

allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the

search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

National HIV Prevention Program Monitoring and Evaluation (NHM&E) (OMB Control No. 0920-0696, Exp. 10/31/2021)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC seeks to request a three-year Office of Management and Budget (OMB) approval to revise the previously approved project and continue the collection of standardized HIV prevention program evaluation data from health departments and community-based organizations (CBOs) who receive federal funds for HIV prevention activities. Health department grantees have the options to key-enter or upload data to a CDC-provided web-based software application (EvaluationWeb®). CBO grantees may only key-enter data to the CDC-provided web-based software application. The evaluation and reporting process is necessary to ensure that CDC receives standardized, accurate, thorough evaluation data from both health department and CBO grantees. For these reasons, CDC developed standardized NHM&E variables through extensive consultation with representatives from

health departments, CBOs, and national partners (*e.g.*, The National Alliance of State and Territorial AIDS Directors and Urban Coalition of HIV/AIDS Prevention Services). This revision includes changes to the data variables to adjust to the different monitoring and evaluation needs of new funding announcements without a substantial change in burden.

CDC requires CBOs and health departments who receive federal funds for HIV prevention to report nonidentifying, client-level and aggregate level, standardized evaluation data to: (1) Accurately determine the extent to which HIV prevention efforts are carried out, what types of agencies are providing services, what resources are allocated to those services, to whom services are being provided, and how these efforts have contributed to a reduction in HIV transmission; (2) Improve ease of reporting to better meet these data needs; and (3) Be accountable to stakeholders by informing them of HIV prevention activities and use of funds in HIV prevention nationwide.

CDC HIV prevention program grantees will collect, enter or upload, and report agency-identifying information, budget data, intervention information, and client demographics and behavioral risk characteristics with an estimate of 204,498 burden hours, representing no change from the previously approved burden hours. Data collection will include searching existing data sources, gathering and maintaining data, document compilation, review of data, and data entry or upload into the web-based system. There are no additional costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Departments	Health Department Reporting	66	2	1,427
Community-based Organizations	Community-based Organization Reporting	150	2	54

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-20PJ]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC)

has submitted the information collection request titled “Formative Research on Community-Level Factors that Promote the Primary Prevention of Adverse Childhood Experiences (ACEs) and Opioid Misuse Among Children, Youth, and Families in Tribal American Indian and Alaska Native (AI/AN) Communities” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and

Recommendations” notice on July 2, 2020 to obtain comments from the public and affected agencies. CDC received three comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open

for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Formative Research on Community-Level Factors that Promote the Primary Prevention of Adverse Childhood Experiences (ACEs) and Opioid Misuse Among Children, Youth, and Families in Tribal American Indian and Alaska Native (AI/AN) Communities—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Adverse childhood experiences (ACEs) are preventable, potentially traumatic events that occur in childhood (0–17 years) such as experiencing violence, abuse, or neglect; witnessing violence in the home; and having a family member attempt or die by suicide. There is a robust evidence base linking ACEs to a variety of poor health outcomes across the life span, including depression, alcohol and substance use disorder, and violence perpetration and victimization. The ongoing opioid epidemic is a complex and significant public health crisis that exposes children to opioid misuse, violence, and other ACEs, and challenges the ability of Health and Human Service (HHS) systems to mitigate the effects of opioid misuse and ACEs on children and families across the U.S. American Indian/Alaska Native (AI/AN) populations experience a disproportionate burden of opioid

misuse and ACEs, and ACE-related health outcomes, including opioid overdose, sexual assault, and suicide attempts. The nature and consequences of ACEs in Tribal communities is unique because of historical trauma and stark socioeconomic disparities. In addition, there are gaps in the provision of adequate healthcare.

This collection addresses critical research gaps and extends efforts to prevent violence and other ACEs before they occur and to build evidence of effectiveness of community-level strategies and approaches at the outer levels of the social ecology to Tribal communities. Results from this data collection will be communicated to relevant public health officials and community stakeholders in the study locations. These local public health officials and community stakeholders will use the study results to guide strategies to further strengthen their local prevention efforts within their regions.

Data collection methods used in this qualitative study include well-established qualitative methods, including in-depth open-ended individual interviews and focus groups. Quantitative methods include brief structured surveys. There will be a total of six Tribal communities (three urban and three rural) in regions identified with higher opioid overdose mortality rates relative to other areas in Indian Country. Due to COVID-19, at the time of the focus groups/interviews, social distancing and public health safety measures will be implemented, including considerations for phone/virtual meetings instead of in-person sessions.

The total estimated annualized burden hours are 441. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adults 18 years or older affected by the opioid epidemic (<i>e.g.</i> , parents/caregivers of AI/AN children, Tribal Elders) living in Tribal urban and rural/reservation communities.	Information Letter	160	1	5/60
	Telephone screening	160	1	25/60
	Confirmation email/letter			
	120	1	5/60
	Reminder email	120	1	5/60
	Informed Consent	120	1	25/60
	Demographic Survey	120	1	25/60
	Focus group/interview	44	1	2
	Focus group/interview	64	1	2
	Focus group/interview	12	1	2

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10054 and CMS-10396]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *June 14, 2021*.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

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 the following:

1. Access CMS' website address at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

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:* Extension of a currently approved collection; *Title of Information Collection:* New Technology Services for Ambulatory Payment Classifications under the Outpatient Prospective Payment System; *Use:* Section 1833(t)(6) of the Social Security Act (the Act) states, "The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services)." In accordance with the Act, CMS needs to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner. It is necessary that we continue to collect appropriate information from interested parties such as hospitals, medical device manufacturers, pharmaceutical companies and others that bring to our attention specific services that they wish us to evaluate for New Technology APC payment.

The information that we seek to continue to collect is necessary to determine whether certain new services are eligible for payment in New Technology APCs, to determine appropriate coding and to set an appropriate payment rate for the new technology service. The intent of these

provisions is to ensure timely beneficiary access to new and appropriate technologies.

Both the New Technology APC provision and the transitional pass-through provisions provide ways for ensuring appropriate payment for new technologies for which the use and costs are not adequately represented in the base year claims data on which the outpatient PPS is constructed. Although individual drugs and biologicals and categories of medical devices will receive transitional pass-through payments for 2 to 3 years from the date payment is initiated for the specific item or category, the underlying statutory provision is permanent and provides an on-going mechanism for reflecting the introduction of new items into the payment structure in a timely manner. New Technology APCs are designed to allow appropriate payment for new technology services that are not covered by the transitional pass-through provisions. *Form Number:* CMS-10054 (OMB control number: 0938-0272); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 160. (For policy questions regarding this collection contact Allison Bramlett at 410-786-6556.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medication Therapy Management Program Improvements; *Use:* Information collected by Part D MTM programs as required by the Standardized Format for the CMR summary is used by beneficiaries or their authorized representatives, caregivers, and their healthcare providers to improve medication use and achieve better healthcare outcomes. Members in a Part D sponsors' plan who are eligible are enrolled in the sponsors' MTM program and offered a CMR which is a consultation between the MTM provider (such as a pharmacist) with the beneficiary to review their medications. After a CMR is performed, the sponsor creates and sends a summary of the CMR to the beneficiary that includes a medication action plan and personal medication list using the Standardized Format; *Form Number:* CMS-10396 (OMB control number 0938-1154); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits; *Number of Respondents:* 807; *Total Annual Responses:* 2,386,955; *Total Annual Hours:* 1,591,383. (For policy questions regarding this collection contact Victoria Dang at 410-786-3991.)