

using a pay-per-call service, that they will not be liable for unauthorized non-toll charges on their telephone bills, and how to deal with disputes about telephone-billed purchases.

**Likely Respondents:** telecommunications common carriers (subject to the reporting requirement only, unless acting as a billing entity), information providers (vendors) offering one or more pay-per-call services or programs, and billing entities.

**Estimated Annual Hours Burden:** 1,029,570 hours (18 + 1,029,552).

**Reporting:** 18 hours for reporting by common carriers.

**Disclosure:** 1,029,552 [(21,240 hours for advertising by vendors + 21,732 hours for preamble disclosure which applies to every pay-per-call service + 7,080 burden hours for telephone-billed charges in billing statements (applies to vendors; applies to common carriers if acting as billing entity) + 11,500 burden hours for dispute resolution procedures in billing statements (applies to billing entities) + 968,000 hours for disclosures related to consumers reporting a billing error (applies to billing entities)].

**Estimated annual cost burden:** \$50,456,136 (solely relating to labor costs).<sup>1</sup>

**Request for Comment**

On August 18, 2021, the FTC sought public comment on the information collection requirements associated with the Rule. 86 FR 46254. The Commission received no germane comments. Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44

U.S.C. 3501 *et seq.*, the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rules.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

**Josephine Liu,**  
*Assistant General Counsel for Legal Counsel.*

[FR Doc. 2021–25104 Filed 11–17–21; 8:45 am]

**BILLING CODE 6750–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS–9132–N]

**Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2021**

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

**ACTION:** Notice

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2021, relating to the Medicare and Medicaid programs and other programs administered by CMS.

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

Addenda	Contact	Phone number
I CMS Manual Instructions .....	Ismael Torres .....	(410) 786–1864
II Regulation Documents Published in the FEDERAL REGISTER .....	Terri Plumb .....	(410) 786–4481
III CMS Rulings .....	Tiffany Lafferty .....	(410) 786–7548
IV Medicare National Coverage Determinations .....	Wanda Belle, MPA .....	(410) 786–7491
V FDA-Approved Category B IDEs .....	John Manlove .....	(410) 786–6877
VI Collections of Information .....	William Parham .....	(410) 786–4669
VII Medicare-Approved Carotid Stent Facilities .....	Sarah Fulton, MHS .....	(410) 786–2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites.	Sarah Fulton, MHS .....	(410) 786–2749
IX Medicare’s Active Coverage-Related Guidance Documents .....	JoAnna Baldwin, MS .....	(410) 786–7205
X One-time Notices Regarding National Coverage Provisions .....	JoAnna Baldwin, MS .....	(410) 786–7205
XI National Oncologic Positron Emission Tomography Registry Sites .....	David Dolan, MBA .....	(410) 786–3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities.	David Dolan, MBA .....	(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
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA .....	(410) 786–3365
All Other Information .....	Annette Brewer .....	(410) 786–6580

<sup>1</sup> Non-labor (e.g., capital/other start-up) costs are generally subsumed in activities otherwise undertaken in the ordinary course of business (e.g., business records from which only existing information must be reported to the Commission, pay-per-call advertisements or audiotext to which

cost or other disclosures are added, etc.). To the extent that entities incur operating or maintenance expenses, or purchase outside services to satisfy the Rule’s requirements, staff believe those expenses are also included in (or, if contracted out, would be comparable to) the annual burden hour and cost

estimates provided below (where such costs are labor-related), or are otherwise included in the ordinary cost of doing business (regarding non-labor costs).

**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>.

The Director of the Office of Strategic Operations and Regulatory Affairs of the Centers for Medicare & Medicaid Services (CMS), Kathleen Cantwell, having reviewed and approved this document, authorizes Tresha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: November 12, 2021.

**Tresha Fultz-Mimms,**  
*Federal Register Liaison, Department of  
Health and Human Services.*

**BILLING CODE 4120-01-P**

### Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 4, 2020 (85 FR 70168), March 17, 2021 (86 FR 14629), May 3, 2021 (86 FR 23373) and August 17, 2021 (86 FR 45986). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

### Addendum I: Medicare and Medicaid Manual Instructions (July through September 2021)

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 Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment, use (CMS-Pub. 100-04) Transmittal No. 10988.

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.

#### Fee-For Service Transmittal Numbers

**Please Note:** Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at [www.cms.gov/Manuals](http://www.cms.gov/Manuals).

Transmittal Number	Manual/Subject/Publication Number
<b>Medicare General Information (CMS-Pub. 100-01)</b>	
10880	Internet Only Manual Updates to Pub. 100-01, 100-02, and 100-04 to Implement Consolidated Appropriations Act Changes and Correct Errors and Omissions (SNF)
<b>Medicare Benefit Policy (CMS-Pub. 100-02)</b>	
10880	Internet Only Manual Updates to Pub. 100-01, 100-02, and 100-04 to Implement Consolidated Appropriations Act Changes and Correct Errors and Omissions (SNF)
<b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b>	
10888	National Coverage Determination (NCD) Removal Extracorporeal Immunoabsorption (ECI) Using Protein A Columns Electrosleep Therapy Implantation of Gastrointestinal Reflux Devices Abarelix for the Treatment of Prostate Cancer Magnetic Resonance Spectroscopy Positron Emission Tomography (PET) Scans FDG PET for Inflammation and Infection
10891	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783.

	Chimeric Antigen Receptor (CAR) T-cell therapy.
10927	National Coverage Determination (NCD) Removal Extracorporeal Immunoabsorption (ECI) Using Protein A Columns Electrosleep Therapy Implantation of Gastrointestinal Reflux Devices Abarelix for the Treatment of Prostate Cancer Magnetic Resonance Spectroscopy Positron Emission Tomography (PET) Scans FDG PET for Inflammation and Infection
10981	National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds Blood-Derived Products for Chronic, Non-Healing Wounds
10985	Claims Processing Instructions for National Coverage Determination 20.33 – Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation
<b>Medicare Claims Processing (CMS-Pub. 100-04)</b>	
10862	Section 50 in Chapter 30 of Publication (Pub.) 100-04 Manual Updates Section 50 in Chapter 30 of Publication (Pub.) 100-04 Manual Updates Advance Beneficiary Notice of Non-coverage (ABN) ABN Scope ABN Uses Optional ABN Uses Issuance of the ABN Triggering Events ABN Standards Completing the ABN Retention Requirements ABN Delivery Requirements Options for Delivery Other than In-Person Effects of Lack of Notification, Medicare Review and Claim Adjudication Using ABNs for Medical Equipment and Supplies Claims When Denials Under §1834(a)(17)(B) of the Act (Prohibition Against Unsolicited Telephone Contacts) Are Expected ABNs for Medical Equipment and Supplies Claims Denied Under §1834(j)(1) of the Act (Because the Supplier Did Not Meet Supplier Number Requirements) ABNs for Claims Denied in Advance Under §1834(a)(15) of the Act ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) ABNs for items listed in a DMEPOS Competitive Bidding Program (CBP) /Collection of Funds and Refunds Physicians' Services DMEPOS RR Provision for Claims for Medical Equipment and Supplies Time Limits and Penalties for Healthcare Providers and Suppliers in Making Refunds Supplier's Right to Recover Resalable Items for Which Refund Has Been Made CMS Regional Office (RO) Referral Procedures ABN Special Considerations Glossary
10865	July Quarterly Update for 2021 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
10872	Annual Updates to the Prior Authorization/Pre-Claim Review Federal Holiday Schedule Tables for Generating Reports
10875	Instructions for Downloading the Medicare ZIP Code Files for October 2021
10876	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction

10877	Changes to the Laboratory National Coverage Determination [NCD] Edit Software for October 2021
10878	Update to the Internet-only Manual (IOM) Publication (Pub.) 100-04, Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, Section 20.9 - Fee Schedule Administration and Coding Requirements National Correct Coding Initiative (NCCI) Correct Coding Modifier Indicators (CCMI) and HCPCS Codes Modifiers Instructions for Codes With Modifiers (A/B MACs (B) Only) Appeals Procedure-to-Procedure (PTP) Edits Medically Unlikely Edits (MUEs) National Correct Coding Initiative (NCCI) Edits Quarterly Updates
10891	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783. Chimeric Antigen Receptor (CAR) T-cell therapy Coverage Requirements Billing Requirements A/B Medicare Administrative Contractor (MAC) (A) Bill Types A/B MAC (A) Revenue Codes A/B MAC Billing Healthcare Common Procedural Coding System (HCPCS) Codes A/B MAC Diagnosis Requirements Payment Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARC), Group Codes, and Medicare Summary Notice (MSN) Messages Claims Editing
10898	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10918	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10919	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10920	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10929	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for FY 2022
10931	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10932	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10934	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10935	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10937	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10940	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10941	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10942	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10943	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2022

10944	Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Updates for Fiscal Year (FY) 2022 Annual Update Cost-of-Living Adjustment (COLA) for Alaska and Hawaii
10947	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10950	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
10959	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10961	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10962	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10964	Combined Common Edits/Enhancements Modules (CEEM) Code Set Update
10965	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10966	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10967	Implement Operating Rules - Phase III Electronic Remittance Advice (ERA) Electronic Funds Transfer (EFT): Committee on Operating Rules for Information Exchange (CORE) 360 Uniform Use of Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Claim Adjustment Group Code (CAGC) Rule - Update from Council for Affordable Quality Healthcare (CAQH) CORE
10968	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
10969	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - October 2021 Update
10970	Shared System Support Hours for Application Programming Interfaces (APIs)
10971	2022 Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
10972	January 2022 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder Clotting Factor Furnishing Fee
10979	Instructions for Retrieving the January 2022 Opioid Treatment Program (OTP) Payment Rates Through the CMS Mainframe Telecommunications System
10981	National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds Policy Healthcare Common Procedure Coding System (HCPCS) Codes, Diagnosis Coding and Frequency Requirements Types of Bill (TOB) Payment Method Place of Service (POS) for Professional Claims Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs), Claim Adjustment Reason Codes (CARCs) and Group Codes
10983	Influenza Vaccine Payment Allowances - Annual Update for 2021-2022 Season

10985	Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation Coding Requirements for Mitral Valve TEER Claims Furnished on or After August 7, 2014 Claims Processing Requirements for Mitral Valve TEER Services on Professional Claims
10987	Home Health Notices of Admission -- Additional Manual Instructions Submission of the Notice of Admission (NOA) HH PPS Claims
10988	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
10991	Instructions for Retrieving the January 2022 Medicare Physician Fee Schedule Database (MPFSDB) Files Through the CMS Mainframe Telecommunications System
10992	Quarterly Update to Home Health (HH) Grouper
10996	October 2021 Integrated Outpatient Code Editor (IOCE) Specifications Version 22.3
10997	October 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)
11000	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>Medicare Secondary Payer (CMS-Pub. 100-05)</b>	
10873	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10921	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10939	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>Medicare Financial Management (CMS-Pub. 100-06)</b>	
10887	Notice of New Interest Rate for Medicare Overpayments and Underpayments – 4th Qtr Notification for FY 2021
10982	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b>	
None	
<b>Medicare Program Integrity (CMS-Pub. 100-08)</b>	
10849	Revising Subsection 3.5.4, Tracking Medicare Contractors' Prepayment and Postpayment Reviews, in Chapter 3 of Publication (Pub.) 100-08 Tracking Medicare Contractors' Prepayment and Postpayment Reviews
10867	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
10868	Third General Update to Chapter 10 of Publication (Pub.) 100-08 Third General Update to Chapter 10 of Publication (Pub.) 100-08 Certified Providers and Certified Suppliers That Enroll Via the Form CMS- 855A Community Mental Health Centers (CMHCs) Comprehensive Outpatient Rehabilitation Facilities (CORFs) End-Stage Renal Disease Facilities (ESRDs) Federally Qualified Health Centers (FQHCs) Histocompatibility Laboratories Home Health Agencies (HHAs) Hospices Hospitals and Hospital Units Indian Health Services (IHS) Facilities Organ Procurement Organizations (OPOs) Outpatient Physical Therapy/Outpatient Speech Pathology Services (OPT/OSP)

	Religious Non-Medical Health Care Institutions (RNHCIs) Rural Health Clinics (RHCs) Skilled Nursing Facilities (SNFs) Miscellaneous Policies Other Enrollment Forms: Information and Processing Form CMS-588 – Electronic Funds Transfer (EFT) Authorization Agreement Form CMS-460 – Medicare Participating Physician or Supplier Agreement Provider and Supplier Business Structures Owning and Managing Information Organizational Owning and Managing Information Individual Owning and Managing Information Owning and Managing Information – Tax Identification Numbers (TINs) Billing Agencies
10879	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10882	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10893	Revision to Medicare Administrative Contractor (MAC) Complaint Screening Process - Checking the Recovery Audit Contractor (RAC) Data Warehouse (RACDW) Prior to Claim Adjustment Complaint Screening Process
10909	Fourth General Update to Chapter 10 of Publication (Pub.) 100-08 Opioid Treatment Programs Opting-Out of Medicare Application Fees Screening: On-Site Inspections and Site Verifications Miscellaneous Enrollment Topics
10910	Updates to Exhibit 16 in Exhibits Chapter of Publication (Pub.) 100-08 Model Payment Suspension Letters Opioid Treatment Programs Opting-Out of Medicare Application Fees Screening: On-Site Inspections and Site Verifications Miscellaneous Enrollment Topic
10911	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10913	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10926	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10945	Removal of Provider Enrollment Policy from Chapter 15 in Publication (Pub.) 100-08
10958	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10975	Changes of Information Involving Certified Providers and Certified Suppliers
10976	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10984	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08 Quality of Care Issues and Potential Fraud Issues Provider Self Audits Signature Requirements Introduction Program Integrity Program Integrity Contractors Unified Program Integrity Contractor Investigations Medicare Drug Integrity Contractor

	Organizational Requirements Liability of Program Integrity Contractor Employees Anti-Fraud Training Procedural Requirements MAC Complaint Screening Referrals to the UPIC Home Health Agency Misuse of Requests for Anticipated Payments RAP Monitoring Education and Additional Monitoring Corrective Action Plans Notification to the HHA CAP Submission CAP Acceptance and Monitoring CAP Closeout Suppression Notice of RAP Suppression Monitoring During RAP Suppression Result of Initial RAP Suppression Monitoring Period
10994	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
<b>Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)</b>	
1900	Updates to Pub. 100-09, Chapter 6 Beneficiary and Provider Communications Manual, Chapter 6, Provider Customer Service Program Note Introduction to Provider Customer Service Program PCSP Electronic Mailing Lists PCUG Call Integration of POE, PCC, and PSS Activities in the PCSP Partners in Progress Meeting Provider Outreach and Education Partnering with External Entities and with Other MACs Analysis of Claims Submission Errors Provider Bulletins/Newsletters Direct Mailings for the PCSP Training Tailored for Small Medicare Providers Remittance Advice (RA) POE Advisory Groups (POE AGs) Ask-the-Contractor Teleconferences POE Reporting Provider Service Plan (PSP) Provider Customer Service Program Activity Report (PAR) Discretionary Reporting Charging Fees to Providers for Medicare Education and Training Reimbursement from Providers for POE Staff Attendance at Provider Meetings Refunds/Credits for Cancellation of Education and Training Activities Provider Contact Center (PCC) Pre-Approved PCC Closures Emergency and Similar PCC Closures Inquiry Triage Process Responding to Coding Questions Provider Telephone Inquiries Provider Inquiries Line Troubleshooting PCC Service Interruptions Requesting Changes to Telephone Configurations Hours of Operation Providing Busy Signals

<p> Provider Telephone Line Staffing  Quality Call Monitoring  Quality Assurance Monitoring (QAM)  Remote Monitoring  Telephone Responses to Provider Inquiries – QWCM Program Minimum Requirements  Recording Calls  QCM Calibration  Provider Written Inquiries  Telephone Responses to Provider Written Inquiries  Electronic Responses to Provider Written Inquiries  Guidelines for High Quality Responses to Provider Written Inquiries  Stock Language/Form Letters  QWCM Calibration  PRRS Operations  Complex Provider Inquiries  Complex Beneficiary Inquiries  Provider Inquiry Tracking  Updates to the CMS Standardized Provider Inquiry Chart  MAC Inquiry Tracking Self-Data Review and Self-Validation Process  Fraud and Abuse  PCSP Staff Development and Education  PCC Staff Development and Training  Required Training for PCC Staff  PCC Training Program  PCC Training Documentation  Provider Self-Service (PSS) Technology  Interactive Voice Response(IVR) System  Provider Education Website  General Requirements  Webmaster and Attestation Requirements  Website Governance  CMS Feedback  Contents  Dissemination of Information from CMS to Providers  Web-based Provider Educational Offerings  Provider Claims Payment Alerts  Electronic Mailing List  Targeted Electronic Mailing Lists  Electronic Mailing List Promotion  Social Media  Internet-based Provider Portal Service Interruptions  Surveys  Provider Satisfaction Survey  MAC Survey Participation Requirements  Closed-Loop Ticketing  MAC Satisfaction Score  Performance Management  Electronic Mailing List Subscribership  Call Completion  Average Speed of Answer (ASA)  Callbacks  PCSP Data Reporting  PIES  Due Date for Data Submission to PIES  MAC Contract and PCSP Data to be Reported in PCID  Additional Data to be Reported Monthly in PCID and Reporting Due Dates </p>
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	<p> Inquiry Tracking Data to be Reported in PCID  PCC Training Closure Information to be Reported in PCID  Provider Electronic Mailing List Subscriber Data to be Reported in PCID  Special Initiatives to be Reported in PCID  Emergency and Similar PCC Closure Data to be Reported in PCID  Telecommunications Service Interruptions to be Reported in PCID  QCM  QWCM  Disclosure of Information </p>
10930	<p> Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions </p>
<b>Medicare Quality Improvement Organization (CMS- Pub. 100-10)</b>	
	None
<b>Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)</b>	
	None
<b>Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)</b>	
	None
<b>Medicare Managed Care (CMS-Pub. 100-16)</b>	
	None
<b>Medicare Business Partners Systems Security (CMS-Pub. 100-17)</b>	
	None
<b>Medicare Prescription Drug Benefit (CMS-Pub. 100-18)</b>	
	None
<b>Demonstrations (CMS-Pub. 100-19)</b>	
10889	<p> Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions </p>
10894	<p> Modifications/Improvements to Value-Based Insurance Design (VBID) Model Implementation </p>
10924	<p> Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions </p>
10936	<p> Federally Qualified Health Center (FQHC) Participation in and Payment Under the Maryland Primary Care Program (MDPCP) – Implementation </p>
10938	<p> Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions </p>
10949	<p> Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions </p>
10956	<p> Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions </p>
10960	<p> Managing Clinician PPA and KCF PBA Implementation </p>
10974	<p> Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions </p>
10978	<p> Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions </p>
10993	<p> Kidney Care Choices (KCC) Kidney Care First (KCF) - Payment Mechanism (PM) and Benefit Enhancements (BEs) - Implementation </p>
<b>One Time Notification (CMS-Pub. 100-20)</b>	
10848	<p> Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions </p>
10852	<p> Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions </p>
10856	<p> Implementation of the Award for the Jurisdiction E (J-E) Part A and Part B Medicare Administrative Contractor (JE A/B MAC) </p>
10861	<p> Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Prior Authorization Coversheet Requirements </p>
10863	<p> User CR: MCS - Beneficiary Do Not Forward DLV Flag Changes Needed </p>

10890	Replacing Home Health Requests for Anticipated Payment (RAPs) with a Notice of Admission (NOA) – Implementation
10895	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10896	Additional Payment Edits for DMEPOS Suppliers of Custom Fabricated and Prefabricated (Custom Fitted) Orthotics. Update to Change Request (CR) 3959, CR 8390, and CR 8730
10899	Viable Information Processing Systems (ViPS) Medicare Systems (VMS) Changes to Accommodate National Provider Identifier Associations
10928	Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions in Maryland Waiver (MW) Hospitals for Medicare Advantage (MA) Beneficiaries
10933	Implementation of the Capital Related Assets Adjustment (CRA) for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Under the End Stage Renal Disease Prospective Payment System (ESRD PPS)
10948	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions
10951	Phase One Changes Needed to Implement the Revised Process for Handling Undeliverable Beneficiary Addresses in VMS
10953	Update to Nursing and Allied Health (N&AH) Education Medicare Advantage (MA) Payment Rates - Calendar Year (CY) 2019
10954	User CR: MCS - Mass Load "PJ" Segments
10955	User CR: Multi-Carrier-System (MCS) - Expand Number of Details on Provider Profiles Inquiry (PI) Screen
10957	Send Electronic Funds Transfer [EFT] Information from Provider Enrollment Chain and Ownership System [PECOS] to Fiscal Intermediary Shared System [FISS] - Implementation CR, Consolidation of January 2022 and April 2022 Releases
10963	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)--January 2022
10977	Replacing Home Health Requests for Anticipated Payment (RAPs) with a Notice of Admission (NOA) – Implementation
10986	Send Electronic Funds Transfer [EFT] Information from Provider Enrollment Chain and Ownership System [PECOS] to ViPS Medicare System [VMS]: Implementation CR
10989	User CR: MCS - Enhancement to Automate the XHIC Error Process
10990	User CR: MCS - Enhance Health Professional Shortage Area (HPSA) Reports
<b>Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)</b>	
10340	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
10980	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
<b>State Payment of Medicare Premiums (CMS-Pub.100-24)</b>	
	None
<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)</b>	
	None

**Addendum II: Regulation Documents Published  
in the Federal Register (July through September 2021)  
Regulations and Notices**

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal**

**Register**, contact GPO at [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys). When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

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

This information is available on our website at:  
<https://www.cms.gov/files/document/regs3q21qpu.pdf>

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

**Addendum III: CMS Rulings  
(July through September 2021)**

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

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

**Addendum IV: Medicare National Coverage Determinations  
(July through September 2021)**

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 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/](http://www.cms.gov/medicare-coverage-database/). For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds	NCD 270.3	10981	09/15/2021	04/13/2021
National Coverage Determination 20.33 - Transcatheter Edge-To-Edge Repair [Teer] For Mitral Valve	NCD 20.33	10985	09/08/2021	01/19/2021
National Coverage Determination (NCD) Removal	"NCD 20.5 NCD 30.4 NCD 100.9 NCD 110.19 NCD 220.2.1 NCD 220.6.16".3	10927	08/02/2021	01/01/2021

**Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2021)**  
(Inclusion of this addenda is under discussion internally.)

**Addendum VI: Approval Numbers for Collections of Information (July through September 2021)**

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

**Addendum VII: Medicare-Approved Carotid Stent Facilities (July through September 2021)**

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/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Effective Date	State
<b>The following facilities are new listings for this quarter.</b>			
Banner Del Webb Medical Center 14502 W. Meeker Boulevard Sun City West, AZ 85375	030093	06/29/2021	AZ
Orlando Health – Health Central Hospital 1222 S. Orange Avenue MP 856. Orlando, FL 32806	1184709057	06/29/2021	FL
WakeMed Cary Hospital 1900 Kildaire Farm Road Cary, NC 27518	340173	04/05/2021	NC
Community Hospital South 1402 East County Line Indianapolis, IN 46227	150128	09/07/2021	IN
Huntsville Health System – Marshall, 431 Highway North Boaz, AL 35957	010005	09/21/2021	AL
Sutter Roseville Medical Center One Medical Plaza Roseville, CA 95661	050309	09/28/2021	CA
<b>The following facilities have editorial changes (in bold).</b>			
<b>FROM: Portsmouth Regional Hospital</b> <b>TO: HCA Healthcare Services of New Hampshire, Inc.</b> 333 Borthwick Avenue Portsmouth, NH 03801	300029	06/01/2005	NH
<b>FROM: Clarian Arnett Health</b> <b>TO: Indiana University Health Arnett</b> 5165 McCarty Lane Lafayette, IN 47905	150173	07/02/2009	IN
<b>FROM: Mills Peninsula Health Services</b> <b>TO: Mills Peninsula Medical Center</b> <b>FROM: 1783 El Camino Real</b> <b>TO: 1501 Trousdale Drive</b> Burlingame, CA 94010	050007	10/11/2005	CA

Facility	Provider Number	Effective Date	State
<b>FROM: Utah Valley Regional Medical Center</b> <b>TO: IHC Health Services, Inc. dba Utah Valley Hospital</b> 1034 N 500 West Provo, UT 84604	460001	05/26/2005	UT
<b>FROM: Mainland Medical Center</b> <b>TO: HCA Houston Healthcare Mainland Campus</b> 6801 Emmett F. Lowry Expressway Texas City, TX 77591	450530	10/20/2006	TX
<b>The following facility has been removed.</b>			
St. Lucie Medical Center 1800 SE Tiffany Avenue Port St. Lucie, FL 34952	10-0260	08/19/2021	FL

**Addendum VIII:**

**American College of Cardiology’s National Cardiovascular Data Registry Sites (July through September 2021)**

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 (July through September 2021)**

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

**Addendum X:**

**List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2021)**

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

**Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2021)**

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 David Dolan, MBA (410-786-3365).

**Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2021)**

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, MBA,  
 (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
<b>The following are new facilities.</b>				
Baylor Scott & White All Saints Medical Center - Fort Worth 1400 8th Avenue Fort Worth, TX 76104  Other information: DNV GL# 10000469761- Assessment Services-DNV GL-USA  Previous Re-certification Dates: n/a	450137	05/26/2021		TX
AU Medical Center 1120 15th Street Augusta, GA 30912  Other information DNV ID # 10000483076- MSC-DNV-USA  Previous Re-certification Dates: n/a	110034	08/06/2021		GA
<b>The following facilities have editorial changes (in bold).</b>				
<b>TO: Adventist Health System/Sunbelt Inc. dba Florida Hospital FROM Adventist Health System/Sunbelt Inc. dba Advent Health</b> 601 East Rollins Street Orlando, FL 32803  Other information: Joint Commission ID # 6873  Previous Re-certification Dates: 10/24/2012; 10/07/2014; 11/15/2016; 01/30/2019	100007	10/24/2012	<b>06/12/2021</b>	FL
Medical University of South Carolina Medical Center 169 Ashley Avenue Charleston, SC 29425  <b>Joint Commission ID # 6584</b>  <b>Previous Re-certification Dates:</b>	420004	09/23/2010	<b>03/24/2021</b>	WI

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
<b>09/23/2010; 09/07/2012; 08/05/2014; 09/13/2016; 09/26/2018</b>				
University of Utah, Hospitals and Clinics 50 N. Medical Drive Salt Lake City, UT 84132  Other information:  Certificate #: 10000435189- MSC-DNV GL-USA Previous Re-certification Dates: 01/13/2009; 07/13/2011; 06/18/2013; 06/23/2015; 08/08/2017; 05/25/2018	460009	01/13/2009	<b>05/21/2021</b>	UT
Medical City Dallas 7777 Forest Lane Dallas, TX 75230  Other information: Joint Commission ID # 9008 Previous Re-certification Dates: 09/09/2008; 08/10/2010; 07/17/2012; 06/27/2014; 07/12/2016	450647	09/09/2008	<b>04/03/2021</b>	TX
Vanderbilt University Medical Center 1211 Medical Center Drive Nashville, TN 37232-2101  Joint Commission ID # 7892  Previous Re-certification Dates: 04/20/2012; 03/11/2014; 04/05/2016; 05/08/2018	440039	04/20/2012	<b>04/28/2021</b>	TN
Memorial Regional Hospital 3501 Johnson Street Hollywood, FL 33021  Joint Commission ID # 6811  Previous Re-certification Dates: 2016-08-11; 2014-08-20	100038	08/20/2014	<b>03/27/2021</b>	FL
Moses H. Cone Memorial Hospital 1200 North Elm Street Greensboro, NC 27401-1020 Other information: Joint Commission ID # 6504	340091	01/07/2014	<b>04/17/2021</b>	NC

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Previous Re-certification Dates: 01/07/2014; 02/09/2016; 02/13/2018				
Hospital of the University of Pennsylvania 3400 Spruce Street Philadelphia, PA 19104  Other information: Joint Commission ID # 6129  Previous Re-certification Dates: 2010-06-08; 2012-05-25; 2014-04-15; 2016-06-15; 2018-07-18	390111	06/08/2010	<b>05/06/2021</b>	PA
University of Iowa Hospitals and Clinics 200 Hawkins Drive Iowa City, IA 52242  Joint Commission ID # 8266  Previous Re-certification Dates: 06/22/2010; 07/26/2012; 07/29/2014; 08/02/2016; 7/11/2018	160058	06/22/2010	<b>04/08/2021</b>	IA
Lutheran Hospital of Indiana 7950 West Jefferson Boulevard Fort Wayne, IN 46804  Other information: Joint Commission ID # 7157  Previous Re-certification Dates: 09/14/2010; 10/24/2012; 10/21/2014; 11/01/2016	150017	09/14/2010	<b>05/05/2021</b>	IN
Emory Saint Joseph's Hospital of Atlanta, Inc. 5665 Peachtree Dunwoody Road Atlanta, GA 30342  Other information: Joint Commission ID # 6652  Previous Re-certification Dates: 07/13/2010; 07/11/2012; 06/03/2014; 07/12/2016; 06/05/2018	110082	07/13/2010	<b>05/08/2021</b>	GA

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Mercy General Hospital 4001 J Street Sacramento, CA 95819  Other information: Joint Commission ID # 10053  Previous Re-certification Dates: 02/11/2014; 03/08/2016; 03/13/2018	050017	02/11/2014	<b>04/14/2021</b>	CA
Providence St. Vincent Medical Center 9205 SW Barnes Road Portland, OR 97225  Other information: Joint Commission ID # 9705  Previous Re-certification Dates: 12/06/2011; 12/10/2013; 01/26/2016; 02/13/2018	380004	12/06/2011	<b>07/24/2021</b>	OR
University of Mississippi Medical Center 2500 North State Street Jackson, MS 39216  Other information: Joint Commission ID # 8064  Previous Re-certification Dates: 08/16/2016; 08/08/2018	250001	08/16/2016	<b>05/20/2021</b>	MS
CHI St. Luke's Health Baylor College of Medicine Medical Ctr 6720 Bertner Avenue Houston, TX 77030  Other information: Joint Commission ID # 9098  Previous Re-certification Dates: 10/07/2008; 11/17/2010; 11/06/2012;	450193	10/28/2003	<b>06/05/2021</b>	TX
University of Cincinnati Medical Center, LLC 234 Goodman Street Cincinnati, OH 45219  Other information: Joint Commission ID # 6988	360003	12/13/2011	<b>05/19/2021</b>	OH

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Previous Re-certification Dates: 12/13/2011; 01/07/2014; 02/23/2016; 03/13/2018				
<b>FROM: Old: Indiana University Health Methodist Hospital</b> <b>TO: Indiana University Health, Inc.</b> 1701 North Senate Boulevard Indianapolis, IN 46202  Other information: Joint Commission ID # 188549  Previous Re-certification Dates: 08/12/2008; 08/17/2010; 08/17/2012; 08/19/2014; 10/04/2016	150056	08/12/2008	<b>05/29/2021</b>	IN
University of Wisconsin Hospitals and Clinics Authority 600 Highland Avenue Madison, WI 53792  Other information: Joint Commission ID # 7656  Previous Re-certification Dates: 08/05/2008; 08/24/2010; 08/07/2012; 07/17/2014; 08/09/2016	520098	08/05/2008	<b>06/04/2021</b>	WI
Loma Linda University Medical Center 11234 Anderson Street Loma Linda, CA 92354  Other information: Joint Commission ID # 9898  Previous Re-certification Dates: 02/07/2012; 01/23/2014; 02/23/2016; 04/10/2018	050327	02/07/2012	<b>05/15/2021</b>	CA
INTEGRIS Baptist Medical Center 3300 Northwest Expressway Oklahoma City, OK 73112  Other information: Joint Commission ID # 8872	370028	08/12/2008	<b>06/19/2021</b>	OK

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Previous Re-certification Dates: 08/12/2008; 07/20/2010; 07/24/2012; 07/08/2014; 08/23/2016				
Catholic Health Initiatives - Iowa, Corp. 1111 6th Avenue Des Moines, IA 50314  Other information: Joint Commission ID # 5518  Previous Re-certification Dates: 10/23/2008; 10/01/2010; 10/03/2012; 09/23/2014; 11/08/2016; 12/5/2018	160083	01/06/2015	<b>07/01/2021</b>	IA
Tufts Medical Center 800 Washington Street Boston, MA 02111  Other information: Joint Commission ID # 5518 Previous Re-certification Dates: 10/23/2008; 10/01/2010; 10/03/2012; 09/23/2014; 11/08/2016; 12/5/2018	220116	10/23/2008	<b>06/23/2021</b>	MA
Brigham and Women's Hospital 75 Francis Street Boston, MA 02115  Other information: Joint Commission ID # 5503  Previous Re-certification Dates: 11/04/2008; 12/09/2010; 12/07/2012; 11/07/2014; 12/13/2016; 2/27/2019	220110	11/04/2008	<b>07/10/2021</b>	MA
<b>FROM: Maine Medical Center</b> <b>TO: MaineHealth</b> 22 Bramhall Street Portland, ME 04102  Other information: Joint Commission ID # 5445  Previous Re-certification Dates: 11/05/2008; 09/27/2016; 10/3/2018	200009	11/05/2008	<b>07/08/2021</b>	ME

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
Sharp Memorial Hospital 7901 Frost Street San Diego, CA 92123  Other information: Joint Commission ID # 3910  Previous Re-certification Dates: 07/17/2008; 06/29/2010; 08/14/2012; 09/09/2014; 08/09/2016; 8/15/2018	050100	07/17/2008	06/05/2021	CA
North Shore University Hospital 300 Community Drive Manhasset, NY 11030  Other information: Joint commission ID # 2091  Previous Re-certification Dates: 09/27/2016; 9/19/2018	330106	09/27/2016	06/26/2021	NY

**Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2021)**

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 was an update to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at [www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage). For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

The following facility has editorial changes in bold.			
Facility Name	Provider #	Certification Date	State

Ohio State University Hospitals 410 West Tenth Avenue, DN 168 Columbus, OH 43210  Other information: Joint Commission ID # 7029  Previous Re-certification Dates: 12/15/2018  Tammie Hayes, Director, LVRS, 614-293-3629	360085	08/28/2021	OH
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**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2021)**

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](http://www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage). For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

**Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2021)**

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

This information is available on our website at [www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage). For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2021-25103 Filed 11-17-21; 8:45 am]

BILLING CODE 4120-01-C

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2021-N-1195]

**Discovery Therapeutics, LLC, et al.;  
Withdrawal of Approval of 18  
Abbreviated New Drug Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 18 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of December 20, 2021.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676,

Silver Spring, MD 20993-0002, 240-402-6980, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040619	Methimazole Tablets, 15 milligrams (mg)	Discovery Therapeutics, LLC, 2831 Deer Hound Way, Palm Harbor, FL 34683.
ANDA 070254	Naloxone Hydrochloride (HCl) Injection, 0.4 mg/milliliters (mL).	Hospira, Inc., 275 North Field Dr., Building H1, Lake Forest, IL 60045.
ANDA 070586	Bupivacaine HCl Injection, 0.25%	Do.
ANDA 071850	Morphine Sulfate Injection, 1 mg/mL	Do.
ANDA 075220	Desmopressin Acetate Injection, 0.004 mg/mL	Do.
ANDA 076498	Tretinoin Cream, 0.05%	ZO Skin Health, Inc., 9685 Research Dr., Irvine, CA 92618.
ANDA 077245	Ciprofloxacin Injection, 200 mg/20 mL (10 mg/mL) and 400 mg/40 mL (10 mg/mL).	Hospira, Inc.
ANDA 080409	Lidocaine HCl Solution, 4%	Do.
ANDA 087446	Chloroprocaine HCl Injection, 3%	Do.
ANDA 087447	Chloroprocaine HCl Injection, 2%	Do.
ANDA 201653	Levocetirizine Dihydrochloride Tablets, 5 mg	Sun Pharmaceutical Industries, Inc., U.S. Agent for Sun Pharmaceutical Industries Ltd., 270 Prospect Plains Rd., Cranbury, NJ 08512.
ANDA 202524	Levetiracetam Extended Release Tablets, 500 mg and 750 mg.	Rouses Point Pharmaceuticals, LLC, 11 Commerce Dr., Cranford, NJ 07016.
ANDA 202857	Daptomycin Powder for Injection, 500 mg/vial	Hospira, Inc.
ANDA 203885	Amiodarone HCl Injection, 50 mg/mL	Do.
ANDA 207864	Eptifibatid Injection, 2 mg/mL and 75 mg/100 mL	The WhiteOak Group, LLC, U.S. Agent for Hybio Pharmaceutical Co., Ltd., 1629 K St. NW, Suite 300, Washington, DC 20006.
ANDA 209489	Casposfungin Acetate Powder for Injection, 50 mg/vial and 70 mg/vial.	Cipla USA, Inc., U.S. Agent for Cipla Limited, 10 Independence Blvd., Suite 300, Warren, NJ 07059.
ANDA 210283	Clofarabine Injection, 20 mg/20 mL (1 mg/mL)	Hospira, Inc.
ANDA 210855	Sodium Nitroprusside Injection, 25 mg/mL	Cipla USA, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 20, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on December 20, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 12, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NICHD.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NICHD.

*Date:* December 3, 2021.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* A report by the Acting Scientific Director, NICHD, on the status of the NICHD