''Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products.'' As one mechanism to inform FDA's RWE program under the 21st Century Cures Act (Pub. L. 114–255), and specifically to help FDA understand the scope and use of RWD/RWE submitted to support regulatory decisions regarding safety and/or effectiveness, the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Oncology Center of Excellence (OCE) track certain types of submissions involving RWD/RWE. As described in this guidance and to promote consistency in this effort, CDER, CBER, and OCE encourage sponsors and applicants to identify whether their submissions include certain uses of RWD/RWE. To assist FDA in tracking of RWD/RWE submissions, FDA recommends that the sponsor or applicant include the following information in their cover letter: (1) purposes of using RWD/RWE, (2) study designs using RWD to generate RWE, and (3) RWD sources used to generate RWE.

This guidance finalizes the draft guidance entitled ''Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics'' issued on May 9, 2019 (84 FR 20368). FDA considered comments received on the draft guidance as the guidance was finalized, and changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 6, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19494 Filed 9–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Intent To Make Temporary Changes in the State Title V Maternal and Child Health Block Grant Allocations

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

ACTION: Response to solicitation of comments.

SUMMARY: HRSA plans to move forward in implementing temporary changes to the method of calculating poverty-based allocations under Title V of the Social Security Act for HRSA's State Title V Maternal and Child Health (MCH) Services Block Grant, beginning in Fiscal Year (FY) 2023. Since FY 2017, the poverty-based allocation has been based on the U.S. Census Bureau's 3-year American Community Survey (ACS) estimates using three pooled 1-year estimates. However, due to the COVID–19 pandemic, there were disruptions in the ACS data collection in 2020 resulting in data quality issues that prevented the Census Bureau from releasing standard 1-year ACS estimates; instead, the Census Bureau released experimental estimates. The ACS 2020 experimental estimates will be excluded from calculating Title V MCH Services Block Grant allocations, and the FY 2023 funding allocation will be based on the same poverty data used in the FY 2022 allocation (*i.e.,* pooled 1-year estimates for 2017, 2018, and 2019 ACS). Funding allocations for FY 2024 and FY 2025 will continue to incorporate the latest 1-year ACS data while skipping 2020 (*i.e.,* for FY 2024, the 2018, 2019, and 2021 ACS data will be used; for FY 2025, the 2019, 2021, and 2022 ACS data will be used). In FY 2026, the temporary change to the method for calculating allocations will no longer be necessary, and HRSA will resume pooling of three consecutive 1-year estimates (2021–2023).

DATES: *Effective Date:* October 1, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher Dykton, Acting Director of the Division of State and Community Health, Maternal and Child Health Bureau, HRSA, Room 18N35, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: (301) 433–2204; email: *MCHBlockGrant@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Beginning in FY 2023, HRSA will temporarily change the method of calculating the poverty-based allocation to States and the District of Columbia under section 502(c) of Title V of the Social Security Act (42 U.S.C. 702(c)). Because of data collection disruptions due to the COVID–19 pandemic, the Census Bureau did not release standard 1-year ACS estimates for 2020. Survey administration methods (mailed questionnaires and interviewing in-person) were impacted beginning in March 2020, which affected response rates, in terms of who was most likely to complete mailed surveys or participate in interviews, etc.[1] The Census Bureau concluded that the 2020 ACS 1-year data were not ''reasonable'' as respondents disproportionately ''had higher levels of education, had more married couples and few never married citizens, had less Medicaid coverage, had higher median household incomes, and fewer non-citizens, and were more likely to live in single-family housing units'' than respondents in previous years. Instead, the Census Bureau decided to provide only experimental estimates for 2020 ACS 1-year data.[2]

HRSA examined the 2020 ACS experimental estimates and compared the change in poverty share using a 3-

[1] *https://www.census.gov/library/working-papers/2021/acs/2021_CensusBureau_01.html.*

[2] The Census Bureau defines experimental data products as ''innovative statistical products created using new data sources or methodologies that benefit data users in the absence of other data products . . . Census Bureau experimental data may not meet all of HRSA's data quality standards. Because of this, HRSA clearly identifies experimental data products and includes methodology and supporting research with their release.'' *https://www.census.gov/data/experimental-data-products.html.*

year estimate incorporating the 2020 experimental estimate with prior year-to-year changes since 2014—the first year of annual updates to poverty share data using 3-year ACS estimates. HRSA noted greater observed data variability and a greater number of States that would experience large decreases in their poverty share. HRSA was concerned about the accuracy of the 2020 experimental estimates as applied to the Title V MCH Services Block Grant allocation.

In order to ameliorate these concerns and because of the nature of the data, the ACS 2020 experimental estimates will not be used in calculating Title V MCH Services Block Grant allocations. Instead, HRSA will base the FY 2023 funding allocation on the same poverty data used in the FY 2022 allocation (*i.e.,* pooled 1-year estimates for 2017, 2018, and 2019 ACS). Funding allocations for FY 2024 and FY 2025 will continue to incorporate the latest 1-year ACS data while skipping the 2020 experimental data (*i.e.,* for FY 2024, the 2018, 2019, and 2021 ACS data will be used; for FY 2025, the 2019, 2021, and 2022 ACS data will be used). In FY 2026, the temporary change to the method for calculating allocations will no longer be necessary, and HRSA will resume pooling of three consecutive 1-year estimates (2021–2023).

The proposed temporary change in State Title V MCH Services Block Grant allocations was announced in the **Federal Register** at 87 FR 37873 on June 24, 2022. A comment period of 30 days was established to allow interested parties to submit comments. HRSA received two responses. One comment expressed support for the proposed temporary change. HRSA appreciates this comment. The other comment is beyond the scope of this notice, as it did not specifically address the proposed changes in the State Title V MCH Services Block Grant allocation, but instead expressed concern about child vaccinations.

Diana Espinosa,

Deputy Administrator.

[FR Doc. 2022–19477 Filed 9–8–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Information Collection: Urban Indian Organization On-Site Review

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments; request for approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on a new information collection titled, ''Urban Indian Organization On-Site Review.'' IHS is requesting the Office of Management and Budget (OMB) to approve this new collection. The purpose of this notice is to announce the IHS' intent to submit this collection to OMB and to allow 30 days for public comment to be submitted directly to OMB.

DATES: Consideration will be given to all comments received by October 11, 2022.

ADDRESSES: A copy of the supporting statement is available at *www.regulations.gov* (see Docket ID: IHS_FRDOC_0001).

Direct Your Comments to OMB: Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Evonne Bennett, Information Collection Clearance Officer at: *Evonne.Bennett@ihs.gov* or 301–443–4750.

SUPPLEMENTARY INFORMATION:

Summary of Comments: There was one comment that was submitted to the Agency regarding the 60-Day **Federal Register** Notice published on February 11, 2022 (87 FR 8020).

Comment Summary: The National Council of Urban Indian Health (NCUIH) was the only comment to the FRN, and a summary of the comments, requests, and recommendations in response to the February 11, 2022, notice, is summarized below. These comments can be found in full on *www.regulations.gov* (see Docket ID: IHS_FRDOC_0001) and based on NCUIH's consultations with Urban Indian Organizations (UIOs) and NCUIH's subject matter expertise. In summary, the NCUIH recommends the following:

- Update the Manual regularly and as needed to remain consistent with other relevant accreditation processes.
- Provide greater flexibility in the Manual to accommodate diverse UIO program/facility goals and services.
- The IHS to provide a consolidated list of requirement documents to UIOs prior to the on-site review.
- Ensure that UIOs can use existing administrative or site visit data in meeting the requirements of the Manual.

Additional Recommendations for UIOs includes that the Office of Urban Indian Health Programs (OUIHP) host an Urban Confer with UIOs to learn directly from UIO leaders about their experiences with the Manual and overall review process. The NCUIH also wanted consideration on (1) Provide a timeline for processing information collected in the annual review process; and (2) Improve overall review by ensuring reviewers are licensed medical providers.

IHS Response: The IHS Urban Indian Organization On-Site Review is conducted annually by the IHS Area Offices to evaluate IHS-funded UIOs' compliance with the Federal Acquisition Regulations (FAR), the Indian Health Care Improvement Act (IHCIA), and other contract and grant requirements. The on-site review requirements are based on best-practice standards for delivering safe and high quality health care. The OUIHP at IHS Headquarters provides national oversight of the annual on-site reviews.

In Fiscal Year (FY) 2018, the OUIHP executed an Indefinite-Delivery, Indefinite Quantity contract to revise the outdated 2013 Annual On-site Review Manual using current Accreditation Association for Ambulatory Health Care (AAAHC), The Joint Commission, and Commission on Accreditation of Rehabilitation Facilities accreditation standards, and the IHS Manual to improve consistency and usefulness of on-site reviews. IHS solicited feedback and recommendations from UIOs by conducting seven site visits: 1 outreach and referral program, 2 limited ambulatory programs, 2 comprehensive ambulatory programs, and 2 residential and outpatient treatment centers. In FY 2020, the OUIHP finalized the Annual On-site Review Manual incorporating UIOs' feedback and recommendations.

In FY 2021, the OUIHP began development of an electronic Annual On-site Review application to replace the hardcopy and a national dashboard to enhance the efficiency of on-site reviews. The application enables IHS Area Office staff and UIOs to document on-site reviews electronically by (1) completing corrective action plans; (2) documenting on-site reviews simultaneously at UIOs by IHS and UIO staff; (3) uploading on-site review documents; (4) calculating compliance scores to provide real-time feedback; (5)