and reporting to conduct an assessment of current methodologies and data/metrics available to represent the MDUFA workforce. Additional details regarding the independent assessments can be found in Section VI of the proposed commitment letter.

P. Performance Reports

FDA proposes to continue to report quarterly and annually on performance against commitments. Additionally, FDA proposes to report quarterly on progress toward hiring goals and funding intended for RWE activities. FDA will report annually on the primary cost drivers for changes to personnel compensation and benefits costs. Additional details regarding performance reporting can be found in Section VII of the proposed commitment letter.

Q. User Fee Revenue and Fee Allocations

As part of MDUFA V, FDA and industry propose updating the base fee amounts for PMAs and annual establishment registrations, as well as the annual total revenue amounts, to reflect negotiated fee levels. The statutory total revenue amounts, base fee amounts, and amounts for potential performance improvement adjustments are proposed in FY 2021 dollars, such that annual inflation adjustments will be used to inflate FY 2021 dollars to the appropriate amounts for each fiscal year in MDUFA V. FDA and industry also propose to change the fee for a PMA Panel-Track supplement from 75 percent to 80 percent of the fee for an original PMA and to change the fee for a 510(k) submission from 3.4 percent to 4.5 percent of the fee for a PMA. Finally, a minor change is proposed to the statutory provisions regarding fee waivers and reductions for small businesses to clarify that an applicant seeking a waiver or reduction is not required to submit a certification from the national taxing authority of the foreign country in which the applicant, or its affiliate, is located, if the country has no national taxing authority.

FDA will post the agenda approximately 5 days before the meeting at: *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.*

IV. Participating in the Public Meeting

Registration: To register for the public meeting, please visit *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.* Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Registrants will receive confirmation after they have been accepted.

Registration is free. Persons interested in attending by webcast the MDUFA virtual public meeting must register online by 4 p.m. Eastern Time, April 18, 2022. Early registration is recommended.

If you need special accommodations because of a disability, please contact Susan Monahan at 240–205–2260 or *Susan.Monahan@fda.hhs.gov* no later than April 11, 2022.

Requests for Oral Presentations: This meeting includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during the public comment session or a specific session, and which topic(s) you wish to address. All requests to make oral presentations virtually by webcast must be received by April 11, 2022, at 4 p.m. Eastern Time. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify speakers by April 12, 2022. If selected for presentation, any presentation materials must be emailed to Mimi Nguyen (see **FOR FURTHER INFORMATION CONTACT**) no later than April 13, 2022, at 4 p.m.. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

FDA is holding this meeting to provide information on the proposed recommendations for the reauthorization of MDUFA for FYs 2023 through 2027. To permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the meeting topics. The docket was opened on March 22, 2022. The proposed commitment letter was posted in the docket and on this website at: *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.* The docket will close on April 21, 2022, 30 days after the proposed commitment letter was posted.

Streaming Webcast of the Public Meeting: The webcast link will be available on the registration web page after April 11, 2022. Organizations are requested to register all participants.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *in the docket 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 approximately 45 days after the public workshop on the internet at: *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.*

Dated: April 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; COVID–19 Provider Relief Fund (PRF) and American Rescue Plan (ARP) Rural Payment Reporting Activities, OMB No. 0906–0068—Revision

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 June 6, 2022.

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 Samantha Miller, the HRSA Acting Information Collection Clearance Officer at (240) 276–7189.

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

Information Collection Request Title: COVID–19 Provider Relief Fund (PRF) Reporting Activities OMB No. 0906–0068—Revision.

Abstract: HRSA disburses the PRF and ARP Rural payments to eligible health care providers to support health care-related expenses or lost revenues attributable to the COVID–19 pandemic. Providers who have attested to the Terms & Conditions (T&Cs) regarding their PRF and ARP Rural payment(s), including the requirement that the provider ''shall submit reports as the Secretary determines are needed to ensure compliance with conditions that are imposed on this Payment, and such reports shall be in such form, with such content, as specified by the Secretary in future program instructions directed to all recipients,'' will be using the PRF Reporting Portal to submit information about their use of PRF and ARP Rural payments. In anticipation of the approved OMB form (control number 0906–0068) expiring on January 31, 2023, HRSA is undergoing the revision of the ICR approval to include the ARP Rural reporting requirements and to allow for data collection beyond the January 31, 2023, expiration.

Need and Proposed Use of the Information: Recipients of a PRF and ARP Rural payment agreed to a set of T&Cs, which, among other requirements, mandate compliance with certain reporting requirements that will facilitate appropriate oversight of recipients' use of funds.

Information collected will allow for (1) assessing whether recipients have met statutory and programmatic requirements, (2) conducting audits, (3) gathering data required to report on findings with respect to the disbursements of PRF and ARP Rural payments, and (4) program evaluation. HRSA staff will also use information collected to identify and report on trends in health care metrics and expenditures before and during the allowable period for expending PRF and ARP Rural payments.

Likely Respondents: PRF and ARP Rural payment recipients who have received more than $10,000 in aggregate PRF and ARP Rural payments during one of the Payment Received Periods outlined below and that agreed to the associated T&Cs are required to submit a report in the PRF Reporting Portal during the applicable Reporting Time Period.

Reporting period	Payment received period (payments exceeding $10,000 in aggregate received)	Reporting time period
Period 1	April 10, 2020, to June 30, 2020	July 1, 2021, to September 30, 2021.
Period 2	July 1, 2020, to December 31, 2020	January 1, 2022, to March 31, 2022.
Period 3	January 1, 2021, to June 30, 2021	July 1, 2022, to September 30, 2022.
Period 4	July 1, 2021, to December 31, 2021	January 1, 2023, to March 31, 2023.
Period 5	January 1, 2022, to June 30, 2022	July 1, 2023, to September 30, 2023.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
PRF Reporting Portal, Reporting Period 1 (Providers who received payments April 10, 2020, to June 30, 2020)	126,831	1	126,831	5.6	710,254
PRF Reporting Portal, Reporting Period 2 (Providers who received payments July 1, 2020, to December 31, 2020)	120,536	1	120,536	4.2	506,251
PRF Reporting Portal, Reporting Period 3 (Providers who received payments, January 1, 2021, to June 30, 2021)	20,493	1	20,493	6.1	125,565
PRF and ARP Rural Reporting Portal, Reporting Period 4 (Providers who received payments July 1, 2021, to December 31, 2021)	51,622	1	51,622	5.6	287,514
PRF and ARP Rural Reporting Portal, Reporting Period 5 (Providers who received payments January 1, 2022, to June 30, 2022)	4,256	1	4,256	5.5	23,288
Total	323,738		323,738		1,652,872

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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