

Solicitation of Public Comment

Written comments and suggestions from the public should address one or more of the following four points:

- (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

B. Purpose

The Federal Acquisition Regulation (FAR) clause at 52.236-13, Accident Prevention, requires Federal construction contractors to provide and maintain work environments and procedures which will safeguard the public and Government personnel, property, materials, supplies, and equipment exposed to contractor operations and activities; avoid interruptions of Government operations and delays in project completion dates; and control costs in the performance of the contract.

For these purposes on contracts for construction or dismantling, demolition, or removal of improvements, the contractor is required to provide appropriate safety barricades, signs, and signal lights; comply with the standards issued by the Secretary of Labor at 29 CFR part 1926 and 29 CFR part 1910; and ensure that any additional measures the contracting officer determines to be

reasonably necessary for the purposes are taken.

Whenever the contracting officer becomes aware of any noncompliance with these requirements or any condition which poses a serious or imminent danger to health or safety, the contracting officer shall provide a notice to the contractor and request immediate corrective action. Per FAR 36.513, the contracting officer should inform the Occupational Safety and Health (OSH) Administration (OSHA), or other cognizant Federal, State, or local officials, of instances where the contractor has been notified to take immediate action to correct serious or imminent dangers. With regard to recordkeeping, the OSH Act specifies that "[e]ach employer shall make, keep and preserve, and make available to the Secretary . . . such records . . . as the Secretary . . . may prescribe by regulation as necessary or appropriate for the enforcement of this Act. . . ." (29 U.S.C. 657(c)(1)). Accordingly, OSHA has received the Office of Management and Budget (OMB) clearance for a number of related OMB Control Nos.

When performance is on a Government facility or will involve work of a long duration or hazardous nature, before commencing the work, the contractor must submit a written proposed plan for implementing this clause, as required by alternate I of the clause. The plan shall include an analysis of the significant hazards to life, limb, and property inherent in contract work performance and a plan for controlling those hazards.

C. Annual Reporting Burden

- Respondents:* 362.
- Responses per Respondent:* 1.
- Total Annual Responses:* 362.
- Hours per Response:* 22.
- Total Burden Hours:* 7,964.
- Affected Public:* Businesses or other for-profit and not-for-profit institutions.
- Frequency:* On occasion.
- Obtaining Copies of Proposals:* Requesters may obtain a copy of the

information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 9000-0060, Accident Prevention Plans, in all correspondence.

Dated: April 23, 2019.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9116-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 2019

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from January through March 2019, relating to the Medicare and Medicaid programs and other programs administered by CMS.

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

Addenda	Contact	Phone No.
I. CMS Manual Instructions	Ismael Torres	(410) 786-1864
II. Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III. CMS Rulings	Tiffany Lafferty	(410) 786-7548
IV. Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V. FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI. Collections of Information	William Parham	(410) 786-4669
VII. Medicare -Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII. American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX. Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
X. One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI. National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII. Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan	(410) 786-3365
XIII. Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV. Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749

Addenda	Contact	Phone No.
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 website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers

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

III. How To Use the Notice

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

Dated: April 11, 2019.

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

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Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: May 4, 2018 (83 FR 19769), August 13, 2018 (83 FR 40043), November 2, 2018 (83 FR 55174) and February 19, 2019 (84 FR 4805). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (January through March 2019)

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 Updates Related to Home Health Certification and Recertification Policy Changes, use (CMS-Pub. 100-02) Transmittal No. 258.

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)	
	None
Medicare Benefit Policy (CMS-Pub. 100-02)	
255	Updates to Reflect Removal of Functional Reporting Requirements and Therapy Provisions of the Bipartisan Budget Act of 2018
256	Update to Intensive Cardiac Rehabilitation (ICR) Programs
257	Update to Publication 100-02 Provide Language-Only Changes for the New Medicare Card Project
258	Manual Updates Related to Home Health Certification and Recertification Policy Changes
Medicare National Coverage Determination (CMS-Pub. 100-03)	
212	Update to Pub. 100-03 to Provide Language-Only Changes for the New Medicare Card Project
213	National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICD)
214	National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS)

Medicare Claims Processing (CMS-Pub. 100-04)	
4192	Quarterly Update for the Temporary Gap Period of the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - April 2019
4193	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 25.1 Effective April 1, 2019
4194	Update to Publication (Pub.) 100-04 Chapter 25 to Provide Language-Only Changes for the New Medicare Card Project
4195	New Waived Tests
4196	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4197	Chapter 30 Revisions in Publication (Pub.) 100-04, Medicare Claims Processing Manual
4198	Skilled Nursing Facility Advance Beneficiary Notice of Non-Coverage (SNF ABN)
4199	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens
4200	2019 Durable Medical Equipment Prosthetics, Orthotics, and Supplies Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction List
4201	Update to Pub. 100-04 Chapter 1 to Provide Language-Only Changes for the New Medicare Card Project
4202	Update to Pub. 100-04 Chapters 8, 20, and 24 to Provide Language-Only Changes for the New Medicare Card Project
4203	Update to Pub. 100-04 Chapter 32 to Provide Language-Only Changes for the New Medicare Card Project
4204	January 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS)
4205	Update to Pub. 100-04 Chapter 15 to Provide Language-Only Changes for the New Medicare Card Project
4206	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4207	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4208	Calendar Year (CY) 2019 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
4209	Calendar Year (CY) 2019 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
4210	Update to Pub. 100-04 Chapter 10 to Provide Language-Only Changes for the New Medicare Card Project
4211	Update to Publication (Pub.) 100-04 Chapter 11 to Provide Language-Only Changes for the New Medicare Card Project
4212	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4213	April 2019 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
4214	Updates to Reflect Removal of Functional Reporting Requirements and Therapy Provisions of the Bipartisan Budget Act of 2018
4215	Issued to a specific audience, not posted to Internet/Intranet due to

	Confidentiality of Instructions
4216	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4217	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4218	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4219	Update to Pub. 100-04 Chapter 34 to Provide Language-Only Changes for the New Medicare Card Project
4220	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
4221	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4222	Update to Intensive Cardiac Rehabilitation (ICR) Programs
4223	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
4224	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4225	Update to Mammography Editing
4226	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4227	Independent Laboratory Billing of Laboratory Tests for End-Stage Renal Disease (ESRD) Beneficiaries and the Sunset of the CB Modifier
4228	Home Health (HH) Patient-Driven Groupings Model (PDGM) - Split Implementation
4229	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)—Clarification of Payment Rules and Expansion of International Classification of Diseases Tenth Edition (ICD-10) Diagnosis Codes
4230	Implementation of the Medicare Performance Adjustment (MPA) for the Maryland Total Cost of Care (MD TCOC) Model
4231	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4232	Update to Publication (Pub.) 100-04 Chapter 26 to Provide Language-Only Changes for the New Medicare Card Project
4233	Update to Publication (Pub.) 100-04 Chapters 4 and 17 to Provide Language-Only Changes for the New Medicare Card Project
4234	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB)--April 2019 Update
4235	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4236	Update to Publication (Pub.) 100-04 Chapter 3 to Provide Language-Only Changes for the New Medicare Card Project
4237	Update to the Internet-Only-Manual (IOM) Publication (Pub.) 100-04, Chapter 32, Section 12.1
4238	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
4239	Healthcare Provider Taxonomy Codes (HPTCs) April 2019 Code Set Update
4240	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions

4241	Instructions for Downloading the Medicare ZIP Code Files for July 2019
4242	April Quarterly Update for 2019 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
4243	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
4244	Home Health (HH) Patient-Driven Groupings Model (PDGM) - Split Implementation
4245	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
4246	Evaluation and Management (E/M) when Performed with Superficial Radiation Treatment
4247	Update to Publication 100-04 Chapters 2, 6, and 18 to Provide Language-Only Changes for the New Medicare Card Project
4248	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4249	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4250	Update to Chapter 30 in Publication (Pub.) 100-04 to Provide Language-Only Changes for the New Medicare Card Project
4251	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4252	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4253	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
4254	Ensuring Only the Active Billing Hospice Can Submit a Revocation
4255	April 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS)
4256	April 2019 Integrated Outpatient Code Editor (I/OCE) Specifications Version 20.1
4257	Implementation of the Medicare Performance Adjustment (MPA) for the Maryland Total Cost of Care (MD TCOC) Model
4258	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April 2019 Update
4259	The purpose of this Change Request (CR) is to provide billing instructions for hospital Part B inpatient services
4260	Update to Chapter 31 in Publication (Pub.) 100-04 to Provide Language-Only Changes for the New Medicare Card Project
4261	Update to the Payment for Grandfathered Tribal Federally Qualified Health Centers (FQHCs) for Calendar Year (CY) 2019
4262	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4263	April 2019 Update of the Ambulatory Surgical Center (ASC) Payment System
4264	July 2019 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
4265	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2019

4266	Quarterly Update to the National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) Edits, Version 25.2 Effective July 1, 2019
4267	Evaluation and Management (E/M) when Performed with Superficial Radiation Treatment
4268	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4269	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
4270	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
4271	Update to the Internet-Only-Manual (IOM) Publication (Pub.) 100-04, Chapters 1 and 3
4272	Correction of the Fiscal Year (FY) 2019 Inpatient Prospective Payment System (IPPS) Pricer
Medicare Secondary Payer (CMS-Pub. 100-05)	
125	Update to Publication (Pub.) 100-05 to Provide Language-Only Changes for the New Medicare Card Project
Medicare Financial Management (CMS-Pub. 100-06)	
310	Notice of New Interest Rate for Medicare Overpayments and Underpayments - 2nd Qtr Notification for FY 2019
311	Updating Chapter 3, Section 200, Limitation on Recoupment; Medicare Overpayments Manual, 2 of 4 CR
Medicare State Operations Manual (CMS-Pub. 100-07)	
186	Revisions to State Operations Manual (SOM) Appendix Z, Emergency Preparedness for All Provider and Certified Supplier Types
187	Revision to the State Operations Manual (SOM 100-07) Appendix Q
Medicare Program Integrity (CMS-Pub. 100-08)	
853	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
854	Local Coverage Determinations (LCDs)
855	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
856	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
857	Local Coverage Determinations (LCDs)
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860	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
861	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
862	Update to Chapter 15 of Publication (Pub.) 100-08
863	Local Coverage Determinations (LCDs)
864	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
865	Update to Chapter 15 of Publication (Pub.) 100-08
866	Update to Chapter 4, Section 4.11 in Publication (Pub.) 100-08

867	Update to Exhibit 16 - Model Payment Suspension Letters in Publication (Pub.) 100-08
868	Update to Chapter 4, Section 4.7 in Publication (Pub.) 100-08
869	Fraud Prevention System (FPS) Edit – FPS36- Enhancement to Denial for Multiple Ankle-Foot/Knee-Ankle-Foot Orthoses Frequency Limit (This CR Rescinds and Fully Replaces CR 10465.)
870	Manual Updates Related to Home Health Certification and Recertification Policy Changes
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
41	Update to Publication (Pub.) 100-09 to Provide Language-Only Changes for the New Medicare Card Project
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)	
217	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
218	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
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222	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
223	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
One Time Notification (CMS-Pub. 100-20)	
2218	ViPS Medicare System (VMS) Prepayment Review File
2219	Shared System Enhancement 2018: Enhance Common Working File (CWF) Internal Testing Facility (ITF) Response Records
2220	Direct Mailing Notification to MACs Regarding Addressing the Opioid Crisis
2221	Fiscal Intermediary Standard System (FISS) Prepayment Review Report
2222	Update to the Medicare Fee-For-Service (FFS) Companion Guides
2223	Multi-Carrier System (MCS) Prepayment Review File
2224	ViPS Medicare System (VMS) Prepayment Review File
2225	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions

2226	Synchronize the Common Working File (CWF) and Enrollment Data Base (EDB) Entitlement Data
2227	New State Code for CA, FL, LA, MI, MS, OH, PA, TN and TX
2228	Fiscal Intermediary Shared System (FISS) Enhancement of PC Print Billing Software
2229	Lock the Claim Term Date on File 41 - Analysis Only
2230	Removal of Quality Programs from the Medicare Physician Fee Schedule (MPFS) Disclosure Report
2231	Processing Veterans Administration (VA) Inpatient Claims Exempt from Present on Admission (POA) Reporting
2232	Revising the Remittance Advice Messaging for the 20-Hour Weekly Minimum for Partial Hospitalization Program (PHP) Services
2233	Shared System Enhancement 2018: Automate Health Insurance Master Record (HIMR) Lookup Within Common Working File (CWF)
2234	Utilizing Data from the USPS Secure Destruction Program to Suppress Mailing Medicare Summary Notices (MSNs) to Undeliverable Addresses
2235	Ensuring Organ Acquisition Charges Are Not Included in the Inpatient Prospective Payment System (IPPS) Payment Calculation
2236	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2237	Viable Information Processing Systems (ViPS) Medicare Systems (VMS) Changes to Accommodate National Provider Identifier Associations Analysis and Development
2238	Reduce/Eliminate Screen-Scraping for Shared Systems by Creating Transaction-based Access to Common Working File (CWF) Beneficiary Data - Analysis and Design
2239	Targeted Probe and Educate
2240	User CR: MCS - Print Report Edit/Audit and PJ/PL/PM Set-Up PJ/PL or PL/PM Segments
2241	Enhancing the Verification Process of Common Working File (CWF) Part A Provider Inquiries
2242	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2243	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)
2244	Multi-Carrier System (MCS) Analysis Change Request (CR) to create Application Program Interfaces (APIs) for Letter Writing
2245	Processing Instructions to Update the Standard Paper Remit (SPR)
2246	Expand Narrative File Message Number Range Implementation
2247	Analysis Call to Discuss Multi-Carrier System (MCS) Limitation When Quantity Allowed is Greater Than Quantity Billed
2248	Implementation to Exchange the list of Electronic Medical Documentation Requests (eMDR) for Registered Providers via the Electronic Submission of Medical Documentation (esMD) System
2249	Analysis on Systems to use Documentation Code References in Additional Documentation Request (ADR) Letters and to Include Non-Medical ADRs for Electronic Medical Documentation Requests (eMDRs) via the Electronic Submission of Medical Documentation (esMD) System

2250	User CR: ViPS Medicare System (VMS) changes to the IC4301 - RAC Reopenings and Appeals Tracking Report to Display the Current Appeal Level
2251	Utilizing the Blank Page on Odd-Numbered Medicare Summary Notices to Promote CMS Priorities
2252	Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)
2253	Implementation of Additional Contact with Providers in the Event of a Rejected Cost Report Filing
2254	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2255	Shared System Enhancement 2018: Rewrite Fiscal Intermediary Shared System (FISS) module FSSB6001, Common Working File (CWF) Unsolicited Response Function
2256	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
2257	User CR: MCS - Health Professional Shortage Area (HPSA) No Pay Remittances Should Not Be Sent for Do Not Forward (DNF) Provider
2258	User CR: MCS - Display Region on Select MCS Screens
2259	Modification of the MCS Claims Processing System Logic for Modifier 59, XE, XS, XP, and XU Involving the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) Column One and Column Two Codes
2260	User CR: MCS - Add MSP Confirmed Flag and Cost Avoid to History Screen, IDR, and other Files
2261	Direct Mailing Notification to MACs Regarding Addressing the Opioid Crisis
2262	Ensuring Organ Acquisition Charges Are Not Included in the Inpatient Prospective Payment System (IPPS) Payment Calculation
2263	Implementation of the Award for the Jurisdiction 8 (J-8) Part A and Part B Medicare Administrative Contractor (J8 A/B MAC)
2264	Implementation to Exchange the list of Electronic Medical Documentation Requests (eMDR) for Registered Providers via the Electronic Submission of Medical Documentation (esMD) System
2265	Revising the Remittance Advice Messaging for the 20-Hour Weekly Minimum for Partial Hospitalization Program (PHP) Services
2266	Revising the Remittance Advice Messaging for the 20-Hour Weekly Minimum for Partial Hospitalization Program (PHP) Services
2267	New State Code for CA, FL, LA, MI, MS, OH, PA, TN and TX
2268	Instructions Relating to the Self-Disallowance Requirement for Determining Jurisdiction over Appeals
2269	User CR: MCS - Health Professional Shortage Area (HPSA) No Pay Remittances Should Not Be Sent for Do Not Forward (DNF) Provider
2270	Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)
2271	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2017 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCHs)
2272	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions

2273	Revision to the Cost Report Acceptability Checklists
2274	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instructions
Medicare Quality Reporting Incentive Programs (CMS-Pub. 100-22)	
82	Update to Publication 100-22 to Provide Language-Only Changes for the New Medicare Card Project
Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)	
	None

Addendum II: Regulation Documents Published in the Federal Register (January through March 2019)

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-1Q19QPU.pdf>

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

Addendum III: CMS Rulings (January through March 2019)

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

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

Addendum IV: Medicare National Coverage Determinations (January through March 2019)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. For the purposes of this quarterly notice, we are providing only the specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published 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).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)	NCD 20.4	213	02/15/2019	02/15/2018

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January through March 2019) (Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (January through March 2019)

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, (January through March 2019)

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

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
West Houston Medical Center 12141 Richmond Avenue Houston, TX 77082	450644	01/10/2019	TX
Pinnacle Hospital 9301 Connecticut Drive Crown Point, IN 46307	1801969670	03/05/2019	IN
The following facilities have editorial changes (in bold).			
FROM: Florida Hospital North Pinellas TO: AdventHealth North Pinellas 1395 South Pinellas Avenue Tarpon Springs, FL 34689	100055	01/20/2009	FL
FROM: St. Anthony's Medical Center TO: Mercy Hospital South 10010 Kennerly Road St. Louis, MO 63128	260077	06/01/2005	MO
Providence-Providence Park	230019	06/27/2005	MI

Facility	Provider Number	Effective Date	State
Hospital 16001 West Nine Mile Road Southfield, MI 48075 Other Information: Providence -Providence Park Hospital's second facility 47601 Grand River Novi, MI 48374			
FROM: Pocono Medical Center TO: LeHigh Valley Hospital – Pocono 206 East Brown Street East Stroudsburg, PA 18301	390201	09/25/2006	PA
FROM: Munroe Regional Medical Center TO: AdventHealth Ocala 1500 S.W. 1st Avenue Ocala, FL 34474	100062	05/23/2005	FL
The following facility has been removed.			
VHS Brownsville Hospital DBA Valley Baptist Medical Center -- Brownsville 1040 West Jefferson Street Brownsville, TX 78520	450028	03/09/2016	TX

Addendum VIII:**American College of Cardiology's National Cardiovascular Data Registry Sites (January through March 2019)**

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

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

Addendum IX: Active CMS Coverage-Related Guidance Documents (January through March 2019)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy

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

Addendum X:**List of Special One-Time Notices Regarding National Coverage Provisions (January through March 2019)**

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) (January through March 2019)

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/MedicareApprovedFacilities/NOPR/list.asp#TopOfPage>. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (January through March 2019)

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

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>. For questions or additional information, contact David Dolan, JD, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
The following facilities are new listings for this quarter.				
TriStar Centennial Medical Center 2300 Patterson Street Nashville, TN 37203 Other information: Joint Commission ID # 7888	440161	12/12/2018		TN
Deborah Heart and Lung Center 200 Trenton Rd Browns Mills, NJ 08015 Other information: DNV GL Certificate #: 283578-2019-VAD	310031	02/05/2019		NJ

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
Geisinger Medical Center 100 North Academy Avenue Danville, PA 17822 DNV GL Certificate #: 283581-2019-VAD	390006	02/06/2019		PA
The following facilities have editorial changes (in bold).				
FROM: Ohio State University TO: Ohio State University Hospitals 410 W 10th Avenue Columbus, OH 43210 Other information: Joint Commission ID #: 7029 VAD Previous Re-certification Dates: 2008-12-19; 2010-10-19; 2012-10-11; 2014-09-09; 2016-10-04	360085	11/12/2003	10/24/2018	OH
St. Francis Hospital 100 Port Washington Boulevard Roslyn, NY 11576 Other information: Joint Commission ID #: 5860	330182	11/09/2016	11/14/2018	NY
NorthShore University Health System 1301 Central Street, Suite 300 Evanston, IL 60201 Other Information: Joint Commission ID #: 7343	140010	10/26/2016	11/15/2018	IL

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
Barnes-Jewish Hospital 1 Barnes Jewish Hospital Drive Saint Louis, MO 63110 Other information: Joint Commission ID #: 8387 VAD Previous Re-certification Dates: 2009-02-13; 2011-08-19; 2013-08-30; 2015-10-02; 2017-11-10	260032	03/06/2007	11/07/2018	MO
The Medical Center of Central Georgia 777 Hemlock Street Macon, GA 312014440 W. 95th Street Oak Lawn, IL 60505 Other information: Joint Commission ID #: 6707 VAD Previous Re-certification Dates: 2014-10-21; 2016-11-22	110107	11/08/2012	11/14/2018	IL
FROM: Tufts-New England Medical Center TO: Tufts Medical Center 800 Washington Street Boston, MA 02111 Other information: Joint Commission ID #: 5518 VAD Previous Re-certification Dates: 2008-10-23; 2010-10-01; 2012-10-03; 2014-09-23; 2016-11-08	220116	11/06/2003	12/05/2018	MA
University of North Carolina Hospitals 101 Manning Drive Chapel Hill, NC 27514 Other information: Joint Commission ID #: 6478 VAD Previous Re-certification Dates: 2008-10-28; 2010-10-19; 2012-10-26; 2014-10-16; 2016-11-08	340061	05/05/2004	11/28/2018	NC

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
Lutheran Hospital of Indiana 7950 W Jefferson Boulevard Fort Wayne, IN 46804 Other information: Hospital was certified by CMS from 2003-10-29 until being de-certified on 2007-07-30. Joint Commission ID #: 7157 VAD Previous Re-certification Dates: 2010-09-15; 2012-10-24; 2014-10-21; 2016-11-01	150017	10/29/2003	12/05/2018	IN
Montefiore Medical Center 111 E 210th Street Bronx, NY 10467 Other information: Joint Commission ID #: 2514 VAD Previous Re-certification Dates: 2008-11-12; 2010-10-08; 2012-10-23; 2014-09-23; 2016-10-18	330059	11/14/2003	11/07/2018	NY
FROM: St. Luke's Episcopal Hospital TO: CHI St. Luke's Health-Baylor College of Medicine Medical Center 6720 Bertner Avenue Houston, TX 77030 Other information: Joint Commission ID #: 9098 VAD Previous Re-certification Dates: 2008-10-08; 2010-11-17; 2012-11-06; 2014-10-16; 2016-11-22	450193	10/28/2003	12/12/2018	TX

Facility	Provider Number	Date of Initial Certification	Date of Recertification	State
Cleveland Clinic 9500 Euclid Avenue Cleveland, OH 44195 Other information: Joint Commission Certified 2008-12-29. Joint Commission ID #: 7001 VAD Previous Re-certification Dates: 2008-12-29; 2010-11-23; 2012-12-11; 2014-12-02; 2016-11-08	360180	12/03/2003	12/12/2018	OH
The following facilities have been removed.				
CHI Health Nebraska Heart 7500 South 91st Street Lincoln, NE 68526 Other information: Joint Commission ID #: 524947 Joint Commission Withdrawal Date: 2019-01-03	280128	11/19/2014	12/13/2016	NE
Oregon Health and Sciences University 3181 SW Sam Jackson Park Road, Portland, OR 97239 Other information: Joint Commission ID #: 9707 VAD Previous Re-certification Dates: 2008-11-12; 2011-02-15; 2013-02-12; 2015-03-03 Joint Commission Withdrawal Date: 2019-01-03	380009	11/21/2003	04/18/2017	OR
Novant Health Forsyth Medical Center 3333 Silas Creek Parkway Winston Salem, NC 27103 Other information: DNV GL Certified on 2018-04-20 DNV GL De-Certified on 2019-02-22	340014	04/20/2018		NC

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)
(January through March 2019)**

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. For the purposes of this quarterly notice, we are providing only the specific 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).

Facility	Provider Number	Date of Approved	Date De-certified.	State
The following facility has editorial changes (in bold).				
Ohio State University Hospitals 410 West Tenth Avenue, DN 168 Columbus, OH 43210 Other information: Joint Commission ID #: 7029 LVRS Re-certification Dates: 2018-12-15	360085	10/29/2016		OH
The following facility has been removed.				
Temple University Hospital, Inc. 3401 North Broad Street Philadelphia, PA 19140	390027	03/25/2017	03/14/2019	PA

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities

(January through March 2019)

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' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (January through March 2019)

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1646]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on June 11, 2019, from 8 a.m. to 5 p.m. and June 12, 2019, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2019-N-1646. The docket will close on June 30, 2019. Submit either electronic or written comments on this public meeting by June 30, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 30, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 30, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before May 28, 2019, will be provided to the committees. Comments received after that date will be taken into consideration by FDA.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-1646 for "Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see the **ADDRESSES** section) will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: DSaRM@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the