

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. Send comments to Anne O'Connor, 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:* Automated Management Information System (MIS) for Diabetes Control Programs—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

**Background**

The National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC) has implemented a Management Information System (MIS) and federally sponsored data collection requirement from all CDC funded diabetes control programs. Diabetes is the sixth leading cause of death in the United States contributing to more than 200,000 deaths each year. An estimated 11.1 million people in the United States have been diagnosed with diabetes and an estimated 5.9 million people have undiagnosed diabetes. The Centers for Disease Control and Prevention's Division of Diabetes Translation (DDT) provides funding to health departments of States and territories to develop, implement, and evaluate systems-based Diabetes Control Programs (DCPs). DCPs are population-

based, public health programs that design, implement and evaluate public health prevention and control strategies that improve access to and quality of care for all, and reach communities most impacted by the burden of diabetes (e.g., racial/ethnic populations, the elderly, rural dwellers and the economically disadvantaged). Support for these programs is a cornerstone of the DDT's strategy for reducing the burden of diabetes throughout the nation. The Diabetes Control Program is authorized under sections 301 and 317(k) of the Public Health Service Act (42 U.S.C. sections 241 and 247b(k)).

In accordance with the original OMB approval (July 20, 2002), this extension will continue to expand and enhance the technical reporting capacity of the MIS. The MIS is a web-based, password access protected repository/technical reporting system that replaced an archaic paper reporting system. The MIS allows the accurate, uniform, and complete collection of diabetes program progress information using the Internet. The MIS has improved upon the old data collection system by:

- Improving accountability;
- Shortening the information cycle;
- Eliminating non-standard reporting;
- Minimizing unnecessary duplication of data collection and entry;
- Reducing the reporting burden on small state organizations;
- Using plain, coherent, and unambiguous terminology that is understandable to respondents;
- Implementing a consistent system for progress reporting and record-keeping processes;

- Identifying the retention periods for recordkeeping requirements;
- Utilizing modern information technology for data collection and transfer;
- Significantly reducing the amount of paper reports that diabetes control programs are required to submit.

The MIS has allowed CDC to more rapidly respond to outside inquiries concerning a specific diabetes control activity occurring in the state diabetes control programs. The data collection requirement has formalized the format and contents of diabetes data reported from the DCPs and provides an electronic means for efficient collection and transmission to the CDC headquarters.

The MIS has facilitated the staff's ability at CDC to fulfill its obligations under the cooperative agreements; to monitor, evaluate, and compare individual programs; and to assess and report aggregate information regarding the overall effectiveness of the DCP program. It has also supported DDT's broader mission of reducing the burden of diabetes by enabling DDT staff to more effectively identify the strengths and weaknesses of individual DCPs and to disseminate information related to successful public health interventions implemented by these organizations to prevent and control diabetes. Implementation of the MIS has provided for efficient collection of state-level diabetes program data. The cost to respondents is \$7,080.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)	Total burden (in hours)
State Program Control Officers .....	59*	1	4	236
Total .....				236

\*Respondents reside in each of the 50 States, 8 Territories, and the District of Columbia and provide progress reporting on an annual frequency.

Dated: December 4, 2002.  
**John Moore,**  
*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**  
**[30DAY-06-03]**  
**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the

Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

*Proposed Project:* Assisted Reproductive Technology (ART) Program Reporting System. (OMB No. 0920-0556)—Extension—National Center for Chronic Disease Prevention

and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC). 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 this act.

The Centers for Disease Control and Prevention (CDC) is seeking to extend approval of a reporting system for Assisted Reproductive Technology (ART) Program from the Office of Management and Budget (OMB). This reporting system has been designed in collaboration with the Society for Assisted Reproductive Technology (SART) to comply with the requirements of the FCSRCA. The reporting system includes all ART cycles initiated by any of the approximately 400 ART programs in the United States, and covers the pregnancy outcome of each cycle, as well as a number of data items deemed important

to explain variability in success rates across clinics and across individuals. Data is to be collected through computer software developed by SART in consultation with CDC.

In developing the definition of pregnancy success rates and the list of data items to be reported, CDC has consulted with representatives of 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. The annual burden for this data collection is 63,400 hours.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)
ART Clinics .....	400	220	37/60
Data Validation .....	40	113	23/60

Dated: December 4, 2002.

**John Moore,**

*Acting Deputy 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**

[30DAY-08-03]

**Agency Forms Undergoing Paperwork Reduction Act Review**

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*Proposed Project:* Human Exposure to Cyanobacterial (blue-green algal) Toxins

in Drinking Water: Risk of Exposure to Microcystin from Public Water Systems (OMB. No. 0920-0527)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

**Background**

Cyanobacteria (blue-green algae) can be found in terrestrial, fresh, brackish, or marine water environments. Some species of cyanobacteria produce toxins that may cause acute or chronic illnesses (including neurotoxicity, hepatotoxicity, and skin irritation) in humans and animals (including other mammals, fish, and birds). A number of human health effects, including gastroenteritis, respiratory effects, skin irritations, allergic responses, and liver damage, are associated with the ingestion of or contact with water containing cyanobacterial blooms. Although the balance of evidence, in conjunction with data from laboratory animal research, suggests that cyanobacterial toxins are responsible for a range of human health effects, however, there have been few epidemiologic studies of this association. We plan to recruit 100 people whose tap water comes from a source with a current cyanobacterial bloom (*i.e.*, *M. aeruginosa*) and who report drinking unfiltered tap water. We

also plan to recruit 100 people who report drinking unfiltered tap water but whose tap water source is groundwater that has not been contaminated with cyanobacteria. This population will serve as our referent population for the analysis of microcystins in blood and for the clinical assays. We will administer a questionnaire and collect blood samples from all study participants. Blood samples will be analyzed using a newly developed molecular assay for levels of microcystins—the hepatotoxin produced by *Micocystis aeruginosa*. We also will analyze blood samples for levels of liver enzymes (a biological marker of hepatotoxicity) and for a number of clinical parameters including hepatitis infection (a potential confounder in our study). We will evaluate whether we can (1) detect low levels of microcystins (<10 ng/ml of blood) in the blood of people who are exposed to very low levels of this toxin in their drinking water, (2) utilize clinical endpoints such as blood liver enzyme levels as biomarkers of exposure and biological effect, and (3) compare the analytical results for the exposed population with the results from the referent population. The total annual burden hours is estimated to be 350.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden/ response (in hrs.)
Telephone contact .....	300	1	10/60
Survey .....	200	1	1