

Number: (202) 395-5806 OR, Email: OIRA_submission@omb.eop.gov.

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>.

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

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:* New collection; *Title of Information Collection:* Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request Form; *Use:* This information collection is necessary for the Medicare beneficiary (or their legal representative), to enroll in an MA or PDP plan, even if switching plans within the same MA or PDP organization. To consider an election complete, the individual must:

- Complete an enrollment request;
- Provide required information to the MA or PDP organization within the required time frames;
- Submit the completed request to the MA or PDP organization during a valid enrollment period.
- MA and PDP organizations, applicants to MA and PDP

organizations, and the CMS will use the information collected to comply with the eligibility and enrollment requirements for Medicare Part C and Part D plans.

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) enacted August 5, 1997, established Part C of the Medicare program, known as the Medicare + Choice program, (now referred to as Medicare Advantage (MA)). As required by 42 CFR 422.50(a)(5), an MA-eligible individual who meets the eligibility requirements for enrollment into an MA or MAPD plan may enroll during the enrollment periods specified in § 422.62, by completing an enrollment form with the MA organization or enrolling through other mechanisms that CMS determines are appropriate.

Section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) enacted December 8, 2003, established Part D of the Medicare program, known as the Voluntary Prescription Drug Benefit Program. As required by 42 CFR 423.32(a) and (b), a Part D-eligible individual who wishes to enroll in a Medicare prescription drug plan (PDP) may enroll during the enrollment periods specified in § 423.38, by completing an enrollment form with the PDP, or enrolling through other mechanisms CMS determines are appropriate. *Form Number:* CMS-10718 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 14,749,256; *Total Annual Responses:* 14,749,256; *Total Annual Hours:* 7,861,354. (For policy questions regarding this collection contact Deme Umo at (410) 786-8854.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS); *Use:* Form CMS-304 (ROSI) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS-304a (PQAS) is required only in those instances where a change to the original rebate data submittal is necessary. *Form Number:* CMS-304 and -304a (OMB control number: 0938-0676); *Frequency:* Quarterly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 1,255; *Total Annual Responses:* 5,020; *Total Annual Hours:* 227,416. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate State Reporting Program Forms; *Use:* We develop the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to us the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the state Medicaid agency during a calendar quarter. Form CMS-R-144 (Quarterly Report Data) is required from states quarterly to report utilization for any drugs paid for during that quarter. Form CMS-368 (Administrative Data) is required only in those instances where a change to the original data submittal is necessary. *Form Number:* CMS-368 and -R-144 (OMB control number: 0938-0582); *Frequency:* Quarterly and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 234; *Total Annual Hours:* 12,101. (For policy questions regarding this collection contact Shannon Evans at 410-786-3083.)

Dated: March 3, 2020.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020-04607 Filed 3-5-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0179]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in

participating in this program to contact CDER.

DATES: Pharmaceutical companies may send proposed agendas to the Agency by May 5, 2020.

FOR FURTHER INFORMATION CONTACT: Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5480, Silver Spring, MD 20993-0002, 301-796-0578, dan.brum@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, which generally lasts a few days, small groups of CDER regulatory project managers, often including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, nonclinical and clinical evaluation, postmarketing activities, and regulatory submission operations. The overall benefit to

regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the Site Tours Program will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms that want to learn more about this training opportunity or that are interested in offering a site tour should respond by sending a proposed agenda by email directly to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: March 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-04604 Filed 3-5-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0907]

Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027; 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) is announcing a public meeting on the reauthorization of the Medical Device User Fee Amendments for fiscal years (FYs) 2023 through 2027 (MDUFA V). The current legislative authority for the medical device user fee program expires on October 1, 2022, and new legislation will be required for FDA to continue collecting user fees for the medical device program in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that before FDA begins negotiations with the regulated industry on MDUFA reauthorization, we publish a notice in the **Federal Register** requesting public input on the reauthorization, hold a public meeting

at which the public may present its views on the reauthorization, provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to MDUFA, and publish the comments on FDA's website. FDA invites public comment on the medical device user fee program and suggestions regarding the commitments FDA should propose for the next reauthorized program.

DATES: The public meeting will be held on April 7, 2020, from 9 a.m. to 5 p.m. EST. Submit either electronic or written comments on the medical device user fee program and suggestions regarding the commitments FDA should propose for the next reauthorized program by May 6, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/about-fda/white-oak-campus-information/public-meetings-fda-white-oak-campus>.

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 May 6, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time on May 6, 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