Subsequent regulations for these programs including the final HHS Notice of Benefit and Payment Parameters for 2014 and the Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 provide further reporting requirements. Based on experience with the first three years of data collection, we request the continuation of data collection and propose revisions to data elements being collected and the burden estimates for years four, five, and six. *Form Number:* CMS–10433 (OMB Control Number: 0938–1187); *Frequency:* Annually; *Affected Public:* Private sector (Business or other For-profits and Not-for-profit institutions); *Number of Respondents:* 26,951; *Total Annual Responses:* 26,951; *Total Annual Hours:* 235,153. (For policy questions regarding this collection contact Leigha Basini at 301–492–4380.)

Dated: July 28, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–18848 Filed 7–31–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9092–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2015

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 April through June 2015, 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	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI Collections of Information	Mitch Bryman	(410) 786–5258
VII Medicare-Approved Carotid Stent Facilities	Lori Ashby	(410) 786–6322
VIII American College of Cardiology—National Cardiovascular Data Registry Sites	Marie Casey, BSN, MPH	(410) 786–7861
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin	(410) 786–7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin	(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	Marie Casey, BSN, MPH	(410) 786–7861
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Marie Casey, BSN, MPH	(410) 786–7861
XIV Medicare-Approved Bariatric Surgery Facilities	Jamie Hermansen	(410) 786–2064
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786–8564
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS 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 July 27, 2015.

Kathleen Cantwell

Director, Office of Strategic Operations and Regulatory Affairs.

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: July 25, 2014 (79 FR 43475), November 14, 2014 (79 FR 68253), February 2, 2015 (80 FR 5537) and April 24, 2015 (80 FR 23013). For the purposes of this quarterly notice, 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 (April through June 2015)

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 Microvolt T-wave Alternans (MTWA), use Medicare National Coverage Determination (CMS-Pub. 100-03) Transmittal No. 182.

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)
91	Manual Updates to Clarify Requirements for Physician Certification and Recertification of Patient Eligibility for Home Health Services Recertifications for Home Health Services Content of the Physician's Certification Method and Disposition of Certifications for Home Health Services Certification and Recertification by Physicians for Home Health Services
92	Manual Updates to Clarify Requirements for Physician Certification and Recertification of Patient Eligibility for Home Health Services Recertifications for Home Health Services Content of the Physician's Certification Method and Disposition of Certifications for Home Health Services Certification and Recertification by Physicians for Home Health Services

Medicare Benefit Policy (CMS-Pub. 100-02)	
205	Updates on Hospice Election Form, Revocation, and Attending Physician Attending Physician Services Hospice Election Hospice Notice of Election Hospice Revocation Hospice Discharge Hospice Notice of Termination or Revocation Election, Revocation and Discharge
206	Private Contracting: Definition of Emergency Care Services and Appeals of Opt Out Determinations Appeals Definition of Emergency and Urgent Care Situations
207	Manual Updates to Clarify Requirements for Physician Certification and Recertification of Patient Eligibility for Home Health Services Home Health Prospective Payment System (HH PPS) National 60-Day Episode Rate Adjustments to the 60-Day Episode Rates Counting 60-Day Episodes Split Percentage Payment Approach to the 60-Day Episode Low Utilization Payment Adjustment (LUPA) Partial Episode Payment (PEP) Adjustment Discharge Issues Consolidated Billing Determination of Coverage Impact of Other Available Caregivers and Other Available Coverage on Medicare Coverage of Home Health Services Patient Confined to the Home Patient's Place of Residence Physician Certification for Medical and Other Health Services Furnished by Home Health Agency (HHA) Use of Oral (Verbal) Orders Under the Care of a Physician Physician Certification and Recertification of Patient Eligibility for Medicare Home Health Services Physician Certification Face-to-Face Encounter Supporting Documentation Requirements Physician Recertification Who May Sign the Certification or Recertification Physician Billing for Certification and Recertification Psychiatric Evaluation, Therapy, and Teaching Intermittent Skilled Nursing Care General Principles Governing Reasonable and Necessary Physical Therapy, Speech-Language Pathology Services, and Occupational Therapy Impact on Care Provided in Excess of "Intermittent" or "Part-Time" Care Counting Visits Under the Hospital and Medical Plans Services Covered Under the End Stage Renal Disease (ESRD) Program Medical and Other Health Services Furnished by Home Health Agencies Content of the Plan of Care
208	Manual Updates to Clarify Requirements for Physician Certification and Recertification of Patient Eligibility for Home Health Services
209	Updates on Hospice Election Form, Revocation, and Attending Physician Attending Physician Services Hospice Election Election, Revocation and Discharge Hospice Revocation Hospice Discharge Hospice Notice of Termination or Revocation Hospice Notice of Election
Medicare National Coverage Determination (CMS-Pub. 100-03)	
182	Microvolt T-wave Alternans (MTWA)
Medicare Claims Processing (CMS-Pub. 100-04)	
3231	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3232	Preventive and Screening Services — Update - Intensive Behavioral Therapy for Obesity, Screening Digital Tomosynthesis Mammography, and Anesthesia Associated with Screening Colonoscopy
3233	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3234	April 2015 Update of the Ambulatory Surgical Center (ASC) Payment System
3235	April 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS) Inpatient-only Services Use of HCPCS Modifier - PO Payment Window for Outpatient Services Treated as Inpatient Services
3236	Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update
3237	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3238	April 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS) Inpatient-only Services Use of HCPCS Modifier - PO Payment Window for Outpatient Services Treated as Inpatient Services
3239	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3240	Medicare Claims Processing Manual - Chapter 15, Section 40, Ambulance - Medical Conditions List Medical Conditions List and Instructions
3241	Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD) Claims Processing Requirements for TMVR for MR Services for Medicare Advantage (MA) Plan Participants Coding Requirements for TMVR for MR Claims Furnished on or After August 7, 2014 Claims Processing Requirements for TMVR for MR Services on Professional Claims Claims Processing Requirements for TMVR for MR Services on Inpatient

	Hospital Claims Transcatheter Mitral Valve Repair (TMVR)
3242	Remittance Advice Remark and Claims Adjustment Reason Code and Medicare Remit Easy Print and PC Print Update
3243	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3244	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3245	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3246	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
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3249	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3250	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3251	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3252	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3253	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3254	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2015 Update Average Sales Price (ASP) Payment Methodology
3255	Correction to the Multi-Carrier System (MCS) Editing on the Service Location National Provider Identifier (NPI) Reported for Anti-Markup and Reference Laboratory Claims Diagnostic Tests Subject to the Anti-Markup Payment Limitation Payment to Physician or Other Supplier for Diagnostic Tests Subject to the Anti-Markup Payment Limitation - Claims Submitted to A/B MACs (B) Billing for Diagnostic Tests (Other Than Clinical Diagnostic Laboratory Tests) Subject to the Anti-Markup Payment Limitation/Claims Submitted A/B MACs (B) Conditional Data Element Requirements for A/B MACs (B) and DMEMACs A/B MAC (B) Specific Requirements for Certain Specialties/Services Paper Claim Submission To A/B MACs (B) Electronic Claim Submission to A/B MACs (B) Items 14-33 - Provider of Service or Supplier Information Payment Jurisdiction for Services Subject to the Anti-Markup Payment Limitation
3256	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - July 2015
3257	July Quarterly Update for 2015 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
3258	July Quarterly Update for 2015 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
3259	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July CY 2015 Update
3260	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction Collection of Specimens
3261	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3262	Manual Update to Pub. 100-04, Chapter 1, to include Claims Submitted by Multiple DMEPOS Suppliers Exact Duplicates
3263	Inpatient Prospective Payment System (IPPS) Hospital Extensions per the Medicare Access and CHIP Reauthorization Act of 2015
3264	July 2015 Integrated Outpatient Code Editor (I/OCE) Specifications Version 16.2
3265	NCD20.30 Microvolt T-wave Alternans (MTWA) Messaging for MTWA Coding and Claims Processing for MTWA Microvolt T-wave Alternans (MTWA)
3266	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3267	New Waived Tests
3268	Corrections to the 2015 Home Health (HH) Pricer Program Decision Logic Used by the Pricer on Claims
3269	Quarterly Update of HCPCS Codes Used for Home Health Consolidated Billing Enforcement
3270	Implement Operating Rules - Phase III ERA EFT: CORE 360 Uniform Use of Claim Adjustment Reason Codes (CARC) and Remittance Advice Remark Codes (RARC) Rule - Update from CAQH CORE
3271	Common Edits and Enhancements Modules (CEM) Code Set Update
3272	Claim Status Category and Claim Status Codes Update
3273	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3274	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
3275	Quarterly Update to the Correct Coding Initiative (CCI) Edits, Version 21.3, Effective October 1, 2015
3276	Instructions for Downloading the Medicare ZIP Code File for October 2015
3277	July Quarterly Update for 2015 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
3278	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3279	July 2015 Update of the Ambulatory Surgical Center (ASC) Payment System
3280	July 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3281	Inpatient Prospective Payment System (IPPS) Hospital Extensions per the Medicare Access and CHIP Reauthorization Act of 2015
3282	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

3283	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April CY 2015 Update
3284	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
3285	Screening for Hepatitis C Virus (HCV) in Adults – Implementation of Additional Common Working File (CWF) and Shared System Maintainer (SSMs) Edits Common Working File (CWF) Edits Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN) Messages Institutional Billing Requirements
3286	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2016
3287	Revisions to Medicare Claims Processing Manual for Foreign, Emergency and Shipboard Claims Emergency and Foreign Hospital Services Services Rendered By Nonparticipating Providers Establishing an Emergency Coverage Requirements for Emergency Hospital Services in Foreign Countries Qualifications of an Emergency Services Hospital Services Furnished in a Foreign Hospital Nearest to Beneficiary's U.S. Residence Coverage of Physician and Ambulance Services Furnished Outside U.S. Claims for Services Furnished in Canada to Qualified Railroad Retirement Beneficiaries Claims from Hospital-Leased Laboratories Not Meeting Conditions of Participation Nonemergency Part B Medical and Other Health Services Elections to Bill for Services Rendered By Nonparticipating Hospitals Processing Claims Contractors Designated to Process Foreign Claims Contractor Processing Guidelines Medicare Approved Charges for Services Rendered in Canada or Mexico Accessibility Criteria Medical Necessity Time Limitation on Emergency and Foreign Claims Payment Denial for Medicare Services Furnished to Alien Beneficiaries Who Are Not Lawfully Present in the United States Appeals on Claims for Emergency and Foreign Services Payment for Services Received By Nonparticipating Providers Payment for Services from Foreign Hospitals Attending Physician's Statement and Documentation of Medicare Emergency Designated Contractors Model Letters, Nonparticipating Hospital and Emergency Claims Letter to Nonparticipating Hospital That Elected to Bill For Current Year Model Letter to Nonparticipating Hospital That Requests to Bill the Program Model Letter to Nonparticipating Hospital That Did Not Elect to Bill for Current Year Full Denial - Hospital-Filed or Beneficiary-Filed Emergency Claim Full Denial - Foreign Claim - Beneficiary Filed Denial - Military Personnel/Eligible Dependents Full Denial - Shipboard Claim - Beneficiary filed Partial Denial - Hospital-Filed or Beneficiary-Filed Emergency Claim
Medicare Secondary Payer (CMS-Pub. 100-05)	
111	None Issued to a specific audience, not posted to Internet /Intranet due to Sensitivity of Instruction
112	Inpatient Hospital Claims and Medicare Secondary Payer (MSP) Claims with Medicare Coinsurance Days and/or Medicare Lifetime Reserve Days Occurring in the Seventh to Fifteenth Years Payment Calculation for Inpatient Bills (MSPPAYAI Module) Return Codes
Medicare Financial Management (CMS-Pub. 100-06)	
250	Notice of New Interest Rate for Medicare Overpayments and Underpayments - 3rd Qtr. Notification for FY 2015
Medicare State Operations Manual (CMS-Pub. 100-07)	
137	Revisions to State Operations Manual (SOM) Appendices A, G, L and T related to Hospitals, Rural Health Clinics, Ambulatory Surgical Centers and Swing Bed
138	Revisions to State Operations Manual (SOM), Appendix W for Critical Access Hospitals
139	Revisions to the Medicare State Operations Manual (SOM), Chapter 2, Rural Health Clinic Certification
140	Revisions to Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services
Medicare Program Integrity (CMS-Pub. 100-08)	
589	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
590	Update of CMS-855A, Physician-Owned Hospital Reporting Via the CMS-855POH and Indirect Payment Procedure Registration Via the CMS-855C in Chapter 15 of Pub. 100-08 Registration Letters Submission of Registration Applications Processing of Registration Applications Disposition of Registration Applications Changes of Information and Other Registration Transactions Hospitals and Hospital Units
591	Revisions to Surety Bond Collection Policies Model Letters for Claims against Surety Bonds Claims against Surety Bonds
592	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
593	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
594	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
595	Comprehensive Error Rate Testing (CERT) Program Treatment of Power Mobility Device (PMD) and Repetitive Scheduled Non-Emergent Ambulance

	Transport Claims in the Prior Authorization Model CERT Program Treatment of Power Mobility Device (PMD) and Repetitive Scheduled Non-Emergent Ambulance Transport Claims in the Prior Authorization Model
596	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
597	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
598	Proof and Date of Delivery Supplier Documentation
599	Annual Improper Payment Reduction Strategy (IPRS)
600	Workload Reporting Prepay Complex Service Specific Review Prepay Complex Provider Specific Review
601	Review of Home Health Claims Home Health
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
	None
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)	
	None
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
	None
Demonstrations (CMS-Pub. 100-19)	
117	Affordable Care Act Bundled Payments for Care Improvement Initiative - Recurring File Updates Models 2 and 4 July 2015 Updates
118	Updates to the Model 4 Bundled Payments for Care Improvement (BPCI) Initiative to Clarify the Payment Calculation to Include New Technology Add-On Payments, Validate Only Claims with Medicare as Primary Payer, Allowing Medical Necessity Denial Claims to Process Effectively, and Correct Processing of Claims Submitted as Model 4 for Beneficiaries Determined to be Ineligible
119	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
One Time Notification (CMS-Pub. 100-20)	
1485	Continuation of Systematic Validation of Payment Group Codes for Prospective Payment Systems (PPS) Based on Patient Assessments
1486	Increasing Tax Withholding to 30% for IRS Federal Payment Levy Program (FPLP)
1487	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
1488	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2012 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCH)
1489	Analysis and Design for Part B Detail Line Expansion
1490	Identification of Obsolete Shared System Maintainer (SSM) Reports - FISS and VMS
1491	Identification of Obsolete Shared System Maintainer (SSM) On-Request Jobs – FISS and VMS
1492	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for July 2015
1493	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
1494	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
1495	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
1496	Modification to the Telehealth Originating Site Facility Fee Billing Requirements for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
1497	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for October 2015
1498	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
1499	Section 504: Implement National Medicare Summary Notices (MSNs) in Alternate Formats
1500	IDR Shared Systems Daily Claims Feeds Expansion to Accommodate Medical Review Data Elements
1501	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
1502	Analysis - Procedures for Undeliverable Medicare Summary Notices (MSNs)
1503	Health Insurance Portability and Accountability Act (HIPAA) EDI Front End Updates for July 2015
1504	ICD-10 Conversion/Coding Infrastructure Revisions/ICD-9 Updates to National Coverage Determinations (NCDs)--2nd Maintenance CR
1505	Analysis for Inserting a Pre-printed Sheet of Paper in Medicare Summary Notice (MSN)
1506	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
1507	HIGLAS Release 12 (R12) Upgrade and Organizational Transitions for A/B MACs - R12 Upgrade
1508	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2013 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCH)
1509	Analysis - Procedures for Undeliverable Medicare Summary Notices (MSNs)
1510	Award of Medicare Administrative Contractor (MAC) Contract for Jurisdiction M
1511	Issued to a specific, audience not to Internet/ Intranet due to a Sensitivity of Instruction
Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)	
41	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction

42	Payments to Long Term Care Hospitals that Do Not Submit Required Quality Data
43	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
44	Payments to Inpatient Rehabilitation Facilities That Do Not Submit Required Quality Data Payments to IRFs That Do Not Submit Required Quality Data
45	Payments to Hospice Agencies That Do Not Submit Required Quality Data
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (April through June 2015)

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-2Q15QPU.pdf

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

Addendum III: CMS Rulings

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 (April through June 2015)

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 list only the specific updates that have 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 (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
NCD20.30 Microvolt T-wave Alternans (MTWA)	NCD 20.30	R182	05/22/2015	01/13/2015
Screening for Hepatitis C Virus (HCV) in Adults – Implementation of Additional Common Working File (CWF) and Shared System Maintainer (SSMs) Edits	NCD 210.3 CPM 210.1	R3285	06/09/2015	06/02/2014

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2015)

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
G150041	Tricuspid Transcatheter Repair System Model 9900	04/01/2015
G150042	PIR System (Pyrocarbon Implant Replacement System)	04/01/2015
G150046	Transcatheter Mitral Valve Implantation System (TMVI)	04/09/2015
G150047	StimGuard Sacral Nerve Stimulator System	04/09/2015
G150051	PD-L1 IHC MSB0010718C PHARMDX KIT	04/16/2015
G150052	NUSURFACE Meniscus Implant Model 50035 To 50090 Lefts and Rights	04/16/2015
G150055	Oocyte Handling Medium (OHM) pre-maturation (OHMpremat) and maturation (OHMmat) media system	04/17/2015
G150016	AMPHORA Overactive Bladder System 3.0 MM (OAB Device)	04/22/2015
G150057	Gore Excluder Conformable AAA Endoprosthesis	04/23/2015
G150060	Vysis MET CDx FISH Kit	04/23/2015
G150054	Checkpoint Surgical Nerve Stimulator/Locator	04/24/2015
G150059	MED-EL Maestro	04/24/2015
G140133	Kona Medical Surround Sound System	04/24/2015
G140142	TransPyloric Shuttle System	05/01/2015
G150065	Normothermic Human Liver Perfusion Machine	05/01/2015
G150066	Cardiac Implantable Electronic Device Magnetic Resonance Imaging Registry (CIED-MRI Registry)	05/04/2015
G140216	Aries Device	05/06/2015
G150067	Lutonix A V Drug Coated Balloon Catheter Model 9010	05/06/2015
G150068	iTIND System	05/06/2015
G150070	NOVOTTF-100A Device	05/07/2015
G150072	Precision Spinal Cord Stimulator	05/08/2015
G150034	MECTA Spectrum 5000Q FEAST Device	05/08/2015
G150071	GORE Excluder Thoracoabdominal Brance Endoprosthesis	05/13/2015
G150073	Millar Mikro-Tip Pressure Catheter (Mikro-Cath)	05/14/2015
G150076	NovoCure/NovoTTF-100A System (Optune)	05/15/2015
G150079	Heartmate PHP (Percutaneous Heart Pump) System	05/20/2015
G140182	BioMimics 3D Stent System	05/21/2015
G150080	Medtronic ACTIV Primary Cell and Sensing (PC+S) Implantable Deep Brain Stimulation System	05/22/2015
G150021	Embozene Microspheres	05/27/2015
G150082	ReDS Wearable System	05/29/2015
G150086	Freedom Spinal Cord Stimulator System Model FR8A-RCV-A1, FR8A-RCV-B1; FR4A-RCV-A1; FR4A-RCV-B1; LBRD-915-2A-HF	05/29/2015
G1500087	Endovascular Repair of Descending Thoraco Abdominal Aortic Pathologies Using Physician Modified Endovascular Prosthesis	05/29/2015
G150089	Aquabeam Console Model REF 210101; Aquabeam Motorpack Model REF 210401; Aquabeam Foot Pedal Model REF 210701	05/29/2015
G150100	Fibroblast Growth Factor Receptor Inhibitor (FGRFI) Clinical Trial Assay	06/02/2015
G150092	SmartPatch PNS System For The Treatment of Back Pain	06/03/2015
G150093	Espiner EMP 400 GYN	06/03/2015
G150096	SIR-Spheres microspheres (Yttrium-90 Microspheres)	06/05/2015
G150107	LARIAT+ Suture Delivery System	06/18/2015
G150106	SITESEAL TM	06/19/2015
G150050	RESCUE-VT	06/19/2015
G150113	STAR S4 IR Excimer Laser System and iDesign Advanced WaveScan Studio for Wavefront-Guided PRK Treatment of Myopic Astigmatism	06/25/2015
G150117	Sinai Vein Stent Registry	06/25/2015
G140101	Raleve	06/25/2015
G150118	Activa PC Implantable Neurostimulation System, Activa SC Implantable Neurostimulation System, Activa RC Implantable Neurostimulation System	06/26/2015

Addendum VI: Approval Numbers for Collections of Information (April through June 2015)

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 Mitch Bryman (410-786-5258).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (April through June 2015)

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 Lori Ashby (410-786-6322).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Southside Hospital – North Shore LIJ Health System 301 East Main Street Bayshore, NY 11706	1043650625	04/14/2015	NY
Bristol Regional Medical Center – Wellmont CVA Heart Institute 1 Medical Park Boulevard Bristol, TN 37620	1124058615	04/21/2015	TN
Sanford Aberdeen Medical Center 2905 3rd Avenue Southeast Aberdeen, SD 57401	1235406455	09/03/2013	SD
Kendall Regional Medical Center 11750 Bird Road Miami, FL 33175	1710931522	05/18/2015	FL
Mercy Fitzgerald Hospital 1500 Landsdowne Avenue Darby, PA	390156	05/29/2015	PA
Beaumont Health System – Royal Oak 3601 W. 13th Mile Road Royal Oak, MI 48072	1689653305	05/29/2015	MI
Medical Center of Trinity 9330 State Road 54 Trinity, FL 34655	100191	06/15/2015	FL
San Juan Regional Medical Center 801 West Maple Street Farmington, NM 87401	1427058510	06/15/2015	NM
Editorial changes (in bold) for this quarter.			
FROM: University of Kansas Medical Center **TO: University of Kansas Hospital** 3901 Rainbow Boulevard Kansas City, KS 66160-7200	170040	05/02/2006	KS
FROM: Exempla St. Joseph Hospital **TO: St. Joseph Hospital** **FROM: 1835 Franklin Street** **Denver, CO 80218-1191** **TO: 1375 E 19th Avenue Denver, CO 80218**	060028	05/10/2005	CO
FROM: Southwest Florida Regional Medical Center **TO: Gulf Coast Medical Center** **13681 Doctors Way Fort Myers, FL 33912**	100220	02/17/2006	FL
FROM: Southern Maryland Hospital Center TO: MedStar Southern Maryland Hospital Center 7503 Surratts Road Clinton, MD 20735	**210062**	05/26/2005	MD
FROM: Sanford Medical Center **TO: Sanford Medical Center - Sioux Falls** 1305 W. 18th Street Sioux Falls, SD 57117-5039	430027	04/19/2005	SD
FROM: St. Lukes Episcopal Hospital **TO: Baylor St Luke's Medical Center** 6720 Bertner Avenue Houston, TX 77030	450193	03/30/2005	TX
FROM: Alegent Creighton Health Creighton University Medical Center **TO: CHI – Creighton University Medical Center** 601 North 30th Street Omaha, NE 68131-2197	280030	06/27/2005	NE
WellStar Cobb **3950 Austell Road Austell, GA 30106**	110143	06/27/2005	GA
WellStar Kennestone **677 Church Street Marietta, GA 30060**	110035	06/27/2005	GA

Addendum VIII:
American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2015)

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 Marie Casey, BSN, MPH (410-786-7861).

Facility	City	State
The following facilities are new listings for this quarter.		
Interfaith Medical Center	Brooklyn	NY
Auxilio Mutuo Hospital	San Juan	PR
University Medical Center Brackenridge	Austin	TX
MemorialCare Surgical Center Saddleback Memorial	Laguna Hills	CA
HIMA San Pablo Bayamon	Bayamon	PR
Seminole Medical Center	Seminole	OK
St. Anthony Regional Hospital & Nursing Home	Carroll	IA
Taylor Station Surgical Center	Columbus	OH
Cleveland Clinic Abu Dhabi	Abu Dhabi	
Samaritan Hospital	Troy	NY
Via Christi Hospital St. Teresa	Wichita	KS
Florida Hospital East Orlando	Orlando	FL
Florida Hospital Celebration	Orlando	FL
CHI Health St. Francis	Grand Island	NE
John D Archbold Memorial Hospital	Thomasville	GA
Guthrie Corning Hospital	Corning	NY
Saint Luke's Memorial Hospital	Ponce	PR
Saint Louise Regional Hospital	Gilroy	CA
Medical Center Alliance (HCA)	Fort Worth	TX
Waco Cardiology Cath Lab and Surgery Center	Waco	TX
Tyler Cardiac & Endovascular Surgery Center	Tyler	TX
The Heart and Vascular Surgery Center	Bryan	TX
Rockdale Medical Center	Conyers	GA
Westerly Hospital	Westerly	RI
Westlake Hospital	Melrose Park	IL

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2015)

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 April through June 2015 quarter. For questions or additional information, contact JoAnna Baldwin (410-786-7205).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2015)

There were no special one-time notices regarding national coverage provisions published in the April through June 2015 quarter. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (April through June 2015)

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 April through June 2015 quarter. 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 (April through June 2015)

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 that have occurred to the list of Medicare-approved facilities that meet our standards 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 Marie Casey, BSN, MPH (410-786-7861).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Community Heart and Vascular Hospital 8075 N Shadeland Avenue Indianapolis, IN 46250	150074	10/01/2014	IN
Editorial changes (in bold) for this quarter.			
South Broward Hospital District DBA Memorial Regional Hospital 3501 Johnson Street Hollywood, FL 33021	10-0038	08/20/2014	FL

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2015)

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 April through June 2015 quarter. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Marie Casey, BSN, MPH (410-786-7861).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2015)

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 April through June 2015 period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For

questions or additional information, contact Jamie Hermansen (410-786-2064).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2015)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the April through June 2015 quarter.

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. 2015–18904 Filed 7–31–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Supplemental Nutrition Assistance Program (SNAP) State Agency Performance Reporting Tool.

OMB No.: New Collection.

Description: State agencies administering a Supplemental Nutrition Assistance Program (SNAP) are mandated to participate in a computer matching program with the federal Office of Child Support Enforcement (OCSE). The outcomes of the computerized comparisons with information maintained in the National Directory of New Hires (NDNH) provide the state SNAP agencies with information to help administer their programs and determine an individual's eligibility. State agencies must enter into a computer matching agreement and adhere to its terms and conditions, including providing OCSE with annual performance outcomes attributable to the use of NDNH information.

The Office of Management and Budget (OMB) requires OCSE to periodically report performance measurements demonstrating how NDNH information supports OCSE's strategic mission, goals, and objectives. OCSE will provide the annual SNAP performance outcomes to OMB.

The information collection activities for the SNAP performance reports are authorized by: (1) Subsection 453 (j)(10) of the Social Security Act (42 U.S.C. 653(j)(10)), which allows the Secretary of the U.S. Department of Health and Human Services to disclose information maintained in the NDNH to state agencies administering SNAP under the Nutrition Act of 2008, as amended by the Agriculture Act of 2014; (2) the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 (5 U.S.C. 552a), which sets for the terms and conditions of a computer matching program; and (3) the Government Performance and Results Modernization Act of 2010 (Pub. L. 111–352), which requires agencies to report program performance outcomes to OMB and for the reports to be available to the public.

Respondents: State SNAP Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (SNAP agencies)	Number of responses per respondent	Average burden hours per response	Total burden hours
SNAP Agency Matching Program Performance Reporting Tool	52	1	1.625	84

Estimated Total Annual Burden Hours: 84.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–18952 Filed 7–31–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2016

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2016 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Amendments of 2013 (ADUFA III), authorizes FDA to collect user fees for certain animal drug applications and supplements, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2016.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplements; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts established for years after FY 2014 are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA