ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Cities	Annual	2	1	75	150
Cities	One-time Addition of Diseases and Data Elements.	2	1	3	6
Total					18,414

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, 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–25–24HQ]

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 ''Division of Diabetes Translation Programmatic & Participant User Experience Data Collection (DDTDC)'' 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 26, 2024 to obtain comments from the public and affected agencies. CDC received zero 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

Division of Diabetes Translation Programmatic & Participant User Experience Data Collection (DDTDC)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Diabetes Translation (DDT) plays a crucial role in helping prevent Type 2 diabetes, reducing diabetes complications and disability, and reducing diabetes-related disparities across the United States. DDT accomplishes this by providing education, training, technical assistance (TA), and engaging in communication/marketing activities for various key audiences. These customers include national, state, and local partners, grantees, providers (*e.g.,* lifestyle coaches, diabetes educators, healthcare providers, health/medical and community-based organizations), people with prediabetes, diabetes and their family, friends, and caregivers, and other consumers of DDT products and programs.

For DDT to be able to efficiently and effectively do this work and fulfill its mission, it needs to be able to collect information and feedback from intended audiences in a timely manner and with enough frequency to ensure DDT can deliver clear, effective, efficient, and appropriate customer service. This includes, for instance, collecting data on key audiences' needs and on the reach, uptake, use, customer experience and satisfaction with DDT's services, products, and related programs, including its education, training, TA and communications services and products.

However, in the interest of timely provision of services, DDT often forgoes the important step of getting input from its key audiences on the clarity, efficiency, effectiveness, and appropriateness of the services and resources it develops and provides for them. Skipping this information collection step, or doing so with less frequency, avoids the delay involved in the standard OMB review process, but increases the risk of DDT wasting both time and money developing and providing education, training, TA, and communication/marketing that will not achieve the intended objectives and will be unclear, irrelevant, or not fully meet the needs of DDT's audiences. It can also have other unintended consequences, such as jeopardizing the credibility of Federal health officials.

The Division of Diabetes Translation Programmatic & Participant User Experience Data Collection (DDTDC) will enable DDT to collect the information they require in a timely manner to:

- Provide clear, effective, efficient, appropriate, and timely education, communication, training, and technical

assistance to key audiences and other interested groups, including consumer audiences (*e.g.,* people with prediabetes, diabetes, and their family, friends, and caregivers), providers (*e.g.,* lifestyle coaches, diabetes care and education specialists, healthcare and other providers, health/medical and community-based organizations); and partners (national, state, and local partners).

- Ensure quality and prevent duplication in the development and dissemination of prevention and health information and program activities by DDT to consumers, providers, and state and local partners.
- Conduct exploratory/formative assessments to inform DDT's development of education, communication/marketing, training, and programmatic materials, tools, and resources to support and improve the prevention and management of diabetes. For example, identifying key audiences' knowledge, attitudes, behaviors, motivators, and information needs.
- Assess the impact of programs, messages, educational and training materials among recipients and determine to what extent they meet relevant service-related DDT objectives and goals.

The following are examples of the areas of focus that the data collection activities under this generic information collection mechanism may include:

- Reach, uptake, use, customer experience, and satisfaction with the CDC-recognized lifestyle change programs for type 2 diabetes prevention, as well as related outcomes (*e.g.,* participant retention and recruitment rates).
- Satisfaction with CDC-recognized lifestyle change programs toolkits, such as the Personal Success Tool and Champion toolkits.
- Reach, uptake, use, customer experience, and satisfaction with diabetes education, type 2 prevention, and diabetes management innovations (such as the Diabetes Self-Management Education and Support services promotion initiative) and related short-term effects on knowledge, awareness, practices (such as information seeking), and outcomes (such as enrollment of people with diabetes or prediabetes).
- Reach, uptake, satisfaction, customer experience, and short-term outcomes of CDC's training and technical assistance resources (such as a webinar or online toolkit).
- Needs assessments for customer experience with, utilization of, and short-term outcomes of technical assistance and trainings for diabetes prevention and management.
- Understandability, ease of use, and appropriateness of diabetes education messages, toolkits, programs, and marketing materials.
- Exploratory assessments of knowledge, attitudes, behaviors, beliefs, barriers, and facilitators to uptake and use of lifestyle change programs for diabetes type 2 prevention and diabetes management services and related innovations, resources, tools, and materials.

Data collection methods proposed include, but are not limited to in-depth individual interviews, cognitive interviews, intercept interviews, group-based discussions (including focus groups and dyads/triads), surveys or questionnaires, knowledge assessments, observational assessments, and implementation and utilization data reporting. Respondents would include key audiences and stakeholders of CDC's work, including representatives of state and local DDT-funded organizations; national, state, and local DDT partners (not CDC-funded); providers of type 2 diabetes prevention and diabetes management programs and services, including lifestyle coaches, diabetes care and educations specialists, healthcare and other providers; heath/medical and community-based organizations implementing programs and services related to type 2 diabetes prevention and diabetes management; people with—and at risk for—diabetes or with prediabetes; family, friends, and caregivers of people with—and at risk for—diabetes or with prediabetes.

As the methods for data collection and audiences may vary with each request submitted under this proposed generic clearance, for each data collection request unique instruments (*e.g.,* surveys, interview guides) will be developed to address the specific topics that information will be collected on. Questions to be asked may focus, for example, on collecting data on the audiences' needs and on the reach, uptake, use, customer experience and satisfaction with DDT's services, products, and programs. Such information will enable DDT to identify ways to improve its services, products, and programs to better meet its audiences' needs and achieve its mission of supporting the prevention of diabetes and reducing diabetes-related complications and disparities across the United States.

CDC requests a three-year approval for 6,000 burden hours for this proposed Generic package. Based on projections, the estimated annualized hourly burden anticipated for all data collection methods would total 2,000 hours and include eight to ten data collection activities over the course of a year. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Data collection methods	Number of respondents across methods	Number responses per respondent	Average burden per response
Representatives of state and local DDT-funded organizations; national, state, and local DDT partners (not CDC-funded); providers of type 2 diabetes prevention and diabetes management programs and services; heath/medical and community-based organizations implementing programs and services related to type 2 diabetes prevention and diabetes management; people with—and at risk for—diabetes or with prediabetes; family, friends, and caregivers of people with—and at risk for—diabetes or with prediabetes.	Interviews; surveys or questionnaires; knowledge assessments; motivation assessments, observational assessments; implementation and utilization data reporting.	4,000	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, 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–10398 #85]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the ''generic'' clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial collections,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates 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 must be received by December 2, 2024.

ADDRESSES: When commenting, please reference the applicable form number (CMS–10398 #85) and the OMB control number (0938–1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10398 #85/OMB control number: 0938–1148, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at 410–786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collection

1. *Title of Information Collection:* 3.1–M State Plan Amendment (SPA) Templates for Eligible Juveniles Who are Inmates of a Public Institution; *Type of Information Collection Request:* New information collection request information request; *Use:* Section 5121 of the Consolidated Appropriation Act of 2023 (CAA, 2023) creates a new mandate for states by amending section 1902(a)(84) of the Social Security Act (the Act) (42 U.S.C. 1396a) to require states to provide specific screening and diagnostic services and targeted case management (including referrals) in the 30 days prior to release from incarceration, and targeted case management (TCM) (including referrals) for at least 30 days post release for eligible juveniles who are inmates of a public institution, post adjudication. The requirements are effective January 1, 2025.

To comply with the amendments states must submit a Medicaid SPA attesting that the state has developed an internal operation plan, and in accordance with such plan, will provide coverage during the statutory pre- and post-release period of screening, diagnostic, and TCM services for eligible juveniles who are within 30 days of release post adjudication.

States have the option to lift the Medicaid inmate payment and CHIP eligibility exclusions and provide coverage of pre-release Medicaid and CHIP services (for electing states) and makes available federal matching funds for the full breadth of Medicaid and CHIP benefits to eligible juveniles who are incarcerated and pending disposition of charges. States selecting this state plan option must provide to eligible juveniles all mandatory and optional services to which they are otherwise entitled under the state plan. During the period when an eligible juvenile is incarcerated and pending disposition of charges, this is essentially a full lifting of the Medicaid inmate payment exclusion and CHIP eligibility exclusion. States cannot choose to provide a limited array of state plan services under this option. An operational plan is not required for this state option.

For states that wish to elect the option in section 5122 of the CAA, 2023, states should submit a SPA attesting to CMS that they are also electing coverage for any Medicaid or CHIP state plan services for eligible juveniles pending disposition of charges to which the beneficiary would otherwise be entitled, if not for their incarceration status.

Form Number: CMS–10398 #85 (OMB control number: 0938–1148); *Frequency:* Once and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 168; *Total Annual Hours:* 4,872. (For policy questions regarding this collection contact: Marlana Thieler at 410–786–6274.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–26713 Filed 11–15–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4467]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.