generic drug user fees for subsequent fiscal years for the generic drug program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of interested parties in developing recommendations for the next GDUFA program. The FD&C Act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent representation by interested parties.

DATES: Submit notification of intention to participate in these series of meetings by September 4, 2025. Meetings will be held monthly throughout the duration of negotiations with regulated industry, and it is anticipated that they will commence in the Fall of 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Submit notification of intention to participate in monthly consultation meetings by email to *GDUFAReauthorization@fda.hhs.gov.* The meetings will be held in person at the FDA campus in White Oak, MD: 10903 New Hampshire Ave., Silver Spring, MD 20993 and virtually using the Microsoft Teams platform.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926, *GDUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that interested parties, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic consultation meetings on the reauthorization of GDUFA. GDUFA authorizes FDA to collect user fees from the regulated industry for the current program (GDUFA III). At the end of September 2027, new legislation will be required for FDA to continue collecting user fees for subsequent fiscal years for the generic drug program. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund human generic drug activities. Section 744C(f)(1) (21 U.S.C. 379j–43(f)(1)) of the FD&C Act requires that FDA consult with a range of interested parties in developing recommendations for the next GDUFA program, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts. FDA will initiate this process by holding a public meeting on July 11, 2025, at which interested parties and other members of the public will be given an opportunity to present their views on reauthorization (90 FR 21313, May 19, 2025). Section 744C(f)(3) (21 U.S.C. 379j–43(f)(3)) of the FD&C Act further requires that FDA continue meeting with these interested parties at least once every month during negotiations with the regulated industry to continue discussions of views from interested parties on the reauthorization. It is anticipated that these monthly consultation meetings will commence in the Fall of 2025.

FDA is issuing this **Federal Register** notice to request that interested representatives from patient and consumer advocacy groups, health care professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on GDUFA reauthorization. FDA believes that consistent representation by interested parties at these meetings will be important to ensure progress in these discussions. If you wish to participate in the consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions, as needed. Interested parties who identify themselves through this notice will be included in all discussions with interested parties during the period that FDA negotiates with the regulated industry. Interested parties who decide to participate in these monthly meetings at a later time may still participate in remaining monthly meetings by notifying FDA (see **ADDRESSES**). These discussions with interested parties will satisfy the periodic consultation requirement in section 744C(f)(3) (21 U.S.C. 379j–43(f)(3)) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Consultation Meetings

If you intend to participate in continued periodic consultation meetings regarding GDUFA reauthorization, please provide notification by email to *GDUFAReauthorization@fda.hhs.gov* by September 4, 2025. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Interested parties will receive confirmation and additional information about the first periodic consultation meeting after FDA receives this notification. Information concerning GDUFA, including the GDUFA III Commitment Letter, key **Federal Register** documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA website at *https://www.fda.gov/gdufa.*

Dated: June 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11769 Filed 6–25–25; 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: 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 August 25, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 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 Information Collection Clearance Officer, at (301) 443–3983.

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

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

Abstract: HRSA disbursed the COVID–19 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. Recipients of PRF and ARP Rural payments agreed to a set of Terms & Conditions (T&Cs), which, among other requirements, mandate compliance with certain reporting requirements that facilitate appropriate oversight of recipients' use of funds. Providers who have attested to the 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,'' and use the PRF Reporting Portal to submit information about their use of PRF and ARP Rural payments.

There will be no changes to the Data Form Elements submitted by recipients of PRF and ARP Rural payments. The supplemental document ''Post-Payment Notice of Reporting Requirements'' has been updated to reflect the removal of reporting periods 8 and 9 (including the applicable payment received period and period of availability dates), as the Public Health Emergency ended on May 11, 2023.

Need and Proposed Use of the Information: 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.

If the information is not collected, HRSA will not meet its responsibility to oversee the mandate regarding reporting requirements that facilitate appropriate oversight of recipients' use of funds. PRF and ARP Rural recipients will not be able to fulfill their statutory reporting requirement. HRSA will also not be able to provide reports to Congress and other stakeholders on the use of more than $178 billion in PRF funds and $8.5 billion in ARP Rural funds.

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 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.
Period 6	July 1, 2022, to December 31, 2022	January 1, 2024, to March 31, 2024.
Period 7	January 1, 2023, to June 30, 2023	July 1, 2024, to September 30, 2024.

While the standard reporting time periods have ended, there are still scenarios in which these documents are required. These include:

- Providers who receive a Final Repayment Notice, based on a HRSA finding of non-compliance, who submit a Decision Review request and are provided an Opportunity to Report. The Opportunity to Report allows providers another chance to submit a report to come into compliance.
- Adjudicative orders that would require HRSA to allow a Provider an opportunity to report.
- Providers who have prevailed in a dispute or have entered into a settlement with HRSA may need to submit a report on how funds were used.

These scenarios make it necessary to retain and extend approval of the information collection activities associated with required reporting to support compliance, validation, and enforcement actions. Providers would provide documentation through the portal based on the reporting period that they received the funds in question.

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)	10	1	10	5.43	54.30
PRF Reporting Portal, Reporting Period 2 (Providers who received payments July 1, 2020, to December 31, 2020)	10	1	10	4.22	42.20
PRF Reporting Portal, Reporting Period 3 (Providers who received payments, January 1, 2021, to June 30, 2021)	10	1	10	5.88	58.80

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
PRF and ARP Rural Reporting Portal, Reporting Period 4 (Providers who received payments July 1, 2021, to December 31, 2021)	10	1	10	5.26	52.60
PRF and ARP Rural Reporting Portal, Reporting Period 5 (Providers who received payments January 1, 2022, to June 30, 2022)	5	1	5	5.18	25.90
PRF and ARP Rural Reporting Portal, Reporting Period 6 (Providers who received payments July 1, 2022, to December 31, 2022)	50	1	50	7.37	368.50
PRF and ARP Rural Reporting Portal, Reporting Period 7 (Providers who received payments January 1, 2023, to June 30, 2023)	5	1	5	5.35	26.75
Total	100		100		629.05

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.

[FR Doc. 2025–11746 Filed 6–25–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Shoshone-Bannock Tribes of the Fort Hall Indian Reservation in Idaho

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Indian Health Service (IHS) has decided to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Shoshone-Bannock Tribes of the Fort Hall Indian Reservation in Idaho (Shoshone-Bannock Tribes or Tribe) to include the Idaho counties of Ada, Bear Lake, Blaine, Bonneville, Butte, Canyon, Cassia, Custer, Elmore, Franklin, Fremont, Gem, Gooding, Jefferson, Jerome, Madison, Minidoka, Oneida, Payette, Teton, Twin Falls, and Washington. The final PRCDA for the Shoshone-Bannock Tribes now includes the Idaho counties of Ada, Bannock, Bear Lake, Bingham, Blaine, Bonneville, Butte, Canyon, Caribou, Cassia, Custer, Elmore, Franklin, Fremont, Gem, Gooding, Jefferson, Jerome, Lemhi, Madison, Minidoka, Oneida, Payette, Power, Teton, Twin Falls, and Washington. The sole purpose of this expansion is to authorize additional Shoshone-Bannock Tribal members and beneficiaries to receive Purchased/Referred Care (PRC) services.

DATES: This expansion is effective as of the date of publication of this notice.

ADDRESSES: This notice can be found at *https://www.federalregister.gov.* Written requests for information should be delivered to: CDR Tracy Sanchez, Acting Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop 10E85C, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: CDR Tracy Sanchez, Acting Director, Office of Resource Access and Partnerships by email at *Tracy.Sanchez@ihs.gov,* or by phone at (301) 443–3216 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The IHS provides services under regulations in effect as of September 15, 1987, and republished at 42 CFR part 136, subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now referred to as a PRCDA, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the PRCDA. Residence within a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC but only potential eligibility for services. Services needed, but not available at an IHS/Tribal facility, are provided under the PRC program depending on the availability of funds, the relative medical priority of the services to be provided, and the actual availability and accessibility of alternate resources in accordance with the regulations.

The regulations at 42 CFR part 136, subpart C provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation. 42 CFR 136.22(a)(6). The regulations also provide that after Consultation with the Tribal governing body or bodies on those reservations included within the PRCDA, the Secretary may, from time to time, redesignate areas within the United States for inclusion in or exclusion from a PRCDA. 42 CFR 136.22(b). The regulations require that certain criteria must be considered before any redesignation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of PRC.

Additionally, the regulations require that any redesignation of a PRCDA be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553). 42 CFR 136.22(c). In compliance with this requirement, the IHS published a notice of proposed redesignation and requested public comments on December 16, 2024, (89