



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-23AP]

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 "TRANSCEND: Transgender status-neutral community-to-clinic models to end the HIV epidemic" 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 November 16, 2022 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

TRANSCEND: Transgender status-neutral community-to-clinic models to end the HIV epidemic - New - National Center for HIV, Viral

Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC requesting public comment and OMB approval on a New information collection request (ICR) for the demonstration project titled "TRANSCEND: Transgender status-neutral community-to-clinic models to end the HIV epidemic."

Transgender (TG) persons, especially transgender women (TGW), have a high prevalence of HIV and lifetime risk of acquiring HIV. In the 2019-2020 National HIV Behavioral Surveillance Trans cycle, 42% of TGW tested positive for HIV. Racial/ethnic disparities were also found, with HIV positivity rates of 62% among Black/African American TGW and 35% among Hispanic/Latina TGW compared to 17% among White TGW. Despite the disproportionate burden of HIV among TGW, receipt of HIV prevention and care services have been suboptimal. Many TG persons experience poverty, homelessness, abuse, and have substance use or mental health disorders, which impact access to and utilization of HIV prevention and care services. Many TG persons seek gender-affirming care, including hormone therapy, at transgender health care organizations (TG clinics), and these encounters provide opportunities for HIV testing and status-neutral HIV services.

In the proposed demonstration project, TG clinics and transgender-serving community-based organizations (CBOs) will work collaboratively to evaluate community-to-clinic models to

provide integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary healthcare, as well as to ensure access to mental health, substance use, and social support services. All services will be culturally and linguistically responsive for TG persons to ensure that they feel welcomed, heard, and cared for. The recipients will also participate in a national learning collaborative to share lessons learned and best practices for TG clinic and TG CBO partnerships to provide status-neutral, community-to-clinic services for TG persons.

This collection of data, which involves creation of a unique identifier so that CDC does not receive any personally identifiable information (PII), will allow CDC to assist TG clinics and CBOs in monitoring and evaluating their programs providing status-neutral HIV services and comprehensive healthcare for TG persons and for community-to-clinic models of service provision. Longitudinal person-level data collection will occur through the clinics' electronic health record (EHR Data Form) and the Client Intake Form, and additional program evaluation data will be collected through client surveys (Client Satisfaction Survey).

The clients will complete the Client Intake Form once when they first join the program, with expected 800 clients per year for a total burden of 107 hours annually. A sample of 100 clients per site (400 total) will respond to the Client Satisfaction Survey once per year, for a total burden of 100

hours annually. The four data managers will extract data from the EHR, perform quality checks, code the data with a unique identifier, and transmit the deidentified data to CDC two times per year, for a total of 64 hours per year. The four data managers will also compile, link, deidentify, and report data from the Client Intake Forms two times per year, with an estimated burden of 16 hours annually. The four data managers will compile and report data from the Satisfaction Survey once per year, with an estimated burden of eight hours annually.

OMB approval is requested for three years. Participation of the funded recipients' data managers is required, and participation from the clients is voluntary. There is no cost to participants other than their time. The total estimated annualized burden is 295 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)
TRANSCEND Recipient Data Manager	Electronic Health Record Data Form	4	2	8
TRANSCEND Recipient Data Manager	Client Intake Form	4	2	2
TRANSCEND Clients	Client Intake Form	800	1	8/60
TRANSCEND Clients	Client Satisfaction Survey	400	1	15/60
TRANSCEND Recipient	Client Satisfaction Survey	4	1	2

Data Manager				
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