performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 3, 2017.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to http://www.regulations.gov. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:


2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT:
William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see ADDRESSES).

CMS–381 Identification of Extension Units of Medicare Approved Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP) Providers and Supporting Regulations

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Identification of Extension Units of Medicare Approved Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP) Providers and Supporting Regulations; Use: The provider uses the form to report to the state survey agency extension locations that it has added since the date of last report. The form is used by the state survey agencies and by our regional offices to identify and monitor extension locations to ensure their compliance with the federal requirements for the providers of outpatient physical therapy and speech-language pathology services. Form Number: CMS–381 (OMB control number: 0938–0273); Frequency: Annually; Affected Public: Private Sector; Business or other for-profit and not-for-profit institutions; Number of Respondents: 2,161; Total Annual Responses: 2,161; Total Annual Hours: 540. (For policy questions regarding this collection contact Sarah Cahrendorf at 410–786–3112.)

Dated: August 1, 2017.
William N. Parham, III, Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

FR Doc. 2017–16483 Filed 8–3–17; 8:45 am
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9104–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April through June 2017

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other Federal Register notices that were published from April through June 2017, relating to the Medicare and Medicaid programs and other programs administered by CMS.

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

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<td>Ismael Torres</td>
<td>(410) 786–1864</td>
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<td>Terri Plumb</td>
<td>(410) 786–4481</td>
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<td>Tiffany Lafferty</td>
<td>(410) 786–7548</td>
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<td>IV Medicare National Coverage Determinations</td>
<td>Wanda Belle, MPA</td>
<td>(410) 786–7491</td>
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<td>V FDA-Approved Category B IDEs</td>
<td>John Manlove</td>
<td>(410) 786–6677</td>
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<td>VI Collections of Information</td>
<td>William Parham</td>
<td>(410) 786–4699</td>
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<td>Sarah Fulton, MHS</td>
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<td>VIII American College of Cardiology-National Cardiovascular Data Registry Sites</td>
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<td>JoAnna Baldwin, MS</td>
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<td>JoAnna Baldwin, MS</td>
<td>(410) 786–7205</td>
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<td>XI National Oncologic Positron Tomography Registry Sites</td>
<td>Stuart Caplan, RN, MAS</td>
<td>(410) 786–6564</td>
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<td>Linda Gousis, JD</td>
<td>(410) 786–8616</td>
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<td>Sarah Fulton, MHS</td>
<td>(410) 786–2749</td>
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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.


Kathleen Cantwell,
Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120–01–C
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: August 5, 2016 (81 FR 51901), November 2016 (81 FR 79489), February 23, 2017 (82 FR 11456), and May 5, 2017 (82 FR 21241). 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 2017)

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

How to Obtain Manuals

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

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

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) use CMS-Pub. 100-03 Transmittal No. 196.

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.

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3745 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction


3747 Payment for Moderate Sedation Services

3748 Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) Edits, Version 23.2, Effective July 1, 2017

3749 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3750 New Fields in the Fiscal Intermediary Shared System (FISS) Inpatient and Outpatient Provider Specific Files (PSF)

3751 Two New “K” Codes for Therapeutic Continuous Glucose Monitors

3752 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

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3754 Implementation of New Influenza Virus Vaccine Code Table of Preventive and Screening Services Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes

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3756 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3757 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3758 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

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3760 July Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule

3761 Screening for Hepatitis B Virus (HBV) Infection Screening for Hepatitis B Virus (HBV) Institutional Billing Requirements Professional Billing Requirements Diagnosis Code Reporting Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Messages

3762 New Physician Specialty Code for Advanced Heart Failure and Transplant Cardiology, Medical Toxicology, and Hematopoietic Cell Transplantation and Cellular Therapy Physician Specialty Codes

3763 Table of Preventive and Screening Services Deductible and Coinsurance

3764 Qualified Medicare Beneficiary Indicator in the Medicare Fee-For-Service Claims Processing System

3765 Modifications to the Common Working File (CWF) In Support of the Coordination of Benefits Agreement (COB/A) Crossover Process Claims Crossover Disposition and Coordination of Benefits Agreement By-Pass Indicators

3766 Screening for the Human Immunodeficiency Virus (HIV) Infection Healthcare Common Procedure Coding System (HCPCS) for HIV Screening Tests Billing Requirements Payment Method Diagnosis Code Reporting Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes (CARCs)

3767 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3768 April Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule

3769 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3770 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3771 New Waived Tests

3772 Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - July CY 2017 Update

3773 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3774 Changes to the Payment Policies for Reciprocal Billing Arrangements and Fee-For-Time Compensation Arrangements (formerly referred to as Locum Tenens) and Payment Under Reciprocal Billing Arrangements - Claims Submitted to A/B MACs Part B Payment Under Fee-For-Time Compensation Arrangements (formerly referred to as Locum Tenens / Arrangements) - Claims Submitted to A/B MACs Part B Billing Procedures for Entities Qualified to Receive Payment on Basis of Reassignment - for A/B MAC Part B Processed Claims Correcting Unacceptable Payment Arrangements Tenens Arrangements)

3775 Two New “K” Codes for Therapeutic Continuous Glucose Monitors

3776 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

3777 July 2017 Integrated Outpatient Code Editor (IOCE) Specifications Version 18.2

3778 Screening for the Human Immunodeficiency Virus (HIV) Infection Healthcare Common Procedure Coding System (HCPCS) for HIV Screening Tests Billing Requirements Payment Method Diagnosis Code Reporting Medicare Summary Notice (MSN) and Claim Adjustment Reason Codes
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| July 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS) |
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| Common Edits and Enhancements Modules (CEM) Code Set Update |
| Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction |
| July 2017 Update of the Ambulatory Surgical Center (ASC) Payment System |
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| Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction |
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- 169 New to State Operations Manual (SOM) Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types

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- 710 Update to Pub. 100-08, Chapter 15 Federally Qualified Health Centers (FQHCs) Section 4 of the Form CMS-8551 Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information File Maintenance Approval Letter Guidance Model Approval Letter Denial Example #5 – Existing or Delinquent Overpayments

- 711 Update to Pub. 100-08, Chapter 15 Diabetes Self-Management Training (DSMT) Section 4 of the Form CMS-8551 Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information File Maintenance Approval Letter Guidance Model Approval Letter Denial Example #5 – Existing or Delinquent Overpayments

- 712 Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction

- 713 Scribe Services Signature Requirements

- 714 Comprehensive Error Rate Testing (CERT) File Layout for Social Security Number Removal Initiative (SSNRI)

- 715 Update to Pub. 100-08, Chapter 15 Federally Qualified Health Centers (FQHCs) Section 4 of the Form CMS-8551 Submission of Paper and Internet-based PECOS Certification Statements Processing Form CMS-855R Applications Electronic Funds Transfer (EFT) Payments and CHOWs Tie-In/Tie-Out Notices and Referrals to the State/RO Ambulatory Surgical Centers (ASCs)/Portable X-ray Suppliers (PXRS) Tie-In/Tie-Out Notices and Referrals to the State/RO Release of Information

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1820 Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1821 Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
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1830 Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1831 Introductory Letters for Suppliers and Providers Related to the Prior Authorization for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items
1832 Update FISS Editing to Include the Admitting Diagnosis Code Field
1833 Implementing the remittance advice messaging for the 20-hour weekly minimum for Partial Hospitalization Program services
1834 Analysis and Design Working Sessions for the Development of a Pre-Payment Common Additional Documentation Request (ADR) Letter
1835 Reason Codes 36233 and 36330 Bypass for Claims Submitted on the 72x Type of Bill for Services Provided to Beneficiaries with Acute Kidney Injury (AKI) and edits related to not separately payable drugs
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Addendum II: Regulation Documents Published in the Federal Register (April through June 2017)

Regulations and Notices

Regulations and notices are published in the daily Federal Register. To purchase individual copies or subscribe to the Federal Register, contact GPO at www.gpo.gov/fdsys. 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-2Q17QPU.pdf

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

Addendum III: CMS Rulings
(April through June 2017)

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

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

Addendum IV: Medicare National Coverage Determinations
(April through June 2017)

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

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

### Table: NCDs

<table>
<thead>
<tr>
<th>Title</th>
<th>NCDM Section</th>
<th>Transmittal Number</th>
<th>Issue Date</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>Screening for Hepatitis B Virus (HBV) Infection</td>
<td>210.6</td>
<td>197</td>
<td>04/28/2017</td>
<td>09/28/2016</td>
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<tr>
<td>Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis</td>
<td>150.13</td>
<td>196</td>
<td>05/22/2017</td>
<td>12/08/2016</td>
</tr>
</tbody>
</table>

### Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2017)

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

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 *Federal Register* (62 FR 19328).

<table>
<thead>
<tr>
<th>IDE</th>
<th>Device</th>
<th>Start Date</th>
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<tbody>
<tr>
<td>G170059</td>
<td>BREATHID MCS</td>
<td>04/05/2017</td>
</tr>
<tr>
<td>G160267</td>
<td>Revolution Peripheral Atherectomy System</td>
<td>04/05/2017</td>
</tr>
<tr>
<td>G170058</td>
<td>Panoramic in ECGi in Patients with Recurrent AF after PV Isolation</td>
<td>04/06/2017</td>
</tr>
<tr>
<td>G170060</td>
<td>Fectoscopic Repair of Myelomeningocele (MMC) in Fetuses with Isolated Spina Bifida</td>
<td>04/07/2017</td>
</tr>
<tr>
<td>G170027</td>
<td>AquaBeam System Water II</td>
<td>04/10/2017</td>
</tr>
<tr>
<td>G170064</td>
<td>INDIIGO Aspiration System</td>
<td>04/13/2017</td>
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<tr>
<td>G170065</td>
<td>Panoramic ECGi to guide Ablation of Non-Paroxysmal AF: Effect of Butylide on AF Source Location and Organization</td>
<td>04/13/2017</td>
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<tr>
<td>G170066</td>
<td>JET-PCB Trial</td>
<td>04/13/2017</td>
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<tr>
<td>G170067</td>
<td>Intramuscular Needle Ablation for the Treatment of Refractory Ventricular Arrhythmias</td>
<td>04/13/2017</td>
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<td>G170068</td>
<td>CardioMEMS HF System</td>
<td>04/14/2017</td>
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<tr>
<td>G170071</td>
<td>Embosephore Microspheres</td>
<td>04/20/2017</td>
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<tr>
<td>G160156</td>
<td>LimFlow System</td>
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</tr>
<tr>
<td>G170073</td>
<td>Osia System</td>
<td>04/21/2017</td>
</tr>
<tr>
<td>G160257</td>
<td>Princess FILLER Lidocaine</td>
<td>04/26/2017</td>
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<tr>
<td>G170078</td>
<td>Avinger's Pantheris Atherectomy Catheter</td>
<td>04/27/2017</td>
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<tr>
<td>G170079</td>
<td>NovoTTF-200A (TTFields)</td>
<td>04/30/2017</td>
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<tr>
<td>G160224</td>
<td>Countour PVA, Embosephore and Embozene Particles</td>
<td>05/02/2017</td>
</tr>
<tr>
<td>BB17426</td>
<td>CliniMACS TCRalpha-beta/CD19 Combined Depletion System</td>
<td>05/02/2017</td>
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<tr>
<td>G160227</td>
<td>Svelte Sirolimus-Eluting Coronary Stent</td>
<td>05/03/2017</td>
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<tr>
<td>G170085</td>
<td>Guardant360 Cdx Test</td>
<td>05/03/2017</td>
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<tr>
<td>G170087</td>
<td>Osia System</td>
<td>05/03/2017</td>
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<tr>
<td>G150110</td>
<td>Emerval Lips</td>
<td>05/05/2017</td>
</tr>
<tr>
<td>G170090</td>
<td>Artimes pro Balloon Dilation Catheter</td>
<td>05/08/2017</td>
</tr>
<tr>
<td>G170049</td>
<td>RADAR: Real-time electrogram Analysis for Drivers of ARrial fibrillation</td>
<td>05/09/2017</td>
</tr>
<tr>
<td>G170095</td>
<td>RADIJESSE (+) Lidocaine 1.5cc</td>
<td>05/11/2017</td>
</tr>
<tr>
<td>G170093</td>
<td>A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk, WNT-Driven Medulloblastoma Patients</td>
<td>05/12/2017</td>
</tr>
<tr>
<td>G170084</td>
<td>pammaCereP</td>
<td>05/16/2017</td>
</tr>
<tr>
<td>BB17455</td>
<td>Cytori Celution System</td>
<td>05/17/2017</td>
</tr>
<tr>
<td>G170098</td>
<td>JUVUERMED VOLBELLA XC for Correction of Infrabital Hollowing</td>
<td>05/18/2017</td>
</tr>
<tr>
<td>G160235</td>
<td>BuMA Supero Biodegradable Drug Coated Coronary Stent System</td>
<td>05/18/2017</td>
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<tr>
<td>G170102</td>
<td>Foundation Medicine Blood First Assay Screening Trial (BEAST) Clinical Trial Assay (CTA)</td>
<td>05/19/2017</td>
</tr>
<tr>
<td>G170105</td>
<td>Insulin Pump System with Predictive Low Glucose Suspend</td>
<td>05/26/2017</td>
</tr>
<tr>
<td>G170109</td>
<td>SPY Portable Handheld Imaging (SPY-PHI) System (HH0000); IC2000 (Indocyanine Green for Injection, USP)</td>
<td>05/26/2017</td>
</tr>
</tbody>
</table>
Addendum VI: Approval Numbers for Collections of Information (April through June 2017)

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, (April through June 2017)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/Medicare/ApprovedFacilities/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers.</td>
<td>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: <a href="http://www.cms.gov/Medicare/ApprovedFacilities/CASF/list.asp#TopOfPage">http://www.cms.gov/Medicare/ApprovedFacilities/CASF/list.asp#TopOfPage</a> For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).</td>
</tr>
<tr>
<td>Facility</td>
<td>Provider Number</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------</td>
</tr>
<tr>
<td>TO: Dell Seton Medical Center at The University of Texas 1500 Red River Street Austin, TX 78701</td>
<td></td>
</tr>
</tbody>
</table>

The following facilities are terminations for this quarter:

- San Ramon Regional Medical Center
  6001 Norris Canyon Road
  San Ramon, CA 94583
  050689 06/07/2005 CA

Addendum VIII:
American College of Cardiology’s National Cardiovascular Data Registry Sites (April through June 2017)

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

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

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

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2017)

CMS issued a guidance document on November 20, 2014 titled “Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document”. Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS’s implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDid=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).
Addendum X:
List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2017)

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

Addendum XI: National Oncologic PET Registry (NOPR) (April through June 2017)

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

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

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (April through June 2017)

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

There were no additions, deletions, or editorial changes 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).

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2017)

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

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

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

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2017)

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

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS’s minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBs in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilities/BariatricSurgery/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 (April through June 2017)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period. This information is available on our website at www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request


OMB No.: 0970–0181.

Description: Form OCSE–396 and Form OCSE–34 are financial reports submitted following the end of each fiscal quarter by grantees administering the Child Support Enforcement Program in accordance with plans approved under title IV–D of the Social Security Act. Submission of these forms enables grantees to meet their statutory and regulatory requirement to report program expenditures and child support collections, respectively, from the previous fiscal quarter.

States use Form OCSE–396 to report quarterly expenditures made in the previous quarter and to estimate program expenditures to be made and the incentive payments to be earned in the upcoming quarter. The Administration for Children and Families provides Federal funding to States for the Child Support Enforcement Program at the rate of 66 percent for all allowable and legitimate administrative costs of this program.

Tribes use OMB Form SF–425 to report quarterly expenditures made in the previous quarter. Form SF–425 is not included as part of this comment request.

ANNUAL BURDEN ESTIMATES

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<tr>
<th>Instrument</th>
<th>Number of respondents</th>
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<td>4</td>
<td>6</td>
<td>1,296</td>
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<tr>
<td>Form OCSE–34</td>
<td>114</td>
<td>4</td>
<td>14</td>
<td>6,384</td>
</tr>
</tbody>
</table>

As part of this request, minor changes are being proposed only in response to amendments to Federal regulations:

- 45 CFR 304.25(b) was amended to extend the quarterly reporting deadline for both reports from “30” to “45” days after the end of each fiscal quarter.
- 45 CFR part 95 was amended to require that all expenditures for a Statewide Child Support Enforcement System will now require an approved Advanced Planning Document (APD).

The necessary instructions are being amended in response to both changes.

Respondents: 54 States (including Puerto Rico, Guam, the Virgin Islands and the District of Columbia) for Forms OCSE–396 and OCSE–34 plus approximately 60 Tribes for Form OCSE–34.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding a meeting and will discuss recommendations regarding programs, policies, and research to promote effective, prevention, treatment and cure of HIV disease and AIDS. The meeting will be open to the public.

DATES: The Council meeting is scheduled to convene on Wednesday, August 30, 2017 from 9:00 a.m. to approximately 5:00 p.m. (ET). The meeting will be open to the public.

ADDRESSES: 200 Independence Avenue SW., Washington, DC 20201 in the Penthouse (eighth floor), Room 800.


SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996. In a memorandum, dated July 13, 2010, and under Executive Order 13703, dated July 30, 2015, the President gave certain authorities to the PACHA for implementation of the National HIV/AIDS Strategy for the United States (Strategy). PACHA is currently operating under the authority given in Executive Order 13708, dated September 30, 2015.

PACHA provides advice, information, and recommendations to the Secretary regarding programs, policies, and research to promote effective treatment, prevention, and cure of HIV disease and AIDS, including considering common co-morbidities of those infected with HIV as needed, to promote effective HIV prevention and treatment and quality services to persons living with HIV disease and AIDS.