survey Exit Conference and Report to the Provider/Supplier Task 7: Exit Conference Revisions to State Operations Manual (SOM) Appendix J, Part II – Interpretive Guidelines – Responsibilities of Intermediate Care Facilities for Individuals with Intellectual Disabilities and Exhibit 355, Probes and Procedures for Appendix J
159	Revisions to the State Operations Manual (SOM), Appendix I – Survey Procedures for Life Safety Code Surveys
160	Revisions to the State Operations Manual (SOM) Chapter 7
161	Revisions to the State Operations Manual (SOM) Chapter 7 Mandatory Immediate Imposition of Federal Remedies Criteria for Mandatory Immediate Imposition of Federal Remedies Effective Dates for Immediate Imposition of Federal Remedies Prior to the Facility's Correction of Deficiencies Responsibilities of the State Survey Agency and the CMS Regional Office when there is an Immediate Imposition of Federal Remedies Imposition of a Civil Money Penalty when a Facility is not allowed an Opportunity to Correct Enforcement Action That Must Be Taken 2 Facilities Given an Opportunity to Correct Deficiencies prior to the Immediate Imposition of Federal Remedies Factors That Must Be Considered When Selecting Remedies Category 2
Medicare Program Integrity (CMS-Pub. 100-08)	
663	Denial Codes for Missing or Insufficient Documentation No Response or Insufficient Response to Additional Documentation Reopening Claims with Additional Information or Denied Due to Late or No Submission of Requested Information Notifying the Provider Prepay Complex Provider Specific Review Prepay Complex Service Specific Review Postpay Complex Provider Specific Review Postpay Complex Service Specific Review
664	The Process of Prior Authorization Prior Authorization Prior Authorization of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Suppliers (DMEPOS)
665	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
666	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
667	Revisions to Instructions Regarding the Fraud Investigation Database (FID) and Other Program Integrity Procedures
668	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
669	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
670	Update of Payment Suspension Instructions
671	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
672	Documentation for Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) Claims for Replacement of Essential Accessories for Beneficiary-Owned Continuous Positive Airway Pressure (CPAP) Devices and Respiratory Assist Devices (RADs)
673	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
674	Duplicate Postpayment Claim Reviews Case Selection
675	Update to Chapter 4, Pub. 100-08
676	Clarification of Certain Policies in Pub. 100-08, Chapter 15 Regarding the Processing of Form CMS-855R Applications
677	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
26	QIO Manual Chapter 2 - Eligibility
Medicare Quality Improvement Organization (CMS- Pub. 100-10)	
	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
	None
Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)	
	None
Medicare Managed Care (CMS-Pub. 100-16)	
123	QIO Manual Chapter 2 - Eligibility
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
151	Shared System Enhancement 2015 Archive/Remove Inactive Medicare Demonstration Projects
152	Shared System Enhancement 2015 Archive/Remove Inactive Medicare Demonstration Projects
153	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
154	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
155	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity Instruction
156	Affordable Care Act Bundled Payments for Care Improvement Initiative – Recurring File Updates Models 2 and 4 January 2017 Updates
One Time Notification (CMS-Pub. 100-20)	
1679	Shared Savings Program (SSP) Accountable Care Organization (ACO) Qualifying Stay Edits
1680	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1681	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2014 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCH)

1682	Issued to a specific audience, not posted to Internet/ Intranet to Sensitivity of Instruction
1683	Shared Savings Program (SSP) Accountable Care Organization (ACO) Qualifying Stay Edits
1684	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1685	Update the Primary Insurer's Policy Number of the Insured Field to 17 Bytes on the Health Insurance Master Record (HIMR) Screen Found in the Medicare Secondary Payer (MSP) Auxiliary File.
1686	Part B Detail Line Expansion – MCS Phase 7
1687	Common Working File (CWF) to Locate Medicare Beneficiary Record and Provide Responses to Provider Queries
1688	Part B Detail Line Expansion – MCS Phase 2
1689	Update Common Working File (CWF) Editing to Not Allow Late Charge Billing by Prospective Payment System (PPS) Providers
1690	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1691	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1692	Remove Part B Batch Eligibility Process (HELG) from the Common Working File (CWF)1693
1693	Common Working File (CWF) to Remove Remaining Federal Tax Information (FTI) Received through the Internal Revenue Service (IRS), Social Security Administration (SSA), Centers for Medicare and Medicaid Services (CMS) Medicare Secondary Payer (MSP) Data Match Program from CWF.
1694	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1695	Fiscal Intermediary Shared System (FISS) Heath Information Technology for Economic and Clinical Health (HITECH) Quarterly Report
1696	Shared System Enhancement 2014 - Additional Removal of Obsolete Reports and On-Request Jobs from the ViPS Medicare System (VMS) – Implementation
1697	Reporting of All Recovery Auditor-Initiated Claim Adjustments and their Subsequent Adjustments for Periodic Interim Payment (PIP) Facilities
1698	Editing Update for Screening for Sexually Transmitted Infections
1699	Appropriate Use Criteria for Advanced Imaging – Analysis and Design
1700	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1701	Combined Common Edits/Enhancements (CCEM) Third Party Software Upgrades
1702	Section 504: Adding a Qualified Reader Preference in Alternate Formats
1703	Recovery Auditor Mass Adjustment and Reporting Process Enhancements – Analysis Only
1704	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1705	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1706	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front End Updates for January 2017
1707	eMSN and Alternate Format MSN Service Improvements
1708	Coding Revisions to National Coverage Determination (NCDs)
1709	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1710	Adding a Foreign Language Tagline Sheet to Medicare Summary Notices (MSNs)
1711	Medicare Appeals System (MAS) Level 1 Part A and Home, Heath, Hospice (HHH) Onboarding Effort
1712	Shared System Enhancement 2014 – Identification of Fiscal Standard System (FISS) Obsolete Reports - Analysis Only
1713	Editing Update for Screening for Sexually Transmitted Infections
1714	Shared System Enhancement 2014 – Identification of Fiscal Intermediary Standard System (FISS) Obsolete Reports - Analysis Only
1715	Updates to the 72X Type of Bill for Home and Self-Dialysis Training, Retraining, and Nocturnal Hemodialysis
1716	Affordable Care Act - Operating Rules - Requirements for Phase II and Phase III Compliance for Batch Processing
1717	Section 504: Adding a Qualified Reader Preference in Alternate Formats
1718	Common Working File (CWF) to Remove Remaining Federal Tax Information (FTI) Received through the Internal Revenue Service (IRS), Social Security Administration (SSA), Centers for Medicare and Medicaid Services (CMS) Medicare Secondary Payer (MSP) Data Match Program from CWF.
1719	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1720	Reporting of All Recovery Auditor-Initiated Claim Adjustments and their Subsequent Adjustments for Periodic Interim Payment (PIP) Facilities
1721	Adding a Foreign Language Tagline Sheet to Medicare Summary Notices (MSNs)
1722	Updating the Fiscal Intermediary Shared System (FISS) to Make Payment for Drugs and Biologicals Services for Outpatient Prospective Payment System (OPPS) Providers
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
58	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
59	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (July through September 2016)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register,** contact GPO at www.gpo.gov/fdsys. When ordering individual

copies, it is necessary to cite either the date of publication or the volume number and page number.

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

This information is available on our website at: http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-3Q16QPU.pdf

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

Addendum III: CMS Rulings (July through September 2016)

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

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

Addendum IV: Medicare National Coverage Determinations (July through September 2016)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. There were no updates that occurred in the 3-month period. This information is available at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2016)

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
G160070	Plasma Delipidation System	07/06/2016
G160123	Teosyal RHA Redensity (TPRL)	07/06/2016
G150157	LifeSeal Kit - LifeSeal Surgical Sealant and Delivery System (LifeSeal Applicator/LifeSeal Laparoscopic Applicator)	07/07/2016
G160128	SIR-Spheres microspheres brachytherapy device plus associated delivery accessories	07/08/2016
G160129	Embozene Microspheres	07/12/2016
G150266	Evoke Closed Loop Stimulator (CLS), Evoke eCLS, Evoke Percutaneous 12C Leads, Evoke Pocket Console (EPC), Evoke 12C Paddle Leads	07/13/2016
G160133	Trailblaze Pharos	07/13/2016
G160135	NUT IHC Companion Diagnostic Assay	07/13/2016
G160130	Biodegradable Temporizing Matrix	07/14/2016
G160139	Infuse Bone Graft/Mastergraft Strip	07/22/2016
G160017	X-Seal 6F Vascular Closure Device	07/26/2016

IDE	Device	Start Date
G160034	Mirabilis System	07/26/2016
G160141	MAGE-A10 Immunohistochemistry (IHC) Clinical Trial Assay	07/26/2016
G160145	JIB System	07/29/2016
G160150	CERAMENT G	08/03/2016
G160026	Medtronic Valiant TAAA Stent Graft System	08/04/2016
G160153	Zepto	08/05/2016
G150186	Sir-Sphere Microspheres	08/09/2016
G160159	Echopulse High Intensity Focused Ultrasound Device	08/12/2016
G160155	Deep Brain Stimulation Surgery for Treatment of Focal Hand Dystonia	08/17/2016
G160157	tteris Antimicrobial Skin & Wound Cleanser	08/18/2016
G160161	Cortical Stimulation	08/19/2016
G160162	MagVenture MagPro X100 with MagOption Magnetic Stimulator, 230V C-B60 Butterfly Coil Coil COOL-B64 A/P (dynmaic cooled butterfly active & sham coil)	08/19/2016
G160170	LINX Reflux Management System	08/19/2016
G160158	6 Month Double-Blind Randomized Placebo-Controlled Trial to Evaluate the Safety and Efficacy of Small Particle Hyaluronic Acid to Treat Acne Scars Located on the Cheeks and Forehead	08/25/2016
G160165	BreathID MCS System ^{13}C-Methacetin Breath Test (MBT)	08/26/2016
G160171	WATCHMAN Left Atrial Appendage Closure (LAAC) Device	08/26/2016
G130156	NEURAL ENABLED PROSTHESIS (NEP)	08/31/2016
G160146	45mm Tongue Implant, 55mm Tongue Implant, 65mm Tongue Implant, 75mm Tongue Implant, Tongue Implanter Kit	09/01/2016
G160173	M6-C Artificial Cervical Disc	09/02/2016
G160178	Ventana DLL3 (SC16.65) IHC Assay	09/07/2016
G150244	Wireless Cardiac Stimulation System, WiCS-LV System, WiCS, WiSE™	09/09/2016
G160177	Arctic Front Advance Cardiac CryoAblation Catheter; Freezor MAX Cardiac CryoAblation Catheter	09/09/2016
G160101	Cerene Cryotherapy Device	09/12/2016
G160085	Chocolate Touch Paclitaxel Coated PTA Balloon Catheter	09/16/2016
G160132	GE Datex-Ohmeda Aisys CS2 Anesthesia System with Optional Et Control Feature	09/16/2016
G160184	GelrinC Cartilage Repair Device	09/22/2016
G160182	Medtronic TAAA Debranching Stent Graft System	09/23/2016
G160183	INTRAVASCULAR TEMPERATURE MANAGEMENT (IVTM) SYSTEM QUATTRO CATHETER	09/23/2016
G160096	Therasphere microspheres	09/26/2016
G160188	SUBCUTANEOUS MEDIAN NERVE NEUROMODULATION FOR DRUG-TREATMENT RESISTANT HYPERTESION	09/29/2016
G160185	Jarvik 2015 Ventricular Assist System	09/30/2016
G160190	AMPLATZER Duct Occluder II Additional Sizes	09/30/2016

Addendum VI: Approval Numbers for Collections of Information (July through September 2016)

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

Addendum VII: Medicare-Approved Carotid Stent Facilities, (July through September 2016)

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
The following facilities are new listings for this quarter.			
Newton-Wellesley Hospital 2014 Washington Street Newton, MA 02462-1607	220101	07/22/2016	MA
Temecula Valley Hospital 31700 Temecula Parkway Temecula, CA 92592	1679816201	07/22/2016	CA
Great Plains Health Heart & Vascular Center 601 West Leota Street PO Box 1167 North Platte, NE 69101	1700855533	09/07/2016	NE
The following facilities have editorial changes (in bold).			
FROM: Presbyterian Hospital of Dallas **TO: Texas Health Presbyterian Hospital of Dallas**	450462	05/10/2005	TX

Facility	Provider Number	Effective Date	State
18200 Walnut Hill Lane Dallas, TX 75231-4496			
FROM: Presbyterian Hospital of Denton **TO: Texas Health Presbyterian Hospital Denton** 3000 I-35N Denton, TX 76201	450743	01/10/2007	TX
FROM: Harris Methodist Fort Worth Hospital **TO: Texas Health Harris Methodist Hospital Fort Worth** 1301 Pennsylvania Avenue Fort Worth, TX 76104	450135	04/20/2005	TX
FROM: Arlington Memorial Hospital **TO: Texas Health Arlington Memorial Hospital** 800 West Randol Mill Road Arlington, TX 76012	450064	11/04/2005	TX
FROM: Harris Methodist HEB **TO: Texas Health Harris Methodist Hospital Hurst-Euless-Bedford** **251 Westpark Way** **Euless, TX 76040**	450639	05/16/2005	TX
Mercy Health Partners **1700 Clinton Street Muskegon, MI 49442**	23-0066	12/21/2005	MI
Manchester Memorial Hospital 71 Haynes Street Manchester, CT 06040	**070027**	03/09/2016	CT
FROM: Mercy Hospital **TO: Regional Hospital of Scranton** 746 Jefferson Avenue Scranton, PA 18501	390237	04/18/2006	PA
FROM: Wyoming Valley Health Care System **TO: Wilkes-Barre General Hospital** **575 North River Street** **Wilkes Barre, PA 18764**	390137	04/26/2005	PA
Mercy Hospital 3663 South Miami Avenue Miami, FL 33133	**10016700**	08/26/2005	FL

Addendum VIII:
American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2016)

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

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

Facility	City	State
The following facilities are new listings for this quarter.		
New York Community Hospital	Brooklyn	NY
Capital Medical Center	Olympia	WA
Bartow Regional Medical Center	Bartow	FL
Central Carolina (LifePoint)	Sanford	NC
CHI St. Luke's Health Memorial Livingston	Livingston	TX
Skypark Surgery Center	Torrance	CA
Victor Valley Global Medical Center	Victorville	CA
Chambersburg Hospital	Chambersburg	PA
Northeastern Nevada Regional Hospital	Elko	NV
Doctors Hospital of Manteca	Manteca	CA
North Hawaii Community Hospital	Kameula	HI

Facility	City	State
St. Luke's Monroe Hospital	Stroudsburg	PA
Heart and Rhythm Institute of Trinity	Elfers	FL
Olean General Hospital	Olean	NY
Monongahela Valley Hospital	Monongahela	PA
Kaiser Permanente Vallejo Cath Lab	Vallejo	CA
Sonora Regional Medical Center	Sonora	CA
Norton Women's and Kosair Children's Hospital	Louisville	KY

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2016)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2016)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2016)

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

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2016)

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
The following facilities are new listings for this quarter.			
University Hospitals and Health System 2500 North State Street Jackson, MS 39216	25-0001	08/17/2016	MS
Cleveland Clinic Florida 3100 Weston Road Weston, FL 33331	10-0289	05/27/2015	FL

Kaiser Sunnyside Medical Center 10180 SE Sunnyside Road Clackamas, OR 97015-9303	38-0091	09/14/2016	OR
The University of Kansas Hospital Authority 3901 Rainbow Boulevard Kansas City, KS 66160	17-0040	04/06/2016	KS
North Shore University Hospital 300 Community Drive Manhasset, NY 11030	33-0106	09/28/2016	NY

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2016)

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

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2016)

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

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2016)

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

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

[FR Doc. 2016–27315 Filed 11–10–16; 8:45 am]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Information Collection: Comprehensive Child Welfare Information System

Notice

The Office of Management and Budget (OMB) has assigned approval number 0970–0463 to the Comprehensive Child Welfare Information System (CCWIS) Final Rule (81 FR 35450, published June 2, 2016) information collection. The CCWIS Final Rule describes an optional child welfare information system. States and tribes electing to build a CCWIS must collect and report certain information to the Administration for Children and Families regarding their CCWIS plans. The information collection described in the Final Rule includes:

- The automated function list (45 CFR 1355.52(i)(1)(ii)–(iii) and (i)(2))
- The data quality plan (45 CFR 1355.52(d)(5))
- The Notice of Intent (45 CFR 1355.52(i)(1))

The authority for the information collection expires on 10/31/2019 12:00:00 a.m.

Authority: 42 U.S.C. 620 *et seq.,* 42 U.S.C. 670 *et seq.;* 42 U.S.C. 1301 and 1302.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–27280 Filed 11–10–16; 8:45 am]
BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4169]

Edward Manookian (Also Known as Ed Manning): Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Edward Manookian from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Manookian was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Mr. Manookian was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Manookian failed to request a hearing. Mr. Manookian's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective November 14, 2016.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Enforcement, Food and Drug Administration, 12420 Parklawn Dr. (ELEM–4144), Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On August 28, 2015, the U.S. District Court for the Middle District of Tennessee entered judgment against Mr. Manookian for two counts of conspiracy to commit an offense against the United States, in violation of 18 U.S.C. 371.

FDA's finding that the debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Mr. Manookian was the President and owner of Melanocorp, Inc. (Melanocorp), a for-profit corporation that conducted operations in the Middle District of Tennessee, and his duties included overseeing the employees and operations of Melanocorp.

Melanotan II (MII) was a peptide, or series of amino acids, that was marketed, sold, and shipped by Melanocorp to customers in the United States and abroad. Mr. Manookian's company advertised MII, an unapproved new drug, as an injectable tanning product through an internet Web site. The Melanocorp Web site also advertised MII as being 100 percent U.S. made, whereas in fact some of the MII sold by Melanocorp was manufactured in and imported from China.

On or about August 30, 2007, Melanocorp received a warning letter from FDA expressing concern about Melanocorp's marketing of MII. The warning letter noted that, based on information and statements on the Melanocorp Web site, MII constituted a new drug under the FD&C Act that could not be introduced or delivered for introduction into interstate commerce without an FDA approved application. The warning letter concluded that the sale of MII without an FDA approved application violated the FD&C Act and instructed Mr. Manookian's company to take prompt action to correct the violations cited in the warning letter.

On or about September 17, 2007, after consulting with counsel, Mr. Manookian sent a letter to FDA stating that Melanocorp had stopped all promotion and sale of MII in the United States and had stopped taking orders for MII from U.S. residents.

On or about November 29, 2007, FDA sent a letter to an attorney representing Melanocorp, which reiterated that MII was considered by FDA to be an unapproved drug and warned that its introduction or delivery for introduction into interstate commerce would be a violation of the FD&C Act. The letter specifically stated that the sale of MII outside of the United States violated the FD&C Act.

On or about December 14, 2007, Mr. Manookian had a letter sent to FDA from his attorney confirming that Melanocorp had stopped taking orders for MII from U.S. residents. This letter also stated that Melanocorp did not disagree that FDA considered MII to be an unapproved new drug, but Mr. Manookian's position was that Melanocorp could lawfully export MII, regardless of its status as an unapproved new drug.

On or about December 28, 2007, FDA sent a letter to Mr. Manookian's attorney which reiterated that unapproved new drugs do not qualify for export.

Following receipt of the December 28, 2007, correspondence from FDA, Melanocorp continued to ship MII in interstate commerce. Melanocorp primarily sold MII to customers located abroad, but also shipped MII domestically on a more limited basis.

From on or about September 17, 2007, and continuing through in or about April 2009, Mr. Manookian conspired with others to defraud the United States by causing Melanocorp to ship MII to customers in the United States despite telling FDA that Melanocorp would not distribute or market MII in the United States.

As a result of these convictions, FDA sent Mr. Manookian by certified mail on