



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-24-0556; Docket No. CDC-2024-0025]

#### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Assisted Reproductive Technology (ART) Program Reporting System. This study is designed to collect information on ART cycles to publish information on pregnancy success rates as required under Section 2(a) of the Federal Clinic Success Rate and Certification Act (FCSRCA).

**DATES:** CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2024-0025 by either of the following methods:

- Federal eRulemaking Portal: [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number.

CDC will post, without change, all relevant comments to [www.regulations.gov](http://www.regulations.gov).

Please note: Submit all comments through the Federal eRulemaking portal

(www.regulations.gov) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: omb@cdc.gov.

**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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and

5. Assess information collection costs.

## Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System (OMB Control No. 0920-0556, Exp. 12/31/2024) – Revision - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

Section 2(a) of Public Law 102-493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a-1(a)) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary through the Centers for Disease Control and Prevention: (1) pregnancy success rates achieved by such ART program; and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory is certified or has applied for such certification under the Act. The required information is currently reported by ART programs to CDC as specified in the Assisted Reproductive Technology (ART) Program Reporting System (OMB Control No. 0920-0556, Exp. 12/31/2024). The current revision seeks to revise burden hour estimates, modify data elements collected, implement a new process for sharing data externally, and to extend OMB approval for a period of three years. The revised total burden estimate is higher than the previous approval, due to an increase in the utilization of ART in the United States and the number of reported cycles. Data elements collected will be modified to remove five data elements no longer needed and add one new data element to reflect current clinical practice. The average estimated burden for reporting information related to each cycle is not anticipated to change from the time burden previously approved (43 minutes). Data will be made available in the National Center for

Health Statistics Research Data Center to increase accessibility of Assisted Reproductive Technology (ART) Program Reporting System data for secondary epidemiological analyses.

The currently approved program reporting system, also known as the National ART Surveillance System (NASS), collects information about all ART cycles initiated by ART programs in the United States. The start of an ART cycle is considered when a woman begins taking medication to stimulate egg production or begins monitoring with the intent of having embryos transferred. For each cycle, CDC collects information about the pregnancy outcome, as well as several data elements deemed by experts in the field to be important to explain variability in success rates across ART programs and individuals.

Each ART program reports its annual ART cycle data to CDC in mid-December. The annual data reporting consists of information about all ART cycles that were initiated in the previous calendar year. For example, ART programs that submit their data in mid-December 2021 will include all ART cycles that were initiated between January 1, 2020, and December 31, 2020.

Data elements and definitions currently in use reflect CDC's prior consultations with representatives of the Society for Assisted Reproductive Technology (SART), the American Society for Reproductive Medicine (ASRM), and RESOLVE: the National Infertility Association (a national, nonprofit consumer organization), as well as a variety of individuals with expertise and interest in this field.

The estimated number of respondents (ART programs or clinics) is 453, based on the number of clinics that provided information in 2021. This number is lower than the previous number of reporting clinics (456). The estimated average number of responses (ART cycles) per respondent is 913. The total burden estimate is higher than the previous approval due to an increase in the utilization of ART in the United States. Additionally, approximately 5-10% of responding clinics will be randomly selected each year to participate in data validation and quality control activities; an estimated 35 clinics will be selected to report validation data on 70

cycles each on average. Finally, respondents may provide feedback to CDC about the usability and utility of the reporting system. The option to participate in the feedback survey is presented to respondents when they complete their required data submission. Participation in the feedback survey is voluntary and is not required by the FCSRCA. CDC estimates that 50% of ART programs will participate in the feedback survey. Due to this lower response rate and reduced number of reporting clinics, CDC estimates 203 clinics will respond to voluntary feedback survey.

The collection of ART cycle information allows CDC to publish clinic-specific success rates annually as specified by the FCSRCA and to provide information needed by consumers. OMB approval is requested for three years. CDC requests approval for 297,352 annual burden hours. 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) | Total Burden (in hours) |
|---------------------|---------------------|-----------------------|------------------------------------|--|-------------------------|
| ART Program/Clinic  | NASS Reporting Form | 453                   | 913                                | 43/60                                  | 296,406                 |
|                     | Data Validation     | 35                    | 70                                 | 23/60                                  | 939                     |
|                     | Feedback Survey     | 203                   | 1                                  | 2/60                                   | 7                       |
| Total               |                     |                       |                                    |  | 297,352                 |

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[FR Doc. 2024-07289 Filed: 4/4/2024 8:45 am; Publication Date: 4/5/2024]