

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response (in hours)	Total hours
Preparation of DHCP letters; § 200.5	6	1.3	8	100	800

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We have identified 24 DHCP letters that 18 distinct sponsors submitted to FDA during the 3-year period (2019 to 2021). Based on our Document Archiving, Reporting, and Regulatory Tracking System, we estimate eight DHCP letters will be submitted annually from six application holders. Based on our experience, we assume that each letter will require 100 hours to prepare and disseminate as recommended in the guidance. Our estimate reflects a downward adjustment by five responses and 500 hours annually. We attribute this decrease to the effectiveness of the guidance and the decreased number of DHCP letters submitted for FDA review.

Dated: June 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13536 Filed 6–23–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Temporary Changes in State Title V Maternal and Child Health Block Grant Allocations

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

ACTION: Notice.

SUMMARY: This notice seeks comments on proposed 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) Block Grant. Since Fiscal Year (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. HRSA proposes that the ACS 2020 experimental

estimates be excluded from calculating MCH block grant allocations and that the FY 2023 funding allocation 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 would 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: Interested persons are invited to comment on this proposed change. Submit written comments no later than July 25, 2022. All comments received on or before this date will be considered.

ADDRESSES: All written comments concerning this notice should be submitted to Christopher Dykton, Acting Director of the Division of State and Community Health, at the contact information below.

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

SUPPLEMENTARY INFORMATION: The purpose of the Title V MCH Block Grant, administered by HRSA's MCHB, is to improve the health of the nation's mothers, infants, children, including children with special health care needs, and their families by creating federal/state partnerships that provide each state/jurisdiction with needed flexibility to respond to its individual MCH population needs. Pursuant to section 502(c) of Title V of the Social Security Act (42 U.S.C. 702(c)), for any available funding in excess of 1983 levels (\$406,649,394), Title V MCH Block Grant funds are allocated to States and the District of Columbia based on the number of children living in poverty in an individual state as a proportion of the total number of children living in poverty in the U.S., using data for the

number of children in poverty in each State from the U.S. Census Bureau's ACS. Incorporating the proportion of total number of children living in poverty into the state funding formula for the Title V MCH Block Grant ensures that a portion of the funding is distributed according to greatest need.

Beginning in FY 2013, data for the number of children in poverty in each state has been based on the U.S. Census Bureau's ACS.¹ In FY 2013, the allocation was based on 3-year rolling ACS estimates instead of 1-year or 5-year ACS estimates also produced at that time to strike a balance between reliability and currency of data. *See* 77 FR 65693 (October 30, 2012). However, since 2014 (for FY 2017), when the Census Bureau discontinued the release of 3-year ACS estimates, HRSA has been using three pooled ACS 1-year estimates for this purpose.

In 2020, due to the COVID-19 pandemic, there were disruptions in the ACS data collection that prevented the Census Bureau from releasing standard 1-year ACS estimates for 2020. According to the Census Bureau report, "An Assessment of the COVID-19 Pandemic's Impact on the 2020 ACS 1-Year Data,"² both survey administration methods (mailed questionnaires and interviewing in-person) were impacted beginning in March 2020. For example, no mailings were completed from April through June 2020, and when they resumed, they did not include the mailing of most of the reminder letters and postcards. Similarly, there was an abrupt switch from in-person to telephone-only interviews from March 2020 through June 2020, and the universe of addresses for which telephone numbers can be obtained is likely different than the universe of addresses obtained through in-person methods, over-representing certain types of addresses. In May, the option to complete the interview online became available. In-person

¹ Prior to this, the formula was based on poverty data from the decennial Census long-form, which was replaced with the American Community Survey.

² https://www.census.gov/library/working-papers/2021/acs/2021_CensusBureau_01.html.

interviewing resumed in July, but not for all areas.

All of these changes affected response rates, in terms of who was most likely to complete the mailed surveys or participate in interviews, etc. 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. Therefore, the Census Bureau decided not to release standard 2020 ACS 1-year estimates. The Census Bureau is providing only “experimental estimates” for 2020 ACS 1-year data.³ The Census Bureau indicated that the experimental 2020 estimates were released in an attempt to account for the differential response from more educated, higher income, single-family households, but also acknowledged the approach has not been thoroughly investigated.⁴

Upon their release, HRSA examined the 2020 ACS experimental estimates and compared the change in poverty share using a 3-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. Using the 2020 experimental estimates, HRSA noted an increase in the variability, with 12 states having their largest observed relative percentage change, 9 states having large (>5 percent) relative percentage changes, and 6 states having large (>5 percent) relative decreases in poverty share from the prior year. Moreover, in years prior, large relative percentage changes were most often increases, but the opposite occurred in 2020 using the experimental estimates, *i.e.*, six states would have a large decrease vs. three states would have a large increase. Thus, due to the greater observed data variability and number of states that would experience large decreases in their poverty share, HRSA has concerns about the accuracy of the 2020

experimental estimates as applied to the MCH allocation. For smaller states, in particular, large relative decreases in poverty share can result in meaningful absolute decreases in the poverty-based allocation. As state budgets are impacted by the COVID-19 pandemic, HRSA proposes a conservative approach that limits such decreases based on uncertain experimental estimates to the extent possible.

In order to ameliorate these concerns and because of the nature of the data, HRSA proposes that the ACS 2020 experimental estimates not be used in calculating MCH block grant allocations. Instead, HRSA proposes that the FY 2023 funding allocation 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 would 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 3 consecutive 1-year estimates (2021–2023). HRSA’s proposal to temporarily change the method of calculating allocations continues to support the objective of distributing funding according to greatest need. In so doing, HRSA will avoid the use of lower quality and potentially inaccurate poverty data for 2020 that would result in larger funding fluctuations than observed in previous years, and will continue to use the latest available data in future years. With this approach, no state will see a decrease in its poverty-based allocation of funding in FY 2023.

If the poverty data used for the FY 2022 allocation is used again for the FY 2023 allocation, all states will receive the same proportion of poverty-based funding as they received in FY 2022, which will prevent potentially inaccurate changes in allocations. HRSA recognizes the possibility that the changes seen with 2020 ACS experimental estimates may actually reflect real changes in the distribution of children in poverty which may be seen when the 2021 ACS 1-year estimates (to be released in Fall 2022) are incorporated. If that is the case, then the difference in FY 2024 allocations as compared to the FY 2023 allocations

will accurately reflect those changes by incorporating the 2021 data.

Diana Espinosa,

Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–xxxx–New]

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Optimizing Virtual Care Grant Program Performance Measures

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 23, 2022.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or by mail to 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 acting HRSA Information Collection Clearance Officer at (301) 443–9094.

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

Information Collection Request Title: Optimizing Virtual Care Grant Program Performance Measures, OMB No. 0906–xxxx–New.

Abstract: The Health Center Program and supplemental awards for health centers are authorized by Section 330(d) of the Public Health Service Act (42 U.S.C. 254b(d)). Notably, HRSA is

³ 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>.

⁴ <https://www.census.gov/programs-surveys/acs/data/experimental-data.html>.