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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-0556]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Ron Otten, at 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System exp. 9/30/2012 – 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 Pub. L. 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 no. 0920-0556, exp. 9/30/2012). CDC seeks to extend OMB

approval for a period of three years and to implement a brief, one-time optional feedback survey to clinics for each reporting year. The revised total burden estimate includes an anticipated increase in the number of participating clinics from 430 to 440 and an increase in the average number of responses per respondent from 321 to 339. There is a 2-minute increase to the estimated burden per response.

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 begin when a woman begins taking ovarian stimulatory drugs or starts ovarian monitoring with the intent of having embryos transferred. The system 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. Data elements and definitions currently in use reflect CDC's 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.

Respondents are the 484 ART programs in the United States. Approximately 440 clinics are expected to report an average of 339 ART cycles each. Ten percent of responding clinics will be randomly selected to participate in full validation of selected ART cycle records and an abbreviated validation of selected ART cycle records. All information is collected electronically. Respondents have the option of entering data directly into a Web-based National ART Surveillance System (NASS) interface or of transmitting system-compatible files extracted from other record systems. The ART program reporting system allows CDC to publish an annual report to Congress as specified by the FCSRCA and to provide information needed by consumers.

CDC, the data collection contractor, and partner organizations engage in ongoing dialogue to identify opportunities for improvement in NASS. During the period of this Revision request, minor changes to NASS data definitions or similar technical adjustments may be proposed through the Change Request mechanism.

Starting with 2012 data reporting year, CDC plans to implement a brief, one-time optional feedback survey to clinics for each reporting year. The purpose of this survey is to obtain insight into NASS usability issues as well as respondents' perspectives on the usefulness of the information collected.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours
ART Programs	NASS	440	339	39/60	96,954
	Feedback Survey	176	1	2/60	6
				Total	96,960

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