minutes, and each speaker may only speak once per meeting.

Written Public Comment: Written comments must be received on or before September 23, 2020. Written public comments submitted by 72 hours prior to the ACIP meeting will be provided to ACIP members before the meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020–17765 Filed 8–13–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10418, CMS–10199, CMS–R–52 and CMS–R–26]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by September 14, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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

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

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

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual MLR and Rebate Calculation Report and MLR Rebate Notices; *Use:* Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the transitional reinsurance, risk corridors, and risk adjustment programs established under sections 1341, 1342, and 1343, respectively, of the Affordable Care Act. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary.

Based upon CMS' experience in the MLR data collection and evaluation process, CMS is updating its annual burden hour estimates to reflect the actual numbers of submissions, rebates and rebate notices. The 2019 MLR Reporting Form and Instructions reflect changes for the 2018 reporting year and beyond. The 2019 MLR Reporting Form and instructions are also modified to eliminate the reporting elements that were required under the risk corridors data submission requirements in 45 CFR 153.530 for the 2014 through 2016 benefit years. For 2019, it is expected that issuers will submit fewer reports and on average, send fewer notices and rebate checks in the mail to policyholders and subscribers, which will reduce burden on issuers. In addition, issuers of qualified health plans will no longer have to submit on the annual report the data for the risk corridors program established under section 1342 of the Patient Protection and Affordable Care Act. *Form Number:* CMS–10418 (OMB control number: 0938–1164); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 494; *Number of Responses:* 1,896; *Total Annual Hours:* 232,427. For policy questions regarding this collection

contact Stephanie Watson at 301–492–4238.

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:* Reinstatement 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: August 11, 2020.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–D–1649 and FDA–2019–D–1651]

Safety and Performance Based Pathway Device-Specific Guidances; Guidances for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of two final device-specific guidance documents for the Safety and Performance Based Pathway—specifically, ''Cutaneous Electrode for Recording Purposes—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' and ''Conventional Foley Catheters—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff.'' The device-specific guidances identified in this notice were developed in accordance with the finalized guidance entitled ''Safety and Performance Based Pathway.''

DATES: The announcement of the guidance is published in the **Federal Register** on August 14, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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