Use: This collection is required by a notice (78 FR 48164–69) published on August 7, 2013 which delineates the process for making a national coverage determination (NCD) including information for external parties to submit a formal request for a new NCD or a reconsideration of an existing NCD. An NCD is defined in 1862(l) of the Social Security Act (the Act) as ''a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.'' This information collection will assist us in obtaining the information we require to make a national coverage determination in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries. *Form Number:* CMS–R–290 (OMB control number: 0938–0776); *Frequency:* Annual; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 1,200. (For policy questions regarding this collection contact Lori M. Ashby at 410–786–6322.)

Dated: June 2, 2020.

William N. Parham, III,

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

[FR Doc. 2020–12287 Filed 6–5–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10114, CMS–10199, CMS–R–52 and CMS–R–26]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by August 7, 2020.

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

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

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

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

1. Access CMS' website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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

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

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

SUPPLEMENTARY INFORMATION:

Contents

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

CMS–10114 National Provider Identifier (NPI) Application and Update Form and Supporting Regulations in 45 CFR 142.408, 45 CFR 162.406, 45 CFR 162.408

CMS–10199 Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy

CMS–R–52 Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services and Supporting Regulations

CMS–R–26 Clinical Laboratory Improvement Amendments (CLIA) Regulations

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

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* National Provider Identifier (NPI) Application and Update Form and Supporting Regulations in 45 CFR 142.408, 45 CFR 162.406, 45 CFR 162.408; *Use:* The National Provider Identifier Application and Update Form is used by health care providers to apply for NPIs and furnish updates to the information they supplied on their initial applications. The form is also used to deactivate their NPIs if necessary. The form is available on paper or can be completed via a web-based process. Health care providers can mail a paper application, complete the application via the web-based process via the National Plan and Provider Enumeration System (NPPES), or have a trusted organization submit the application on their behalf via the Electronic File Interchange (EFI) process. The Enumerator uses the NPPES to process the application and generate the NPI. NPPES is the Medicare contractor tasked with issuing NPIs, and maintaining and storing NPI data. *Form Number:* CMS–10114 (OMB Control

Number: 0938–0931); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Federal government; *Number of Respondents:* 996,042; *Total Annual Responses:* 996,042; *Total Annual Hours:* 169,327. (For policy questions regarding this collection contact Da'Vona Boyd at 410–786–7483.)

2. *Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection:* Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy; *Use:* CMS provides coverage for carotid artery stenting (CAS) with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis between 50 percent and 70 percent or have asymptomatic carotid artery stenosis ≥80 percent in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1, or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7 CMS also covers CAS with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis ≥70 percent performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. In accordance with this criteria, we consider coverage for CAS reasonable and necessary (section 1862 (A)(1)(a) of the Social Security Act). *Form Number:* CMS–10199 (OMB control number: 0938–1011)*; Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,420; *Total Annual Responses:* 3,313; *Total Annual Hours:* 30,057. *(For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)*

3. Type of Information Collection Request: Extension of a previously approved collection; *Title of Information Collection:* Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services and Supporting Regulations; *Use:* The information collection requirements described herein are part of the Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities. The requirements fall into three categories: Record keeping, reporting, and disclosure. With regard to the record keeping requirements, CMS uses these conditions for coverage to certify health care facilities that want to participate in the Medicare or Medicaid programs. For the reporting requirements, the information is needed to assess and ensure proper distribution and effective utilization of ESRD treatment resources while maintaining or improving quality of care. All of the reports specified in this document are geared toward ensuring that facilities achieve quality and cost-effective service provision. Collection of this information is authorized by Section 1881 of the Act and required by 42 CFR 405.2100 through 405.2171 (now at 42 CFR 414.330, 488.60, and 494.100–494.180). Depending on the outcome of litigation, disclosures may be required by Medicare-certified dialysis facilities that make payments of premiums for individual market health plans. *Form Number:* CMS–R–52 (OMB Control Number: 0938–0386); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 8,246; *Total Annual Responses:* 171,795; *Total Annual Hours:* 1,260,491. (For policy questions regarding this collection contact Eric Laib at 410–786–9759.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Regulations; *Use:* The information is necessary to determine an entity's compliance with the Congressionally-mandated program with respect to the regulation of laboratory testing (CLIA). In addition, laboratories participating in the Medicare program must comply with CLIA requirements as required by section 6141 of OBRA 89. Medicaid, under the authority of section 1902(a)(9)(C) of the Social Security Act, pays for services furnished only by laboratories that meet Medicare (CLIA) requirements. *Form Number:* CMS–R–26 (OMB Control Number: 0938–0612); *Frequency:* Monthly, occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions, State, Local or Tribal Governments, and the Federal government; *Number of Respondents:* 34,579; *Total Annual Responses:* 74,476,376; *Total Annual Hours:* 14,514,802. (For policy questions regarding this collection contact Raelene Perfetto at 410–786–6876).

Dated: June 2, 2020.

William N. Parham, III,

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

[FR Doc. 2020–12285 Filed 6–5–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0128]

Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is hosting a virtual public meeting to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FYs) 2023 through 2027. PDUFA authorizes FDA to collect user fees to support the process for the review of human drug applications. The current legislative authority for PDUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting prescription drug user fees in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) directs that FDA begin the PDUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input and holding a public meeting where the public may present its views on the reauthorization. FDA invites public comment as the Agency begins the process to reauthorize the program in FYs 2023 through 2027. These comments will be published and available on FDA's website.

DATES: The public meeting will be held on July 23, 2020, from 9 a.m. to 2 p.m., and will take place virtually and will be held by webcast only. Submit either electronic or written comments on this public meeting by August 23, 2020.

ADDRESSES: Registration to attend the meeting and other information can be found at *https://pdufavii-publicmeeting.eventbrite.com.* See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 23, 2020. The