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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14-0556]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System (OMB No. 0920-0556, expires 8/31/2015) – 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 reported by ART programs to CDC as specified in the Assisted Reproductive Technology (ART) Program Reporting System (OMB No. 0920-0556, exp. 8/31/2015).

The currently approved program reporting system, also known as the National ART Surveillance System (NASS), includes information about all ART cycles initiated by any of the ART programs in the United States. An ART cycle is considered to be initiated when a woman begins taking ovarian stimulatory drugs or starts ovarian monitoring with the intent of transferring one or more embryos. CDC also collects information about the pregnancy outcome of each cycle, as well as a number of data

items deemed important to explain variability in success rates across ART programs and across 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, the December 2013 reports described ART cycles that were initiated between January 1, 2012, and December 31, 2012. 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, 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.

CDC, the data collection contractor, and partner organizations engage in ongoing dialogue to identify opportunities for improvement. As a result of these discussions, a number of changes to the NASS data elements and the NASS reporting platform are under consideration and will be submitted to OMB for approval. Changes to the NASS data elements are essential to keep pace with changes in medical practice, ensure that reported success rates reflect standardized definitions, and provide additional insight into factors that may affect success rates. Specific changes to the NASS data elements

include the addition of new items as well as modification or discontinuation of selected items. CDC also plans to redesign the graphical interface for NASS. In addition to reflecting the changes in data items, NASS data entry pages will be redesigned for more intuitive grouping of data items and will employ embedded skip logic to route users to the minimum number of applicable questions. Respondents will have the option of entering data directly into the Web-based NASS interface or of transmitting system-compatible files extracted from other record systems. On an annual basis, approximately ten percent of responding clinics are also selected to participate in data validation and quality control activities.

Implementation of these changes for ART cycles initiated on or after January 1, 2015, is under consideration, but may be deferred until January 1, 2016. During the period of this revision, the estimated number of respondents (ART programs or clinics) will increase from 440 to 450; the estimated number of ART cycles reported by each clinic will increase from 339 to 360; and the estimated burden per response will increase from 39 minutes to 40 minutes.

In addition, 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. However,

participation in the feedback survey is voluntary and is not required by the FCSRCA. CDC estimates that 75% of ART programs will participate in the feedback survey.

The collection of ART cycle information allows CDC to publish an annual report to Congress as specified by the FCSRCA and to provide information needed by consumers. Overall, the proposed changes will support CDC's ability to generate timely, accurate, and relevant information about fertility clinic success rates and improve user satisfaction with the NASS interface.

OMB approval is requested for three years and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
ART Programs	NASS	450	360	40/60	108,000
	Feedback Survey	338	1	2/60	11
Total					108,011

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Leroy Richardson,
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Office of Scientific Integrity,
Office of the Associate Director for Science,
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