

methods). Although it is possible that notifications or responses may be intercepted or seen by someone who is not part of the team collecting the data, it is not likely that this will have a major impact on the respondents' privacy.

CDC and contractors will also conduct periodic usability and user experience tests of StopAnthrax™ in conjunction with points of dispensing (PODs) exercises conducted by state and local

health departments across the US. The purpose of these tests would be to evaluate the acceptability of the program with members of the potential target audience following an anthrax incident and to ensure proper functionality of the StopAnthrax™ protocols within the system. These tests will occur no more than twice a year and feedback on the program will be collected from volunteers participating

in the jurisdictional exercises through one or more of the following mechanisms; in-person focus groups, online survey, online discussion groups.

CDC is requesting approval for this new generic clearance for data collection for a period of three years. The total burden hours for respondents is 38,000 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)
Adult MCM recipient .....	60-day StopAnthrax™ program .....	20,000	1	90/60	30,000
POD volunteer participating in user experience/usability testing of shortened StopAnthrax™ protocol.	Shortened (10-day) StopAnthrax protocol.	4,000	1	30/60	2,000
POD volunteer participating in user experience/usability testing.	Online Survey .....	2,000	1	1	2,000
POD volunteer participating in user experience/usability testing.	Discussion/focus groups .....	2,000	1	2	4,000
Total .....	.....	.....	.....	.....	38,000

**Jeffrey M. Zirger,**

*Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2018-11648 Filed 5-30-18; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Docket No. CDC-2018-0054]

#### Proposed Assisted Reproductive Technology (ART) Success Rates Reporting and Data Validation Procedures

**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) in the Department of Health and Human Services (HHS) requests comments on a plan to (1) revise the definition and characterization of Assisted Reproductive Technology (ART) success rates and (2) introduce clinic validation footnotes for the annual ART Fertility Clinic Success Rates Report. The footnotes will identify clinics that are selected by CDC to participate in the validation process of the National ART

Surveillance System (NASS) data and that: (1) Do participate, (2) do participate and have major data discrepancies identified through this process, and/or (3) decline to participate in the data validation process. CDC requests comments on this plan in order to continue to ensure that the public has access to accurate and transparent data pursuant to the Fertility Clinic Success Rate and Certification Act of 1992.

**DATES:** Written comments must be received on or before July 2, 2018.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2018-0054 by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Sara Crawford, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS F-74, Atlanta, Georgia 30341. Phone: (770) 488-6370. Email: [artinfo@cdc.gov](mailto:artinfo@cdc.gov).

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Sara Crawford, Division of Reproductive

Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS F-74, Atlanta, Georgia 30341. Phone: (770) 488-6370. Email: [artinfo@cdc.gov](mailto:artinfo@cdc.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Success Rates

###### A. Background

Section 2(a) of Public Law 102-493 (42 U.S.C. 263a-1(a)), the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), requires that each assisted reproductive technology (ART) program report annually to the Secretary of the Department of Health and Human Services through the Centers for Disease Control and Prevention (CDC) pregnancy success rates achieved through assisted reproductive technology. The FCSRCA also requires the CDC to annually publish and distribute to the public reported pregnancy success rates. According to the FCSRCA, the definitions of pregnancy success rates should be developed in consultation with appropriate consumer and professional organizations, should take into account the effect on success rates of age, diagnosis, and other significant factors, and should include the live birth rate per attempted ovarian stimulation procedure and the live birth rate per successful oocyte retrieval.

Specifics about the reporting process and requirements are described in

“Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs” (80 FR 51811). Specifics about the definition and characterization of ART success rates were last described in “Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs” (69 FR 5548). Success rates for fresh, nondonor cycles were defined as: (1) The rate of pregnancy after completion of ART according to the number of all ovarian stimulation or monitoring procedures;

(2) the rate of live birth after completion of ART according to the number of all ovarian stimulation or monitoring procedures, the number of oocyte retrieval processes, and the number of embryo (or zygote or oocyte) transfer procedures; (3) the rate of singleton live birth after completion of ART according to the number of all ovarian stimulation or monitoring procedures and the number of embryo (or zygote or oocyte) transfer procedures. Success rates for cycles using thawed embryos and cycles using donor oocytes or embryos were defined as: (4) The rate of live birth after completion of ART according to the number of embryo (or zygote or oocyte) transfer procedures; (5) the rate of singleton live birth after completion of ART according to the number of embryo (or zygote or oocyte) transfer procedures.

Effective for reporting year 2017, CDC is proposing substantial changes to the definition and characterization of ART success rates due to changes in clinical practice and more variation in treatment options, including improvements in cryopreservation resulting in more segmentation of typical treatment cycles. The field of ART is moving toward the calculation and reporting of cumulative success rates where data collection systems can collect successes over all embryo transfers from a single oocyte retrieval or across several oocyte retrievals and embryo transfers. After consultation with consumer and professional organizations with expertise in ART, CDC will begin cumulative ART success rates reporting in reporting year 2017. The ART success rates described in this **Federal Register** notice shall replace those previously described in 2004.

#### *B. ART Procedures Among Patients Using Their Own Oocytes*

ART success rates for ART procedures among all patients using their own eggs will be defined as:

1. The rate of live birth or singleton live birth resulting from the transfer of oocytes retrieved from the patient in the

year prior to the reporting year or from the transfer of embryos created from oocytes retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, transfer procedures must have started within 12 months of the start of the retrieval procedure. Oocytes must have been retrieved in the year prior to the reporting year in order to allow for a full year to perform transfers of the retrieved oocytes (either in the prior reporting year or in the current reporting year). The live birth rate and singleton live birth rate will be presented according to the number of:

a. All ovarian stimulation or monitoring procedures started from the year prior to the reporting year with the intent to retrieve oocytes from the patient.

b. All ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient in which at least one oocyte was retrieved.

c. All transfer procedures of at least one oocyte retrieved from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

2. The number of ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient presented according to the number of:

a. Live births resulting from all transfers of at least one oocyte retrieved from the patient in the year prior to the reporting year, or transfers of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

Other rates for ART procedures among all patients using their own eggs may be defined as—

3. The rate of cancellation, implantation, pregnancy, live birth, singleton live birth, multiple live birth, twin live birth, triplet or higher order live birth, preterm live birth, low birthweight live birth or term, normal birthweight and singleton live birth resulting from the transfer of oocytes retrieved from the patient in the year prior to the reporting year or the transfer of embryos created from oocytes retrieved from the patient in the year

prior to the reporting year. For the purpose of this definition, transfer procedures must have started within 12 months of the start of the retrieval procedure. These other rates may be presented according to the number of:

a. All ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient.

b. All ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient in which at least one oocyte was retrieved.

c. All transfer procedures of at least one oocyte retrieved from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

d. All first, second, third, or more transfer procedures after retrieval of at least one oocyte from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

Rates for ART procedures among new ART patients (*i.e.*, patients that have never had a prior ART cycle ever) using their own oocytes will be defined as—

4. The rate of live birth resulting from the transfer of oocytes or embryos from all first intended oocyte retrievals presented according to the number of:

a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures. For the purpose of this definition, the retrieval procedure must have started in the year prior to the reporting year.

5. The rate of live birth resulting from the transfer of oocytes or embryos from all first or second intended oocyte retrievals presented according to the number of:

a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures. For the purpose of this definition, the retrieval procedure must have started in the year prior to the reporting year.

6. The rate of live birth resulting from the transfer of oocytes or embryos from all intended oocyte retrievals presented according to the number of:

a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures. For the purpose of this definition, the retrieval procedure must have started in the year prior to the reporting year.

7. The number of ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient presented according to the number of:

a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures.

8. The number of transfer procedures of at least one oocyte retrieved from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year presented according to the number of:

a. Ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure. Also, ART patients must have reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures.

#### C. ART Procedures Among Patients Using Oocytes or Embryos From a Donor

Success rates for ART procedures among patients using oocytes or embryos from a donor will be defined as—

9. The rate of live birth or singleton live birth presented according to the number of:

a. Transfer procedures of at least one donor egg, embryo created from a donor egg, or donated embryo started in the current reporting year.

Other rates for ART procedures among patients using oocytes or embryos from a donor may also be defined as—

10. The rate of cancellation, implantation, pregnancy, live birth, singleton live birth, multiple live birth, twin live birth, triplet or higher order live birth, preterm live birth, low birthweight live birth, or term, normal birthweight and singleton live birth presented according to the number of:

a. ART procedures to prepare a patient (recipient) for the transfer of at least one donor egg, embryo created from a donor egg, or donated embryo, started in the current reporting year.

b. Transfer procedures of at least one donor egg, embryo created from a donor egg, or donated embryo started in the current reporting year.

#### D. ART Procedures Among All Patients and All Cycle Types

ART reporting may also include:

11. The number, average number or percentage of ART procedures or ART patients with certain characteristics, such as:

a. Patient characteristics (e.g. patient age or reason for ART).

b. ART procedure characteristics (e.g. type of treatment (fertility preservation, short term banking, in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer), stimulation protocol, source of the oocytes or embryos (patient or donor), the state of the oocytes or embryos (fresh or frozen), the intent of the procedure, the use of prenatal genetic diagnosis or screening, the use of intracytoplasmic sperm injection, the use of assisted hatching, the use of a gestational carrier, the stage of the embryo at transfer, or the number of embryos transferred).

All ART patient and procedure characteristics, ART success rates, and other rates for patients using their own oocytes as well as for patients using oocytes or embryos from a donor may be stratified by factors thought to influence the outcome of an ART procedure.

12. Factors for stratification may include:

a. Characteristics of the ART patient such as patient age or reason for ART.

b. Characteristics of the ART procedure such as type of treatment (fertility preservation, short term banking, in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer), stimulation protocol, the source of the oocytes or embryos (patient or donor), the state of the oocytes or embryos (fresh or frozen), the intent of the procedure, the use of prenatal genetic diagnosis or screening, the use of intracytoplasmic sperm injection, the use of assisted hatching, the use of a gestational carrier, the stage of the embryo at transfer, or the number of embryos transferred.

#### Section II. Validation

A description of external validation of clinic data conducted annually as a part of the ART surveillance program is described in “Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs” (80 FR 51811). This notice explains, “If major data discrepancies are identified during data validation (e.g., lack of supporting information for pregnancy outcomes, underreporting

cycles, etc.), CDC may re-select these ART programs for data validation during the following reporting year(s) to assess corrections of identified data errors.”

Additionally, effective as of the 2019 reporting year, CDC will include a footnote in the annual *ART Fertility Clinic Success Rates Report* to identify clinics that are selected by CDC to participate in the validation process of the NASS data and that: 1) do participate, 2) do participate and have major data discrepancies identified through this process, and/or 3) decline to participate in the data validation process. CDC will include this footnote pending the availability of the necessary resources. This footnote is a new addition to the annual *ART Fertility Clinic Success Rates Report*. Pursuant to the Fertility Clinic Success Rate and Certification Act of 1992, the CDC is mandated to publish the clinic-specific success rates reported by each clinic. These footnotes will help to alert the public if there is evidence that the reported success rates may be of questionable quality, thereby increasing the transparency of the data reporting process.

If a clinic is selected to participate in the NASS data validation process and does participate, the following footnote will be added:

This clinic was visited for validation of (*insert: reporting year*) data. See Appendix A for additional information.

If a clinic is selected to participate in the NASS data validation process, does participate, and major data discrepancies are identified for either the number of reported ART cycles or the ART pregnancy outcome, the following footnote will be added:

This clinic was visited for validation of (*insert: reporting year*) data. Major data discrepancies were identified for (*insert: “the number of reported cycles” or “the pregnancy outcomes” or “the number of reported cycles and the pregnancy outcomes”*). See Appendix A for additional information.

If a clinic is selected to participate in the NASS data validation process and declines to participate, the following footnote will be added:

This clinic was selected for validation of (*insert: reporting year*) data, but declined to participate. See Appendix A for additional information.

Appendix A of the *ART Fertility Clinic Success Rates Report* contains information about the validation of NASS data, including methods used for clinic selection, and displays aggregate validation results. Aggregate validation results include national discrepancy

rates; clinic-specific discrepancy rates are not reported. Any footnote added to a clinic's success rates page in the *ART Fertility Clinic Success Rates Report* will appear only for the reporting year that the clinic was selected for validation; it will be removed the following reporting year.

Dated: May 24, 2018.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

[FR Doc. 2018-11628 Filed 5-30-18; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10599]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send 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 July 30, 2018.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. 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://](http://www.regulations.gov)

[www.regulations.gov](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: Document Identifier/OMB Control Number \_\_\_\_\_, 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, 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>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

#### CMS-10599 Pre-Claim Review Demonstration for Home Health Services

Under the 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 requires federal agencies to publish a 60-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.

## Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Pre-Claim Review Demonstration for Home Health Services; *Use:* Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) authorizes the Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act)." Pursuant to this authority, the CMS seeks to develop and implement a Medicare demonstration project, which CMS believes will help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among Home Health Agencies (HHA) providing services to Medicare beneficiaries.

This revised demonstration would help assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud. The demonstration would help make sure that payments for home health services are appropriate through either pre-claim or postpayment review, thereby working towards the prevention and identification of potential fraud, waste, and abuse; the protection of Medicare Trust Funds from improper payments; and the reduction of Medicare appeals. CMS proposes initially implementing the demonstration in Illinois, Ohio, North Carolina, Florida, and Texas with the option to expand to other states in the Palmetto/JM jurisdiction. Under this demonstration, CMS proposes to offer choices for providers to demonstrate their compliance with CMS' home health policies. Providers in the demonstration states may participate in either 100 percent pre-claim review or 100 percent postpayment review. These providers will continue to be subject to a review method until the HHA reaches the target affirmation or claim approval rate. Once a HHA reaches the target pre-claim review affirmation or post-payment review claim approval rate, it may choose to be relieved from claim reviews, except for a spot check of their claims to ensure continued compliance. Providers who do not wish to participate in either 100 percent pre-claim or postpayment reviews have the option to furnish home health services and submit the associated claim for payment without undergoing such reviews; however, they will receive a 25 percent payment reduction on all claims