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

### **Information Collection**

1. Type of Information Collection Request: Extension of a currently approved collection; Title: Hospital Wage Index Occupational Mix Survey; Use: Section 304(c) of Public Law 106-554 amended section 1886(d)(3)(E) of the Social Security Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

CMS takes the data collected from the approximately 3,200 IPPS providers participating in the Medicare program and runs the data through mathematical formulas to create the occupational mix adjustment to the wage index. CMS informs hospitals of the occupational mix adjusted wage indexes through notice and comment rulemaking each year. Form Number: CMS-10079 (OMB Control Number: 0938-0907); Frequency: Annually; Affected Public: Private Sector, Business or other forprofit and not-for-profit institutions; Number of Respondents: 3,200; Number of Responses: 3,200; Total Annual *Hours:* 1,536,000. (For policy questions regarding this collection contact Noel Manlove at 410-786-5161.)

2. Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; Title: Basic Health Program (BHP) Supporting Regulations; Use: In accordance with Section 1331 of the Patient Protection and Affordability Care Act, Public Law 111-148 (ACA), BHP is federally funded by determining the amount of payments that the federal government would have made through premium tax credits and cost-sharing reductions for people enrolled in BHP had they instead been enrolled in an Exchange. States must submit a BHP Blueprint to CMS for certification prior to the state implementing a BHP and must submit a revised Blueprint in the event that a state seeks to make significant changes that alter program operations; the BHP benefit package; or enrollment, disenrollment, and verification policies described in the Blueprint. Such States must also submit a BHP annual report. In addition to the reinstatement, this 2022 iteration proposes changes that are associated with the March 12, 2014 (79 FR 14112) BHP final rule that have not previously received PRA approval; Form Number: CMS-10510 (OMB

Control Number: 0938–1218); Frequency: Monthly and annually; Affected Public: State, Local or Tribal Government; Number of Respondents: 2; Number of Responses: 27; Total Annual Hours: 2,568. (For policy questions regarding this collection contact Cassie Lagorio at 443–721–8022.)

Dated: July 29, 2022.

### William N. Parham, III,

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

[FR Doc. 2022–16681 Filed 8–3–22; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Medicare & Medicaid Services

[CMS-9137-N]

## Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2022

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

**ACTION:** Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other Federal Register notices that were published from April through June 2022, 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  II Regulation Documents Published in the Federal Register  III CMS Rulings  IV Medicare National Coverage Determinations  V FDA-Approved Category B IDEs  VI Collections of Information  VII Medicare-Approved Carotid Stent Facilities  VIII American College of Cardiology—National Cardiovascular Data Registry  | Ismael Torres Terri Plumb Tiffany Lafferty Wanda Belle, MPA John Manlove William Parham Sarah Fulton, MHS Sarah Fulton, MHS  | (410) 786–1864<br>(410) 786–4481<br>(410) 786–7548<br>(410) 786–7491<br>(410) 786–6877<br>(410) 786–4669<br>(410) 786–2749<br>(410) 786–2749 |
| Sites.  IX Medicare's Active Coverage-Related Guidance Documents  X One-time Notices Regarding National Coverage Provisions  XI National Oncologic Positron Emission Tomography Registry Sites  XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities.  XIII Medicare-Approved Lung Volume Reduction Surgery Facilities  XIV Medicare-Approved Bariatric Surgery Facilities  XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials | JoAnna Baldwin, MS JoAnna Baldwin, MS David Dolan, MBA David Dolan, MBA Sarah Fulton, MHS Sarah Fulton, MHS David Dolan, MBA | (410) 786–7205<br>(410) 786–7205<br>(410) 786–3365<br>(410) 786–3365<br>(410) 786–2749<br>(410) 786–2749<br>(410) 786–3365                   |

| Addenda               | Contact        | Phone No.      |
|-----------------------|----------------|----------------|
| 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 <a href="http://www.cms.gov/manuals">http://www.cms.gov/manuals</a>.

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 Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the Federal Register.

Dated: July 28, 2022.

### Trenesha 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: August 17, 2021 (86 FR 45986), November 18, 2021 (86 FR 64492), February 9, 2022 (87 FR 7458) and May 13, 2022 (87 FR 29327). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

## Addendum I: Medicare and Medicaid Manual Instructions (April through June 2022)

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 Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2 (CMS-Pub. 100-02) Transmittal No. 11399.

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.

| Transmittal | Manual/Subject/Publication Number   |
|-------------|---|
| Number      | Medicare General Information (CMS-Pub, 100-01)  |
| 11395       | Updated Instructions for the Change Request Implementation Report (CRIR) and Technical Direction Letter (TDL) Compliance Report (TCR)           |
| 11438       | Issued to a specific audience, not posted to internet/intranet due to a Confidentiality of Instruction  |
|             | Medicare Benefit Policy (CMS-Pub. 100-02)   |
| 11355       | Update to Publication 100-04, Chapter 18 and Publication 100-02, Chapter 15, Section to Add Data Regarding Novel Coronavirus (COVID-19) and its |
|             | Administration to Current Claims Processing Requirements and Other General Updates  |
|             | Supplementary Medical Insurance (SMI) Provisions<br>Immunizations   |
|             | Services and Supplies Furnished Incident To a Physician's/NPP's Professional Service  |
|             | Preventive and Screening Services   |
| 11386       | Update to Chapter 7, "Home Health Services," of the Medicare Benefit Policy Manual (Pub 100-02)   |
|             | Submission of the Notice of Admission (NOA)   |
|             | Requirements for Submission of NOA  |
|             | Definition of an Allowed Practitioner   |

|       | Screening Pap Smears: Diagnoses Codes   |
|-------|---|
|       | Diagnoses Coues  Stem Cell Transplantation  IICPCS and Diagnosis Coding for Stem Cell Transplantation -ICD-10-CM  |
|       | Applicable<br>Suggested MSN and RA Messages   |
|       | Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS) General  |
|       | Constant<br>On and after July 1, 1999)  |
|       | Vagus Nerve Stimulation for TRD for Battery Replacement<br>Professional Billing Requirements  |
|       | Institutional Billing Requirements  Medicare Summary Notice (MSN), Remittance Advice Remark Code  |
|       | (RARC) and Claim Adjustment Reason Code (CARC) Messages<br>Advance Beneficiary Notice and HINN Information  |
|       | Other Claims Processing Requirements for Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) on Professional   |
|       | Claims Chains Processing Requirements for PILD for Outpatient Facilities  |
|       | A/B MAC (A) KeVenue Code<br>A/B MAC Billing HCPCS Codes   |
|       | A/B MAC Diagnosis and Procedure Code Requirements  Parament Requirements  |
|       | Administration of the Color of |
|       | Messages  |
|       | Claims Processing General Information<br>Institutional Claims Bill Type and Revenue Coding Information  |
|       | Common Working File (CWF) FISS, and Multi-Carrier System (MCS) Editing  |
| 11355 | Update to Publication 100-04, Chapter 18 and Publication 100-02, Chapter 15, Society to Add Date Departing New York Communication (COVID-19) and its  |
|       | 12, Section to Add Data Regarding Novel Coronavirus (COVID-17) and its Administration to Current Claims Processing Requirements and Other   |
|       | General Updates<br>Table of Contents  |
|       | Table of Preventive and Screening Services  Paramococcal Paramonia Influenza Virus Henatitis B and Coronavirus  |
|       | Disease (COVID-19) Vaccines and Administration Coverage Requirements  |
|       | COVID-19 Vaccine Billing Requirements  Healthcare Common Procedure Coding System (HCPCS) and Diagnosis  |
|       | Codes Claims Received with Missino Data   |
|       | Claims Submitted to MACs Using Institutional Formats  |
|       | Payment for Pneumococcal Pneumonia Virus, Influenza Virus, Hepatitis B Virus and, COVID-19 Vaccines and Their Administration on Institutional   |
|       | Claims  |
|       | Special Instructions for Independent and Provider-Based Kural Health Clinics/Federally Qualified Health Center (RHCs/FOHCs)   |
|       | Institutional Claims Submitted by Home Health Agencies and Hospices Payment Procedures for Renal Dialysis Facilities (RDF)  |
|       | Hepatitis B Vaccine Furnished to ESRD Patients  |
|       | Claims Submitted to MACs (Part B)   |
|       | MAC (Part B) Payment Requirements   |

| 11399 | Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2  |
|-------|---|
| 11426 | An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage Pulmonary Rehabilitation (PR) Program Services Furnished On or After January 1, 2010 Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010 |
| 11447 | Update to Chapter 7, "Home Health Services," of the Medicare Benefit Policy Manual (Pub 100-02) Submission of the Notice of Admission (NOA Requirements for Submission of NOA   |
| 11448 | Revisions to Medicare Part B Coverage of Pneumococcal Vaccinations for the Medicare Benefit Policy Manual Chapter 15, Section 50.4.4.2  |
| 11263 | Medicare National Coverage Determination (CMS-Pub, 101-03)  Revisions to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) and 240.2.2 (Home Oxygen Use for Cluster Headache   |
| 11272 | An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage Medical Nutrition Therapy Entertal and Parenteral Nutritional Therapy Positron Emission Tomography (PET) Scans   |
| 11388 | National Coverage Determination (NCD) 210.14 Reconsideration – Screening for Lung Cancer with Low Dose Computed Tomography (LDCT Lung Cancer Screening with Low Dose Computed Tomography (LDCT)   |
| 11426 | An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage Medical Nutrition Therapy Entertal and Parenteral Nutritional Therapy Positron Emission Tomography (PET) Scans   |
| 11429 | Revisions to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) and 240.2.2 (Home Oxygen Use for Cluster Headache) Home Use of Oxygen Home Oxygen Use to Treat Cluster Headache (CH)  |
| 11341 | Medicare Claims Processing (CMS-Pub, 100-04)  Corrections to Home Health Billing for Denial Notices and Calculation of 60- Day Gans in Services   |
| 11344 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  |
| 11348 | Revisions to Chapters 3, "Inpatient Hospital Billing" of the Medicare Claims Processing Manual (Pub 100-04), 18, "Preventive and Screening Services" of the Medicare Claims Processing Manual (Pub 100-04), and 32 "Billing Requirements for Special Services" of the Medicare Claims Processing Manual (Pub 100-04) to Update Coding Stem Cell Transplantation (AuSCT)  Autologous Stem Cell Transplantation (AuSCT)  HCPCS and Diagnosis Codes for Mammography Services                                     |

|           | Suggested MSN and RA Messages<br>Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation  |
|-----------|--|
|           | (HSCT) for Myelodysplastic Syndrome (MDS)  |
|           | Octieral Control Diagnosis Codes for Vagus Nerve Stimulation (Covered since DOS  |
|           | on and aries (up) 1, 1927)  Sugais Nerve Stimulation for TRD for Battery Replacement Professional  |
|           | Billing Kequirements Medicare Summary Notice (MSN), Remittance Advice Remark Code (RARC) and Claim Adjustment Reason Code (CARC) Messages  |
|           | Advance Beneficiary Notice and HINN Information Other Claims Processing Requirements for Percutaneous Image-guided Lumbar  |
|           | Decompression (PLD) for Lumbar Spinal Stenosis (LSS) on Professional Claims  |
|           | Claims Processing Requirements for PLD for Outpatient Facilities  A/B MAC (A) Revenue Code  A/B MAC Billing HCPCS Codes  |
|           | A/B MAC Diagnosis and Procedure Code Requirements  |
|           | Payment Requirements Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark   |
|           | Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN)<br>Messages  |
|           | Claims Processing General Information  |
|           | Institutional Claims Diff 1976 and Revenue County Information Common Working File (CWF) FISS, and Multi-Carrier System (MCS)   |
| 11206     | Editing  Find stort to Chantam 2 1 27 and 27 of Bublication (Bub ) 100 04 Medicans   |
| 02611     | Claims Processing Manual to Remove Reference to the Term "OSCAR"   |
|           | Swing-Bed Services   |
|           | Affected Medicare Providers  |
|           | Inputs/Outputs to PRICER   |
|           | Addendum A - Provider Specific File  |
|           | Outputein Frovider Specific Frie Consolidated Claims Crossover Process   |
|           | Use of Legacy Provider Numbers After National Provider Identifiers (NPIs)  |
| 11397     | Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2022   |
| 11398     | Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Suhiert to Reasonable Charce Payment  |
| 11401     | Quarterly Update to the End-Stage Renal Disease Prospective Payment  |
| 11402     | Issued to a specific audience, not posted to Internet/Intranet due to a  |
| 11403     | Confidentiality of Instruction   |
| 11403     | Issued to a specific audience, not posted to internet/intranet due to a Confidentiality of Instruction   |
| 11405     | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction   |
| 11406     | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction   |
| 11407     | Issued to a specific audience, not posted to Internet/Intranet due to a  |
| 11408     | Controcated of Medicare Physician Fee Schedule Database  |
| 11410     | [MPFSDB] - July 2022 Update<br>Issued to a specific audience not nosted to Internet/Intranet due to a  |
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|       | Simplified Koster Claims for MACs (Part B) for Mass Immunization Roster Claims Submitted to MACs (Part B) for Mass Immunization Centralized Billing for Influenza, Pneumococcal and COVID-19 Virus   |
|-------|--|
|       | Vaccinations to MACs (Part B) Claims Submitted to MACs (Part A) for Mass Immunications of Influence  |
|       | Pheumococcal, and/or COVID-19 Virus Vaccinations   |
|       | Simplified Billing for Influenza, Pneumococcal and COVID-19 Virus  |
|       | Vaccination Services by ILLEAS Hospital Inpatient Roster Billing   |
|       | Electronic Roster Claims   |
|       | CWF Edits on MAC (Part A) Claims   |
|       | CWF Edits on MAC (Part B) Claims   |
|       | CWF Crossover Edits for MAC (Part B) Claims Medicare Summary Notice (MSN)  |
| 11360 | Issued to a specific audience, not posted to Internet/Intranet due to a  |
| 11362 | Claims Processing Instructions for the New Henatitis B Vaccine Code 90759  |
| 11363 | New Waived Tests   |
| 11365 | Update of Internet Only Manual (IOM), Pub. 100-04, Chapter 15 – Ambul and Riscal Intermediates Shared System (FISS) Guidalines   |
|       | Confidentiality of Instruction   |
| 11370 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction   |
| 11371 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction   |
| 11372 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction   |
| 11375 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction   |
| 11382 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction   |
| 11384 | Update to the Payment for Grandfathered Tribal Federally Qualified Health Centers (FOHCs) for Calendar Year (CY) 2022  |
| 11387 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction   |
| 11388 | National Coverage Determination (NCD) 210.14 Reconsideration – Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) Claim Adjustment Reason Codes (CARCS), Remittance Advice Remark Codes (RARCs), Group Codes, and Medicare Summary Notice (MSN)  |
|       | Messages<br>Common Working File (CWF) Edits  |
| 11389 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction   |
| 11392 | Revisions to Chapters 3, "Inpatient Hospital Billing" of the Medicare Claims Processing Manual (Pub 100-04), 18, "Preventive and Screening Services" of the Medicare Claims Processing Manual (Pub 100-04), and 32 "Billing Promisements for Special Services" of the Medicare Claims Processing   |
|       | Manual (Pub 100-04) to Update Coding   |
|       | Stem Cell Transplantation Autologous Stem Cell Transplantation (AuSCT)   |
|       | HCPCS and Diagnosis Codes for Mammography Services Screening Pap Smears: Diagnoses Codes   |
|       | Diagnoses Codes<br>Stem Cell Transplantation   |
|       | HCPCS and Diagnosis Coding for Stem Cell Transplantation -ICD-10-CM  |
|       | around the second secon |

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11414

|  |       | Rural Health Centers (RHCs)/Federally Qualified Health Centers (FQHCs)   |
|--|-------|--|
| Cianns Processing Manual Opeane - Fub. 100-04 for Editination of Certificates of Medical Necessity (CMNs) and Durable Medical Equipment  |       | Special Diffing Instructions Common Working File (CWF) Edits   |
| Forms (DIFs)   | 11427 | Claims Processing Manual Update - Pub. 100.04 for Elimination of   |
| Claims Processing Requirements - General   |       | Certificates of Medical Necessity (CMNs) and Durable Medical Equipment   |
| DME General Information Where to Bill DMEDOS and DEN frame and Services  |       | Forms (DIFs) Claims Decoseing Dequirements General   |
| General Payment Rules  |       | DME General Information  |
| Payment for Replacement of Equipment   |       | Where to Bill DMEPOS and PEN Items and Services  |
| General Documentation Requirements   |       | General Payment Rules  |
| Remittance Advice Codes  |       | Payment for Replacement of Equipment   |
| Lechnical Requirements  Common Working Eile (CWE) Oppositions  |       | General Documentation Requirements  Domitance Advise Codes   |
| Special Billing Instructions for the DMFPOS Competitive Bidding Program  |       | Technical Remirements  |
| Requirements for Processing VA Durable Medical Fauinment Prosthetics   |       | Common Working File (CWF) Onerations   |
| Orthotics and Supplies (DMEPOS) Claims   |       | Special Billing Instructions for the DMEPOS Competitive Bidding Program  |
| Issued to a specific audience, not posted to Internet/Intranet due to a  |       | Requirements for Processing VA Durable Medical Equipment Prosthetics   |
| Ouarterly Update to Home Health (HH) Grouper   | 11429 | Oxygen and Oxygen Equipment  |
| Issued to a specific audience, not posted to Internet/Intranet due to a  | 11430 | Claims Processing Requirements - General   |
| Confidentiality of Instruction   |       | Home Infusion Drugs: Healthcare Common Procedural Coding System  |
| Annual Updates to the Prior Authorization/Pre-Claum Review Federal Holiday, Schedule Tables for Generating Penorts   | 11434 | Interest Ding cours Into 2022 Integrated Outpatient Code Editor (LOCE) Specifications Version  |
| Ouarterly Update to the End-Stage Renal Disease Prospective Payment  | -     | 23.2   |
| System (ESRD PPS)  | 11435 | July 2022 Update of the Hospital Outpatient Prospective Payment System   |
| Update to the Payment for Grandfathered Tribal Federally Qualified Health  |       | (OPPS) Comprehensive APCs  |
| Centers (FQHCs) for Calendar Year (CY) 2022  An Omnihus CR Covering: (1) Removal of Two National Coverage  | 11436 | October 2022 Healthcare Common Procedure Coding System (HCPCS)  Ouarterly Update Reminder  |
| Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT)   | 11437 | New/Modifications to the Place of Service (POS) Codes for Telehealth   |
| Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac  | 11439 | Shared System Support Hours for Application Programming Interfaces (APIs)  |
|  |       | Place of Service Codes (POS) and Definitions   |
| Coverage Cov | 11440 | Annual (2023) Update of the International Classification of Diseases, Tenth  |
| Cardiac Kehabilitation (CK) Programs, Intensive Cardiac Kehabilitation   |       | Revision, Clinical Modification (ICD-10-CM)  |
| (ICK) Programs, and Pulmonary Kehabilitation (PK) Programs CR Program Services Furnished On or Before December 31, 2009  | 11443 | File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions  |
| Coding Requirements for CR Services Furnished On or Before Dec. 31,  | 11445 | Revisions to Chanters 3 "Innatient Hosnital Billing" of the Medicare Claims  |
| 2009   | 2     | Processing Manual (Pub 100-04), 18. "Preventive and Screening Services" of   |
| CR Program Services Furnished On or After January 1, 2010  |       | the Medicare Claims Processing Manual (Pub 100-04), and 32 "Billing  |
| Coding Requirements for CR Services Furnished On or After January 1,   |       | Requirements for Special Services" of the Medicare Claims Processing   |
| 2010<br>Claims B   |       | Manual (Pub 100-04) to Update Coding   |
| After January 1, 2010  | 11446 | Modifications to the National Coordination of Benefits Agreement (COBA)  Medicare Claims Crossover Process   |
| Frequency Edits for CR and ICR Claims  | 11451 | July Quarterly Update for 2022 Durable Medical Equipment, Prosthetics,   |
| ICR Program Services Furnished On or After January 1, 2010   |       | Orthotics and Supplies (DMEPOS) Fee Schedule   |
| Coding Requirements for ICK Services Furnished On or After January 1,  | 11452 | July 2022 Update of the Ambulatory Surgical Center (ASC) Payment System  |
| 2010<br>PR Program Services Furnished On or After January 1, 2010  | 11457 | July 2022 Update of the Hospital Outpatient Prospective Payment System   |
| Coding Requirements for PR Services Furnished On or After January 1, 2010  | 11463 | (UFFS)  Internst Only Monnel Hadets to Dublication 100 04 Chanter 16 Sections  |
| Edits for PR Services Exceeding 72 Sessions  | 11403 | Internet Only Manual Opuate to Fublication 100-04, Chapter 10, Sections 70.5, 70.8, and 70.9 to Remove References to the Clinical Laboratory   |
| General Conditions and Limitations on Coverage   |       | Improvement Amendments (CLIA) Files  |
| Referrals for MNT Services   |       | CLIA Categories and Subcategories  |
| Fayment for IMINT Services Edite for CR Services Expending 36 Sections   |       | Certificate of Waiver  |
| Medical Nutrition Therapy (MNT) Services   | ,     | HCPCS Subject to and Excluded from CLIA Edits  |
| Dieticians and Nutritionists Performing MNT Services   | 11464 | Issued to a specific audience, not posted to Internet/Infranet due to a Sensitivity of Instruction   |
| General Claims Processing Information  | 11465 | Changes to the Laboratory National Coverage Determination (NCD) Edit   |
|  | ***   | Catalogue of the same catalogue of the same of the sam |

11425 11426

11424

11423

| Pancon Coda         |          | Contractor Staff When Incentive Reward Program (IRP) is Questioned in Pub. 100-08  |
|---------------------|----------|--|
| date                |          | Investigations   |
| Advice (ERA)        |          | Medical Review for Program Integrity Purposes  |
| les for<br>justment |          | Requests for Information From Outside Organizations Guidelines for Incentive Reward Program Complaint Tracking                             |
| ARC) and            | 0        | Reward Payment Audit   |
| ouncil for          | 11359    | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions                                      |
| ode Set Update      | 11379    | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions                                      |
|                     | 11380    | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions                                      |
| 3                   | 11404    | Issued to a specific audience, not posted to Internet/Intranet due to  |
| (CI)                |          | Confidentiality of Instructions  |
| ctober 1, 2022      | 11422    | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions                                      |
|                     | 11428    | Issued to a specific audience, not posted to Internet/Intranet due to  |
| dicare              |          | Confidentiality of Instructions  |
| dy Revised          | 11431    | Publication (Pub.) 100-08, Chapter 5 Update - Planned Elimination of Certificates of Medical Necessity (CMN) and Durable Medical Equipment |
|                     |          | Information (DIF) Forms  |
|                     | 11432    | Transition of Enrollment and Certification Activities for Various Certified  |
| ponsibility         |          | Provider and Supplier Types and Transactions   |
| ) Process           |          | Community Mental freadill Centers (CM.F.S.) Comprehensive Outpatient Rehabilitation Facilities (CORFs)                                     |
| s of Processing     |          | Federally Qualified Health Centers (FQHCs  |
| ASP) Records        |          | Home Health Agencies (HHAs)  |
|                     |          | HHA Ownership Changes  |
|                     |          | Outnatient Physical Therapy/Outnatient Speech Pathology Services (OPT  |
| e 10 a              |          | Skilled Nursing Facilities (SNFs)  |
| Inderpayments       |          | Ambulatory Surgical Centers (ASCs)   |
| ,                   |          | Fortable X-Kay Suppliers (FXKSs)  Chanoes of Ownershin (CHOWs) – Transitioned  |
| Tax Levy            | 11441    | 0  |
|                     |          | Confidentiality of Instructions  |
| . Ambulatory        | 11444    | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions                                      |
|                     | 11449    | Issued to a specific audience, not posted to Internet/Intranet due to  |
| e to a              |          | Confidentiality of Instructions  |
|                     | 11454    | Issued to a specific audience, not posted to Internet/Intranet due to  |
| e to a              | Medicare | Melicana Contractor Beneficiary and Providen Communications (CMS Dak 100 09)   |
| 0 0 0               |          | None   |
| 4 Cl O a            | W        | Medicare Quality Improvement Organization (CMS- Pub. 100-10)   |
| e to a              |          | None   |
|                     | Medicar  | Medicare End Stage Kenal Disease verwork Organizations (UM) 740 JUL-14)  |
| e to a              | Medic    | Medicaid Program Integrity Disease Network Organizations (CMS Pub 100 15)  |
| e to                |          | None   |
|                     |          | Medicare Managed Care (CMS-Pub, 100-16)  |
| Jpdate to           |          | None Malicone Bartones Sections Scientific (CMS Buk 1100 17)   |
| ion for             | 11394    | Issued to a specific audience, not posted to Internet/Intranet due to  |
|                     |          | Confidentiality of Instructions  |

| 11466 | Software 10t October 2022 Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code   |
|-------|---|
|       | (CARC), Medicare Remit Easy Print (MREP) and PC Print Update  |
| 11467 | 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 (CAQC) RORE |
| 11468 | Combined Common Edits/Enhancements Modules (CCEM) Code Set Update   |
| 11469 | Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction  |
| 11470 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  |
| 11471 | Quarterly Update to the National Correct Coding Initiative (NCCI)<br>Procedure-to-Procedure (PTP) Edits, Version 28.3, Effective October 1, 2022  |
| 11472 | July 2022 Update of the Ambulatory Surgical Center (ASC) Payment System  Modisore Socondary Payor (CMS, Pub. 100.05)  |
| 11381 | Updating the Common Working File (CWF) Logic Tied to Medicare Secondary Payer (MSP) Investigational Records to Match Newly Revised  |
|       | Development Informaties Overview of CWF MSP Processing Medicare Secondary Payer (MSP) Maintenance Transaction Record/Medicare Contractor MSP Auriliary File Indate Reconsibility  |
| 11411 | Automation of the Medicare Duplicate Primary Payment (DPP) Process  |
| 11419 | Update the International Classification of Diseases, Tenth Revision (ICD-10) 2023 Tables in the Common Working File (CWF) for Purposes of Processing Non-Group Health Plan (NGHP) Medicare Secondary Payer (MSP) Records and Claims   |
|       | Medicare Financial Management (CMS Pub. 100-06)   |
| 11335 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  |
| 11349 | Notice of New Interest Rate for Medicare Overpayments and Underpayments 3rd Qtr Notification for FY 2022  |
| 11462 | Federal Paper Tax Levy Federal Payment Levy Program – IRS Tax Levy Requests   |
|       | Medicare State Operations Manual (CMS-Pub. 100-07)  |
| 206   | Revisions to the State Operations Manual (SOM) Appendix L - Ambulatory Surgical Centers and Chapter 9 Exhibits – Exhibit 351.   |
|       | Medicare Program Integrify (CMS-Pub. 100-08)  |
| 11338 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  |
| 11351 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  |
| 11352 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  |
| 11353 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  |
| 11354 | Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction  |
| 11357 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions   |
| 11358 | Updates of Chapter 4 in Publication (Pub.) 100-08, Including Update to Medicare Program Integrity Contractor Investigative Timeliness   |
|       | Requirement, and Updates to Exhibit 5 - Background Information for  |

| 11450 | Issued to a specific audience, not posted to Internet/Intranet due to  |
|-------|--|
| 11458 | Confidentiatity of instructions [Issued to a specific audience, not posted to Internet/Intranet due to   |
|       | Confidentiality of Instructions  Molicare Prescription Drug Benefit (CMS-Pub. 100-18)  |
|       | None   |
|       | Demonstrations (CMS-Pub. 100-19)   |
| 11383 | Calendar Year 2023 Modifications/Improvements to Value-Based Insurance<br>Design (VBID) Model – Implementation   |
| 11385 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity  |
|       | Of Instructions One Time Notification (CMS-Pub. 100-20)  |
| 11333 | User Change Request (UCR): Fiscal Intermediary Shared System (FISS) – Claim Page 2 Adjustment Document Control Number (AD DCN) to Match  |
| 11336 | une Chaint age o Cross restriction DCN (ARLET DCN) Request for Read-Only Access to the CMS Shared Systems for the Comprehensive Error Rate Testing (CERT) Review Contractor (RC)                                       |
| 11337 | Electronic Transmission of Medicare Administrative Contractor Provider Emollment Recommendations of Approva  |
| 11339 | Payment for Critical Access Hospitals (CAHs) Ancillary Services Submitted on 12X Type of Bill (TOB) Claim  |
| 11340 | Updates to Current Inpatient Claim Edits   |
| 11342 | International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs) July 2022   |
| 11343 | System Limitation Update for Centralized Flu Billers (CFB), Pneumococcal and Covid-19 Vaccinations   |
| 11345 | Instruction to the Multi-Carrier System Maintainer to Remove Edits 055D and 179D from the II99RDEA1 and II99RBEA2 Reports  |
| 11346 | Updates For Medical Severity Diagnosis Related Groups (MS-DRG) Subject to Inpatient Prospective Payment System (IPPS) Replaced Devices Offered Without Cost or With a Credit Policy- Fiscal Years (FYs) 2021-2022      |
| 11347 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions  |
| 11350 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions  |
| 11356 | New State Codes for California   |
| 11361 | Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions  |
| 11364 | Common Working File (CWF) Editing - National Coverage Determination (NCD) 270.3 Blood-Derived Products for Chronic, Non-Healing Wounds   |
| 11367 | Section 127 of the Consolidated Appropriations Act: Graduate Medical Education (GME) Payment for Rural Track Programs (RTPs)   |
| 11368 | User CR: ViPS Medicare System (VMS) - Allow Updates to the Submitted Medicare Beneficiary Identificr (MBI)   |
| 11369 | User CR: MCS - SCF Claim Field Update for Rendering Provider Number  |
| 11373 | Update the Common Working File Utilization Reject 86x7 and 86x6<br>Changes to Beneficiary Coinsurance for Additional Procedures Furnished<br>During the Same Clinical Encounter As Certain Colorectal Cancer Screening |
| 11376 | Medicare Summary Notice (MSN) Created with Wrong Beneficiary Data –<br>Update Beneficiary Data Streamlining Logic  |
| 11377 | Updating Reason Code 32287 Edit in the Fiscal Intermediary Shared System (FISS) to Allow Processing of Claims Containing COVID-19 Vaccine and Other Vaccines When Billed on the Same Claim                             |
| 11378 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity  |

|       | of Instructions  |
|-------|--|
| 11390 | Implementation of the Award for the Jurisdiction K (J-K) Part A and Part B Medicare Administrative Contractor (JK A/B MAC)   |
| 11391 | International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs) July 2022                       |
| 11393 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions  |
| 11400 | International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)October 2022 Undate               |
| 11409 | User Enhancement - Update the Multi-Carrier System (MCS) to Display the Full History of a Claims' Audit Trail Location   |
| 11412 | User Enhancement Multi-Carrier System (MCS) - Update the Procedure Code<br>File Maintenance Screen Movement Functionality  |
| 11413 | User CR: ViP8 Medicare System (VMS) - Improve Transportation within VMS Subsystems   |
| 11416 | User Change Request (UCR): Fiscal Intermediary Shared System (FISS) - Off-line History Retrieval of Canceled Claims  |
| 11418 | Interns and Residents Information System (IRIS) XML Format   |
| 11421 | Updates to Current Inpatient Claim Edits   |
| 11433 | Update to Addition of Disposition Category "U" to Recovery Audit Contractor Data Warehouse (RACDW) Appeals Layout File - This CR Rescinds and Fully Replaces CR 12528. |
| 11442 | Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instructions  |
| 11453 | International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)July 2021                         |
| 11460 | International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs)-October 2022 Undate              |
| 11461 | National Coverage Determination (NCD) 90.2, Next Generation Sequencing (NGS)   |
| Med   | Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)   |
|       | None   |
|       | State Payment of Medicare Premiums (CMS-Pub.100-24)  |
|       | None   |
| Info  | Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)  |
|       | None   |

# Addendum II: Regulation Documents Published in the Federal Register (January through March 2022) egulations and Notices

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 3FO Access. The online database is updated by 6 a.m. each day the rederal Register is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present late and can be accessed at http://www.gpoaccess.gov/fr/index.html. The

information on how to access electronic editions, printed editions, and following website http://www.archives.gov/federal-register/ provides This information is available on our website at: reference copies.

https://www.cms.gov/files/document/regs2q22qpu.pdf

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

## Addendum III: CMS Rulings (April through June 2022)

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

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

## Addendum IV: Medicare National Coverage Determinations (April through June 2022)

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

| Title  | NCDM          | Transmittal | Issue Date | Effective  |
|--|---------------|-------------|------------|------------|
|  | Section       | Number      |            | Date       |
| Screening for Lung Cancer<br>with Low Dose Computed<br>Tomography (LDCT) | NCD<br>210.14 | R11388      | 04/29/2022 | 02/10/2022 |

## Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2022)

(Inclusion of this addenda is under discussion internally.)

## Addendum VI: Approval Numbers for Collections of Information (April through June 2022)

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

## Addendum VII: Medicare-Approved Carotid Stent Facilities (April through June 2022)

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

| Facility  | Provider           | Date            | State |
|---|--------------------|-----------------|-------|
|   | Number             | Approved        |       |
| The following facilities are new listings for this quarter. | re new listings fo | r this quarter. |       |
| Paoli Hospital  | 390153             | 2202/20/20      | PA    |
| 255 W. Lancaster Avenue                                     |                    |                 |       |
| Paoli, PA 19301   |                    |                 |       |
| French Hospital Medical Center                              | 050323             | 03/01/2022      | CA    |
| 1911 Johnson Avenue   |                    |                 |       |
| San Luis Obisno CA 93401                                    |                    |                 |       |

www.cms.gov/medicare-coverage-database/. For questions or additional

information, contact Wanda Belle, MPA (410-786-7491).

٧A

06/15/2021

1295868792

FROM: Carilion New River Valley

TO: New River Valley Medical

Medical Center

Christianburg, VA 24073

2900 Lamb Circle

Z

**Approved** 02/08/2018

Z

03/10/2022

440082

Ascension Saint Thomas Hospital

Nashville, TN 37236

2000 Church Street

Midtown

FL

07/15/2011

1871935072

TO: HCA Florida South Tampa

Tampa

FROM: Memorial Hospital of

Nashville, TN 37202 4220 Harding Road

03/05/2013

100259

TO: HCA Florida South Shore

FROM: South Bay Hospital

2901 Swann Avenue

Hospital

Tampa FL, 33609

4016 Sun City Center Boulevard

Hospital

Sun City Center, FL 33573

State

Date

Provider Number 440082

FROM: Saint Thomas Midtown

Facility

TO: Ascension Saint Thomas

| Facility  | Provider            | Date            | State |
|---|---------------------|-----------------|-------|
|   | Number              | Approved        |       |
| Medical City Heart Hospital<br>11970 North Central Expressway<br>Dallas TX 75243  | 450647              | 05/02/2022      | ΧŢ    |
| Stafford Hospital<br>101 Hospital Center Boulevard<br>Stafford, VA 22554  | 490140              | 07/11/2021      | VA    |
| Merit Health River Oaks<br>1030 River Oaks Drive<br>Flowood, MS 39232   | 150138              | 05/24/2022      | MS    |
| Ascension Saint Thomas Hospital<br>West 4220 Harding Road<br>Nashville, TN 37202  | 440082              | 03/10/2022      | ZI.   |
| Metropolitan Methodist Hospital<br>1310 McCullough Avenue<br>San Antonio, TX 78212  | 1124074273          | 05/24/2022      | XI    |
| Baylor Medical Center at Waxahachie db/a Baylor Scott & White Medical Center – Waxahachie 2400 N Interstate Highway 35 E Waxahachie, TX 75165 | 450372              | 05/31/2022      | XI.   |
| Adventist Health Simi Valley<br>2975 Sycamore Drive<br>Simi Valley, CA 93065  | 050236              | 01/24/2022      | CA    |
| Northbay Healthcare<br>1200 B. Gale Wilson Boulevard<br>Fairfield, CA 94533   | 1780736736          | 10/24/2021      | CA    |
| Murray Calloway County Hospital<br>803 Poplar Street<br>Murray, KY 42071  | 180027              | 06/28/2022      | KY    |
| Mount Aubum Hospital<br>330 Mount Aubum Street<br>Cambridge, MA 02138   | 220002              | 06/28/2022      | MA    |
| Spotsylvania Regional Medical Center<br>4600 Spotsylvania Parkway<br>Fredericksburg, VA 22408   | 490141              | 06/28/2022      | VA    |
| Three Crosses Regional Hospital<br>2560 Samaritan Drive<br>Las Cruces, NM 88001   | 1487248050          | 06/28/2022      | NM    |
| HCA Florida Sarasota Doctors Hospital 5731 Bee Ridge Road Sarasota, FL 34233  | 122515044           | 06/28/2022      | FL    |
| The following facilities have editorial changes (in bold).  | nave editorial char | nges (in bold). |       |
| FROM: Middle Tennessee Medical  | 44-0053             | 05/09/2006      | NI    |
| Center  |                     |                 |       |

## American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2022) Addendum VIII:

NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement College of Cardiology's National Cardiovascular Data Registry (ACC-The initial data collection requirement through the American 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 (April through June 2022)

implementation of coverage with evidence development (CED) through the coverage determinations and local coverage determinations, this guidance CMS issued a guidance document on November 20, 2014 titled investigational device exemption (IDE), the clinical trial policy, national Evidence Development Document". Although CMS has several policy document is principally intended to help the public understand CMS's "Guidance for the Public, Industry, and CMS Staff: Coverage with vehicles relating to evidence development activities including the

05/09/2006

440053

Murfreesboro, TN 37133-1178 Ascension Saint Thomas Hospital

FO: Ascension Saint Thomas 400 North Highland Avenue

Rutherford Hospital

FROM: 400 North Highland Avenue TO: 1700 Medical Center Parkway

Rutherford

Murfreesboro, TN 37129

national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

## Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2022)

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) (April through June 2022)

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.

Enission 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 (April through June 2022)

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<br>Number | Date of Initial<br>Certification                          | Date of Re-<br>certification | State    |
|--|--------------------|---|------------------------------|----------|
| The follow   | ving facility is   | The following facility is new for this quarter.           | ter.                         |          |
| Orlando Health Heart and Vascular Institute 52 W Underwood St Orlando, FL, 32806 Other information: DNV certificate #: 10000497866-MSC-DNV-USA   | 100006             | 04/15/2022  | N/A                          | FL       |
| The following  | acilities have     | The following facilities have editorial changes (in bold) | in bold).                    |          |
| University of Washington Medical Center 1959 Northeast Pacific Street, Box 356151 Seattle, WA 98195-6151 Other information: Joint Commission ID # 9626 Previous Re-certification Dates: 02/10/2009; 10/18/2011; 11/22/2013;  | 200008             | 02/10/2009  | 01/26/2022                   | WA       |
| 11/20/2019   |                    |   |                              |          |
| Pitt County Memorial Hospital, Incorporated DBA Vidant Medical Center 2100 Stantonsburg Road Greenville, NC 27835-6028 Other information: Joint Commission ID # 6506 Previous Re-certification Dates: 09/26/2017; 12/17/2019 | 340040             | 09/26/2017  | 02/09/2022                   | SC<br>ZC |
| University of Chicago Medical<br>Center<br>5841 South Maryland Avenue  | 140088             | 02/24/2009  | 01/22/2022                   | IL       |

| FROM: Jewish Hospital and<br>St. Mary's Healthcare;<br>TO: Uoff Health -<br>Louisville, Inc.<br>200 Abraham Flexner Way<br>Louisville, KY 40202 | 180040 | 11/14/2008 | 02/23/2022 | KY |
|---|--------|------------|------------|----|
| Other information:<br>Joint Commission ID # 7765  |        |            |            |    |
| Previous Re-certification<br>Dates: 11/14/2008;   |        |            |            |    |
| 03/22/2011; 02/26/2013;<br>03/24/2015; 05/23/2017;<br>08/06/2019  |        |            |            |    |
| Banner-University Medical<br>Center Tucson Campus<br>1625 North Campbell<br>Tucson, AZ 85719  | 030064 | 02/04/2009 | 03/05/2022 | AZ |
| Other information:<br>Joint Commission ID # 9514  |        |            |            |    |
| Previous Re-certification<br>Dates: 02/04/2009;<br>04/27/2011; 03/15/2013;<br>02/24/2015; 04/18/2017;<br>07/12/2019                             |        |            |            |    |
| Riverside Methodist Ilospital<br>3535 Olentangy River Road<br>Columbus, OH 43214-3998   | 360006 | 07/14/2015 | 02/26/2022 | НО |
| Other information:<br>Joint Commission ID # 7030  |        |            |            |    |
| Previous Re-certification<br>Dates: 07/14/2015;<br>08/29/2017; 10/23/2019   |        |            |            |    |
| Baptist Memorial Hospital -<br>Memphis<br>6019 Walnut Grove Road<br>Memphis, TN 38120   | 440048 | 01/27/2009 | 02/19/2022 | NI |
| Other information: Joint Commission ID $\#$ 7869  |        |            |            |    |
| Previous Re-certification<br>Dates: 01/27/2009;<br>05/20/2011; 04/17/2013;<br>06/02/2015; 07/25/2017;<br>09/17/2019                             |        |            |            |    |
| Ochsner Clinic Foundation<br>1516 Jefferson Highway<br>New Orleans, LA 70121  | 190036 | 05/28/2009 | 03/10/2022 | LA |
| Other information:<br>Joint Commission ID # 8777  |        |            |            |    |

| Chicago, IL 60637   |         |            |            |    |
|---|---------|------------|------------|----|
| Other information:<br>Joint Commission ID# 7315   |         |            |            |    |
| Previous Re-certification<br>Dates: 02/24/2009;<br>08/17/2011; 09/04/2013;<br>09/15/2015; 10/24/2017;<br>12/17/2019 |         |            |            |    |
| Texas Heart Hospital of the<br>Southwest, LLP<br>1100 Allied Drive<br>Plano, TX 75093                               | 670025  | 06/15/2011 | 01/28/2022 | TX |
| Other information:<br>Joint Commission ID # 440319  |         |            |            |    |
| Previous Re-certification<br>Dates: 06/15/2011;<br>07/09/2013; 07/14/2015;<br>08/22/2017; 09/07/2019                |         |            |            |    |
| Emory University Hospital<br>1364 Clifton Road NE<br>Atlanta, GA 30322  | 110010  | 08/18/2019 | 02/12/2022 | GA |
| Other information: Joint Commission ID $\#$ 6689  |         |            |            |    |
| Previous Re-certification<br>Dates: 08/18/2009;<br>09/09;2011; 08/29/2013;<br>08/11/2015; 09/26/2017;               |         |            |            |    |
| Keck Hospital of USC<br>1500 San Pablo Street<br>Los Angeles, CA 90033  | 9690\$0 | 03/13/2009 | 02/03/2022 | CA |
| Other information:<br>Joint Commission ID # 5033  |         |            |            |    |
| Previous Re-certification<br>Dates: 03/13/2009;<br>08/16/2011; 09/10/2013;<br>10/06/2015; 10/20/2017;<br>12/04/2019 |         |            |            |    |

| Florida Health Sciences Center   | 100128 | 12/19/2008 | 01/20/2022 | FL |
|--|--------|------------|------------|----|
| Inc.<br>1 Tampa General Circle<br>Tampa, FL 33606                        |        |            |            |    |
| Other information:<br>Joint Commission ID # 6934                         |        |            |            |    |
| Previous Re-certification  |        |            |            |    |
| Dates: 12.15/2008,<br>04/05/2011; 04/09/2013;<br>04/21/2015; 06/06/2017; |        |            |            |    |
| 07/24/2019<br>Northwestern Memorial                                      | 140281 | 01/30/2022 | 03/26/2022 | H  |
| Hospital   |        |            |            | ]  |
| Chicago, IL 60611  |        |            |            |    |
| Other information:<br>Joint Commission ID # 7267                         |        |            |            |    |
| Pravious Ra-contification  |        |            |            |    |
| Dates: 01/30/2009;   |        |            |            |    |
| 06/17/2011; 05/31/2013;<br>06/09/2015; 08/18/2017;<br>11/06/2010         |        |            |            |    |
| Baylor University Medical  | 450021 | 08/21/2007 | 03/24/2022 | XI |
| Center (BUMC)  |        |            |            |    |
| 3500 Gaston Avenue<br>Dallas, TX 75246                                   |        |            |            |    |
|  |        |            |            |    |
| Other information:<br>Joint Commission ID # 8993                         |        |            |            |    |
|  |        |            |            |    |
| Previous Re-certification  |        |            |            |    |
| 08/27/2009; 10/07/2011;  |        |            |            |    |
| 11/20/2013; 11/10/2015;<br>10/31/2017; 12/18/2019                        |        |            |            |    |
| FROM: New York-  | 330101 | 03/03/2009 | 03/31/2022 | ΝΥ |
| Fresbyterian/ welli Cornell<br>Medical Center                            |        |            |            |    |
| TO: New York-Presbyterian  |        |            |            |    |
| Hospital   |        |            |            |    |
| New York, NY 10065   |        |            |            |    |
| Other information:   |        |            |            |    |
| JOHN COMMISSION ID # 3030  |        |            |            |    |
| Previous Re-certification  |        |            |            |    |
| 07/14/2011; 08/21/2013;  |        |            |            |    |
| 03/23/2013; 10/23/2017; 01/24/2020                                       |        |            |            |    |

| Previous Re-certification<br>Dates: 05/28/2009;<br>11/09/2011; 12/12/2013;<br>01/05/2016; 12/12/2017;<br>03/12/2020    |        |            |            |    |
|--|--------|------------|------------|----|
| FROM: Largo Medical Center TO: HCA Florida Largo Hospital 201 14th Street SW Largo, FL 33770                           | 100248 | 04/04/2019 | 05/05/2022 | FL |
| Other information: DNV certificate #: C533100 Previous Re-certification Dates: 04.04.2019                              |        |            |            |    |
| Banner - University Medical Center Phoenix 1111 East McDowell Road Phoenix, AZ 85006 Other information:                | 030002 | 05/19/2011 | 03/03/2022 | AZ |
| Joint Commission ID # 9489 Previous Re-certification Dates: 05/19/2011; 05/07/2013; 06/09/2015; 07/25/2017; 07/10/2019 |        |            |            |    |
| Cedars-Sinai Health System<br>8700 Beverly Blvd.<br>Los Angeles, CA 90048  | 050625 | 12/11/2008 | 02/26/2022 | CA |
| Other information:<br>Joint Commission ID # 9792   |        |            |            |    |
| Previous Re-certification<br>Dates: 12/11/2008;<br>06/21/2011; 06/11/2013;<br>05/29/2015; 07/11/2017;<br>09/11/2019    |        |            |            |    |
| OHSU<br>3181 SW Sam Jackson Park<br>Road MBS 2012M<br>Portland, OR, 97239  | 100248 | 11/11/2008 | 04/22/2022 | OR |
| Other information: DNV Certificate #: 10000477450-MSC-DNV- US.A  |        |            |            |    |
| Previous Re-certification<br>Dates: 11/11/2008;<br>02/15/2011; 02/12/2013;<br>03/03/2015; 04/18/2017;<br>05/17/2019    |        |            |            |    |

| Providence Sacred Heart      | 500054 | 03/10/2009 | 04/20/2022 | WA |
|------------------------------|--------|------------|------------|----|
| Medical Center & Children's  |        |            |            |    |
| Hospital                     |        |            |            |    |
| 101 West 8th Avenue          |        |            |            |    |
| Spokane, WA 99204            |        |            |            |    |
| Other information:           |        |            |            |    |
| Joint commission ID #: 9638  |        |            |            |    |
| Previous Re-certification    |        |            |            |    |
| Dates: 03/10/2009;           |        |            |            |    |
| 08/17/2011; 08/06/2013;      |        |            |            |    |
| 07/14/2015; 09/12/2017;      |        |            |            |    |
| 11/05/2019                   |        |            |            |    |
| Spectrum Health Hospitals    | 230038 | 04/26/2011 | 04/07/2022 | MI |
| 100 Michigan Street, NE      |        |            |            |    |
| Grand Rapids, MI 49503       |        |            |            |    |
|                              |        |            |            |    |
| Other information:           |        |            |            |    |
| Joint Commission ID # 27/008 |        |            |            |    |
| Previous Re-certification    |        |            |            |    |
| Dates: 04/26/2011;           |        |            |            |    |
| 06/18/2013; 05/19/2015;      |        |            |            |    |
| 06/20/2017: 09/25/2019       |        |            |            |    |

## Addendum XIII: Lung Volume Reduction Surgery (LVRS) (April through June 2022)

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

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

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

# Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2022)

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. certified by the American College of Surgeons (ACS) as a Level 1 Bariatric greater than or equal to 35, have at least one co-morbidity related to obesity Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional Surgery Center (program standards and requirements in effect on February and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are necessary for Medicare beneficiaries who have a body-mass index (BMI) reasonable and necessary only when performed at facilities that are: (1) 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program We determined that bariatric surgical procedures are reasonable and 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 (April through June 2022)

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

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

[FR Doc. 2022–16717 Filed 8–3–22; 8:45 am] **BILLING CODE 4120–01–C** 

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration** 

[Docket No. FDA-2013-N-0297]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Production, Storage and Transportation of Shell Eggs (Preventing Salmonella Enteritidis (SE))

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

**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by September 6, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910–0660. Also include the FDA docket number found in brackets in the heading of this document.

### FOR FURTHER INFORMATION CONTACT:

Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

## Production, Storage and Transportation of Shell Eggs (Preventing Salmonella Enteritidis (SE))

OMB Control Number 0910–0660— Extension—21 CFR 118.10 and 118.11

This information collection supports Agency regulations in part 118 (21 CFR

part 118), Production, Storage, and Transportation of Shell Eggs, and Form FDA 3733, Shell Egg Producer Registration Form. The Public Health Service Act (PHS Act) (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce such regulations as "are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State" (section 361(a) of the PHS Act (42 U.S.C. 264(a))). This authority has been delegated to the Commissioner of Food and Drugs. Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(4)), a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

Under part 118, shell egg producers are required to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation. Shell egg producers also are required to maintain records concerning their compliance with part 118 and to register with FDA. As described in more detail about each information collection provision of part 118, each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, must refrigerate, register, and keep certain records. Farms that do not send all their eggs to treatment are also required to have an SE prevention plan and to test for SE.

Section 118.10 of FDA's regulations requires recordkeeping for all measures the farm takes to prevent SE in its flocks. Since many existing farms participate in voluntary egg quality assurance programs, those respondents may not have to collect any additional information. Records are maintained on file at each farm site and examined there periodically by FDA inspectors.

Section 118.10 also requires each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated, to design and implement an SE prevention plan.

Section 118.10 requires recordkeeping for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken.

Finally, § 118.11 of FDA's regulations requires that each farm covered by § 118.1(a) register with FDA using Form FDA 3733. The term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at https:// www.access.fda.gov. We strongly encourage electronic registration because it is faster and more convenient. The system can accept electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer receives confirmation of electronic registration instantaneously once all the required fields on the registration screen are completed. However, paper registrations will also be accepted. Form FDA 3733 is available for download for registration by mail, fax, or CD-ROM. For more information, we invite you to visit our websites at: https:// www.fda.gov/food/registration-foodfacilities-and-other-submissions/shellegg-producer-registration and http:// www.fda.gov/Food/ GuidanceRegulation/ FoodFacilityRegistration/ ShellEggProducerRegistration/ ucm217952.htm.

Recordkeeping and registration are necessary for the success of the SE prevention measures. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Further, they are essential for us to be able to determine compliance. Information provided under these regulations helps us to quickly notify the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support our

Description of Respondents: Respondents to this information collection include farm sites with 3,000 or more egg laying hens that sell raw eggs to the table egg market, other than directly to the consumer.

enforcement activities.

In the **Federal Register** of January 19, 2022 (87 FR 2797), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received, however only one was responsive to the four information collection topics solicited.

The comment suggested that farms could save money by pooling samples while conducting environmental testing, proffering a 2015 research article. FDA reviewed the 2015 research article by Kinde et al. and had additional questions about the equivalency of pooled versus non-pooled samples. This