

Programs," as implemented by 45 CFR part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." As soon as possible, the applicant should discuss the project with the State Single Point of Contact (SPOC) for the state in which the applicant is located. The application kit contains the currently available listing of the SPOCs which have elected to be informed of the submission of applications. For those states not represented on the listing, further inquiries should be made by the applicant regarding the submission to the relevant SPOC. The SPOC's comment(s) should be forwarded to the Office of Grants Management, Office of Population Affairs, 4350 East-West Highway, Suite 200, Bethesda, Maryland 20814. Such comments must be received by the Office of Population Affairs within 60 days of the closing date of this announcement, listed under **DATES** above.

When final funding decisions have been made, each applicant will be notified by letter of the outcome. The official document notifying an applicant that a project application has been approved for funding is the Notice of Grant Award, which specifies to the grantee the amount of money awarded, the purposes of the grant, and terms and conditions of the grant award.

Dated: August 30, 1999.

Denese O. Shervington,

Deputy Assistant Secretary for Population Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[INFO-99-33]

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 the CDC Reports Clearance Officer on (404) 639-7090.

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 for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

1. Interstate shipment of etiologic agents are regulated by 42 CFR part 7. This rule establishes minimal packaging

requirements for all viable microorganisms, illustrates the appropriate shipping label, and provides reporting instructions regarding damaged packages and failure to receive a shipment. In recent years the threat of illegitimate use of infectious agents has attracted increasing interest from the perspective of public health. CDC is concerned about the possibility that the interstate transportation of certain infectious agents could have adverse consequences for human health and safety. CDC has already requested that all those entities that ship dangerous human infectious agents exercise increased vigilance prior to shipment to minimize the risk of illicit access to infectious agents. Of special concern are pathogens and toxins causing anthrax, botulism, brucellosis, plague, Q fever, tularemia, and all agents classified for work at Biosafety Level 4. This information collection ensures that selected infectious agents are not shipped to parties ill-equipped to handle them appropriately, or who do not have legitimate reasons to use them and to implement a system whereby scientists and researchers involved in legitimate research may continue transferring and receiving these agents without undue burdens. Respondents include laboratory facilities such as those operated by government agencies, universities, research institutions, and commercial entities. This request is for the information collection requirements contained in 42 CFR 71.54, 72.3(e) and 72.4 relating to the importation and shipment of etiologic agents. The complete request for clearance is currently under development at CDC and this request for a 6-month extension will ensure that data collection activities remain in effect through the clearance process. The total maximum cost to respondents is \$1,000,000.

CFR section	Number of respondents	Number of responses/respondents	Average burden/responses (in hrs.)	Total burden (in hrs.)
Application for Permit	1,000	1	20/60	333
72.3(3)	50	1	3/60	3
72.4	2	1	3/60	1
72.6 (a)	1,000	1	15/60	250
72.6 (d)	1,000	3	30/60	1,500
72.6 (e)	120	21	10/60	420
72.6 (f)	1,000	3	8/60	400
Total				2,907

Dated: August 30, 1999.

Nancy Cheal,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Draft: Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs

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

ACTION: Request for comments.

SUMMARY: This notice is a request for comment and review of the draft document for the Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs as required by the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). This Announcement supersedes, Announcement 97-226611 which was published in the **Federal Register**, August 26, 1997 (vol 62, no. 165).

DATES: To ensure consideration, written comments on this document must be received on or before October 4, 1999. Please do not FAX comments.

ADDRESSES: Comments shall be submitted to: Assisted Reproduction Technology Epidemiology Unit, Women's Health and Fertility Branch, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), Mailstop K-34, 4770 Buford Hwy, N.E., Atlanta, Georgia 30341-3724.

FOR FURTHER INFORMATION CONTACT: Assisted Reproductive Technology Epidemiology Unit at (770) 488-5250.

SUPPLEMENTARY INFORMATION: Section 2(a) of Pub. L. 102-493 (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 this act.

Pub. L. 102-493, Sec. 8 (42 U.S.C. 263a-7) defines "Assisted reproductive

technology" (ART) as "all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency).

The Secretary is directed in Section 2b (42 U.S.C. 263a-1(b)) to define pregnancy success rates and "make public any proposed definition in such a manner as to facilitate comment from any person during its development."

Section 2c (42 U.S.C. 263a-1(c)) states, "the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies."

Section 6 (42 U.S.C. 263a-5) states that the Secretary, through the CDC, shall annually "publish and distribute to the States and the public—pregnancy success rates reported to the Secretary under section 2(a)(1) and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under each section, the name of each such program and each pregnancy success rate which the program failed to report."

In developing the definition of pregnancy success rates, CDC has consulted with representatives of the Society for Assisted Reproductive Technology (a national professional association of ART clinical programs), the American Society for Reproductive Medicine (a national society of professional individuals who work with infertility issues), 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.

This notice provides opportunity for public review and comment (see appendix).

Dated: August 27, 1999.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

Appendix—Notice for the Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs

Introduction

This notice includes four sections:
I. Who Reports . . . describes who shall report to CDC.

- II. Description of Reporting Process . . . describes the reporting system and process for reporting by each ART clinic.
- III. Data to be Reported . . . describes the data items and definitions to be included in the reporting database.
- IV. Content of the Published Report . . . describes terms, and how pregnancy success rates will be defined and reported, and outlines the topics that will be included in the annual published reports, using the data collected in the reporting database.

I. Who Reports

The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires that each assisted reproductive technology program shall annually report to the Secretary of the Department of Health and Human Services through the CDC.

The Society for Assisted Reproductive Technology (SART), an affiliate of the American Society for Reproductive Medicine (ASRM), maintains a national database of cycle specific data reported by each of its members. CDC has reviewed the SART reporting database and system and finds that it provides the necessary information to publish an annual report as required by the FCSRCA. Rather than duplicate SART's reporting system, and thereby burden ART clinics and patients, CDC has contracted with SART to annually obtain a copy of their clinic specific database.

An ART program or clinic is defined as a legal entity practicing under State law, recognizable to the consumer, that provides assisted reproductive technology to couples who have experienced infertility or are undergoing ART for other reasons. This can be an individual physician or a group of physicians who practice together and share resources and liability. This definition precludes individual physicians who practice independently from pooling their results for purposes of data reporting.

ART clinics that are participating in the ASRM/SART reporting system as described in this notice, will be considered to be in compliance with federal reporting requirements of FCSRCA. Both SART and non-SART clinics shall contact SART for reporting information, instructions, and fees charged (fees are for the purposes of covering all cost associated with this activity, including data collection, processing, analysis, publication, and administration; additional fees may be charged if SART needs to provide technical assistance to clinics submitting a dataset with errors.) It is the responsibility of the practice director of each clinic performing ART