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

https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 23, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2010–N–0128 for ''Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

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

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. Transcripts of the meeting will be available on the FDA website at: *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee* approximately 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: Patrick Zhou, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1148, Silver Spring, MD 20993–0002, 301–348–1817, *Patrick.Zhou@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a virtual public meeting to begin the reauthorization process of PDUFA, the legislation that authorizes FDA to collect user fees to support the process for the review of human drugs, including various components in FDA including the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Office of the Commissioner (OC), and the Office of Regulatory Affairs (ORA). The current authorization of the program (PDUFA VI) expires in September 2022. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process. Section 736B(f)(2) of the FD&C Act (21 U.S.C. 379h–2(f)(2)) requires that before FDA begins negotiations with the regulated industry on PDUFA reauthorization, the Agency performs the following: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting where the public may present its views on the reauthorization; (3) provide a period of 30 days after the public meeting to obtain written comments from the public; and (4) publish the comments at *https://www.fda.gov.* This notice, the public meeting, the 30-day comment period after the meeting, and the posting of the comments on the FDA website will satisfy these requirements. The purpose of the meeting is to hear stakeholder views on PDUFA as we consider the features to propose, update, and discontinue in the next PDUFA. FDA is interested in responses to the following three questions and welcomes any other pertinent information stakeholders would like to share:

- What is your assessment of the overall performance of PDUFA VI thus far?
- What current features of PDUFA should be reduced or discontinued to ensure the continued efficiency and effectiveness of the human drug review process?
- What new features should FDA consider adding to the program to enhance the efficiency and effectiveness of the human drug review process?

II. What is PDUFA? What does it do?

The following information is provided to help potential meeting participants better understand the history and evolution of PDUFA and its status. The Prescription Drug User Fee Act (PDUFA) is a law that authorizes FDA to collect fees from drug companies that submit marketing applications for certain human drug and biological products. PDUFA was originally enacted in 1992 as the Prescription Drug User Fee Act (Pub. L. 102–571) for a period of 5 years.

In 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA, Pub. L. 105–115), which renewed the program (PDUFA II) for an additional 5 years. Congress extended PDUFA again for another 5 years (PDUFA III), through FY 2007, in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). In 2007, Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA, Pub. L. 110–85) reauthorized PDUFA through FY 2012 (PDUFA IV, Pub. L. 112–144) and in 2012 the Food and Drug Administration Safety and Innovation Act (FDASIA) reauthorized the law again through FY 2017 (PDUFA V). PDUFA was most recently renewed in 2017 under Title I of the FDA Reauthorization Act of 2017 (FDARA) which lasts through FY 2022 (PDUFA VI).

PDUFA's intent is to provide additional revenues so that FDA can hire more staff, improve systems, and establish a better managed human drug review process to make important therapies available to patients sooner without compromising review quality or FDA's high standards for safety, efficacy, and quality. As part of FDA's negotiated agreement with industry during each reauthorization, the Agency agrees to certain performance and procedural goals and other commitments that apply to aspects of the human drug review program. These goals apply, for example, to the process for the review of original new human drug and biological product applications, postmarket safety activities, and new data standards and technology enhancements.

During the first few years of PDUFA I, the additional funding enabled FDA to eliminate backlogs of original applications and supplements. Phased in over the 5 years of PDUFA I, the goals were to review and act on 90 percent of priority new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements within 6 months of submission of a complete application; to review and act on 90 percent of standard original NDAs, BLAs, and efficacy supplements within 12 months, and to review and act on resubmissions and manufacturing supplements within 6 months. Over the course of PDUFA I, FDA exceeded all these performance goals and significantly reduced median review times of both priority and standard NDAs and BLAs.

Under PDUFA II, the review performance goals were shortened, and new procedural goals were added to improve FDA's interactions with industry sponsors and to help facilitate the drug development process. The procedural goals, for example, articulated time frames for scheduling sponsor-requested meetings intended to address issues or questions regarding specific drug development programs, as well as time frames for the timely response to industry-submitted questions on special study protocols. FDA met or exceeded all the review and procedural goals under PDUFA II. However, concerns grew that overworked review teams often had to return applications as ''approvable'' because they did not have the resources and sufficient staff time to work with the sponsors to resolve issues so that applications could be approved in the first review cycle.

A sound financial footing and support for limited postmarket risk management were key themes of PDUFA III. Base user fee resources were significantly increased and a mechanism to account for changes in human drug review workload was adopted. PDUFA III also expanded the scope of user fee activities to include postmarket surveillance of new therapies for up to 3 years after marketing approval. FDA committed to the development of guidance for industry on risk assessment, risk management, and pharmacovigilance, as well as guidance to review staff and industry on review management principles. In September 2018 the draft guidance, ''Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications'' (GRMPs), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-review-management-principles-and-practices-new-drug-applications-and-biologics-license,* was published.[1] Initiatives to improve application submission and Agency-sponsor interactions during the drug development and application review processes were also adopted.

With PDUFA's reauthorization under FDAAA Title I (PDUFA IV), FDA obtained a significant increase in base fee funding and committed to full implementation of GRMPs, which included providing a planned review timeline for premarket review, development of new guidance for industry on innovative clinical trials, modernization of postmarket safety, and elimination of the 3-year limitation on fee support for postmarket surveillance. Additional provisions in FDAAA (Titles IV, V, and IX) gave FDA additional statutory authority that increased the pre- and postmarket review process requirements, added new deadlines, and effectively increased review workload. Specifically, the new provisions expanded FDA's drug safety authorities, such as the authority to require risk evaluation mitigation strategies (REMS), order safety labeling changes, and require postmarket studies.

Under Title I of FDASIA, the fourth renewal of PDUFA, FDA implemented a new review program (''the Program'') to promote greater transparency and increase communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applied to all new molecular entity (NME) NDAs and original BLAs received by the Agency from October 1, 2012, through September 30, 2017. The Program added new opportunities for communication between the FDA review team and the applicant during review of a marketing application, including mid-cycle communications and late-cycle meetings, while adding 60 days to the review clock to provide for this increased interaction and to address review issues for these complex applications. PDUFA V also required an assessment of the impact of the Program. The independent assessment of the Program entitled ''Assessment of the Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs in PDUFA V,'' is available at: *https://www.fda.gov/media/101907/download.*

In addition to continued commitment to a significant set of review, processing, and procedural goals, PDUFA V also included commitments related to enhancing regulatory science and expediting drug development, enhancing benefit-risk assessment in regulatory decision-making, modernizing the FDA drug safety system, and improving the efficiency of human drug review by requiring electronic submissions and standardization of electronic drug application data.

In August 2017, FDARA was enacted, which renewed the prescription drug user fee program for a sixth time. This iteration of the program continued and built upon the successes of PDUFA V. In PDUFA VI, FDA and industry members agreed to continue ''the Program'' model developed in PDUFA V to continue to promote the efficiency and effectiveness of the first cycle review process. PDUFA VI includes commitments to enhance regulatory science and expedite drug development by focusing on enhancing communication between FDA and sponsors during drug development,

[1] When finalized this will represent FDA's current thinking on this issue.

early consultation on the use of new surrogate endpoints, and exploring the use of real world evidence for use in regulatory decision-making, among other enhancements. This iteration includes commitments to enhance the use of regulatory tools to support drug development and review through incorporation of the patient's voice in drug development, expanded use of a benefit-risk framework in drug reviews, and advancing the use of complex innovative trial designs and model informed drug development. More information on these commitments can be found in the PDUFA VI commitment letter at: *https://www.fda.gov/media/99140/download.*

As part of the current authorization, FDA also modernized the user fee structure to improve program funding predictability, stability, and administrative efficiency. The new structure eliminated the supplement fees, replaced the establishment and product fees with a program fee, and shifted a greater proportion of the target revenue to the new more predictable and stable annual program fee. The agreement also included commitments to enhance management of user fee resources through the development of a resource capacity planning capability and third-party evaluation of program resource management, along with the publication and annual update of a 5-year financial plan.

Recognizing the challenges with hiring in PDUFA V, the current authorization also includes several commitments to improve the hiring and retention of critical review staff through modernization of FDA's hiring system, augmentation of hiring staff capacity and capabilities, creation of a dedicated function focused on staffing the program, reporting on hiring metrics, and a comprehensive and continuous assessment of hiring and retention. A list of the deliverables developed to meet PDUFA VI commitments is available on the FDA web page at: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/completed-pdufa-vi-deliverables.*

III. Public Meeting Information

A. Purpose and Scope of the Meeting

In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder groups. We will also provide an opportunity for other stakeholders to provide public comment at the meeting. FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on process enhancements and funding issues, and not focus on policy issues.

B. Participating in the Public Meeting

Registration: Persons interested in attending this virtual public meeting should register online by 11:59 p.m. Eastern Time on June 23, 2020, at *http://pdufavii-publicmeeting.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone.

Opportunity for Public Comment: Those who register online by June 23, 2020, will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All requests to make a public comment during the meeting must be received by July 9, 2020, 11:59 p.m. Eastern Time. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by July 16, 2020. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is available at *https://collaboration.fda.gov/pdufajuly2020/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments.*

Dated: June 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–12317 Filed 6–5–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Maternal Health Portfolio Evaluation Design, OMB No. 0906–xxxx—NEW

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than August 7, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Maternal Health Portfolio Evaluation Design OMB No. 0906–xxxx—NEW.

Abstract: HRSA programs provide health care to people who are geographically isolated, economically, or medically vulnerable. HRSA programs help those in need of high quality primary health care, such as pregnant women and mothers. Improving maternal health outcomes and access to quality maternity care