

Data Confidentiality Provisions

All MEPS-IC data collected, both identifiable and non-identifiable, will be stored at the Census Bureau. Their confidentiality is protected under the U.S. Census Bureau confidentiality statute, Section 9 of Title 13, United States Code. In addition, because the Census sample lists are developed using Internal Revenue Service (IRS) Tax Information, the data also fall under the review of the IRS which conducts regular audits of the data collection storage and use (Title 26, United States Code).

The confidentiality provisions of the AHRQ statute at 42 USC 299c-3(c) apply to all data collected for research that is supported by AHRQ. All data products listed below must fully comply with the data confidentiality statute under which their raw data was collected as well as any additional confidentiality provisions that apply.

Data Products

Data will be produced in two forms: (1) Files containing employer information will be available for use by researchers at the Census Bureau's Research Data Centers (all research output is reviewed by Census employees and no identifiable data may leave the Center) and (2) a large

compendium of tables of estimates, produced by Census and containing no identifiable data, will be made available on the AHRQ website. These tables will contain descriptive statistics, such as, numbers of establishments offering health insurance, average premiums, average contributions, total enrollments, numbers of self insured establishments and other related statistics for a large number of population subsets defined by firm size, state, industry and other establishment characteristics such as, age, profit/nonprofit status and union/nonunion status of the workforce.

- The data are intended to be used for purposes such as:
- Generating National and State estimates of employer health care offerings;
 - Producing estimates to support the Bureau of Economic Analysis and the Center for Medicare and Medicaid Services in their production of health care expenditure estimates for the National Health Accounts and the Gross Domestic Product;
 - Producing National and State estimates of spending on employer-sponsored health insurance to study the results of National and State health care policies; and
 - Supplying data for modeling the demand for health insurance.

These data provide the basis for researchers to address important questions for employers and policymakers alike.

Method of Collection

The data will be collected using a combination of modes. The Census Bureau's first contact with employers will be made by telephone. This contact will provide information on the availability of health insurance from that employer and essential persons to contact. Based upon this information, Census will mail a questionnaire to the employer. In order to assure high response rates, Census will follow-up with a second mailing after an interval of approximately 30 working days, followed by a telephone call to collect data from those who have not responded by mail.

For larger respondents with high burdens, such as State employers and very large firms, Census may follow special procedures, as needed. These include performing personal visits and doing customized collection, such as accepting data in computerized formats and using special forms. The response rate for the most recent survey was approximately 79%.

ESTIMATED ANNUAL RESPONDENT BURDEN

| Survey years | Annual number of respondents | Estimated time per respondent in hours | Estimated total annual burden hours | Estimated annual cost to the Government |
|--------------|------------------------------|--|-------------------------------------|---|
| 2008 | 33,262 | .57 | 19,032 | \$9,650,000 |
| 2009 | 33,262 | .57 | 19,032 | 9,950,000 |

Request for Comments

In accordance with the above cited legislation, comments on the AHRQ information collection proposal are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden (including hours and costs) 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 the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and

included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Carolyn M. Clancy,
Director.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day-07-0527]

Proposed Data Collections Submitted for Public Comment and Recommendations

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) 639-5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Human Exposure to Cyanobacterial Toxins in Water (OMB No. 0920-0527)—Reinstatement—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

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, there have been few epidemiologic studies of this association.

During August 2006, we conducted our first study to assess exposure to microcystins in recreational waters with a bloom of *Microcystis aeruginosa*. We recruited 104 people who gave informed consent to participate. Ninety seven people did their recreational activities on Lake 1, which had a confirmed *M. aeruginosa* bloom, and 7 others did

their activities on Lake 2, which had no bloom. Study participants completed a pre-activity questionnaire, a post-activity questionnaire, provided a 10-ml blood sample, and completed a telephone symptom survey 7–10 days after exposure. The concentrations of microcystins in Lake 1 ranged from 2 to 5 ug/L and in Lake 2 were all below the limit of detection (LOD). When we designed the study, we calculated that a person exposed to recreationally-generated aerosols from water containing 10 ug/L of microcystins should have levels of microcystins in their blood. However, the microcystin concentrations in Lake 2 were below the LOD and in Lake 1 were actually 2ug/L to 5ug/L, much lower than we anticipated based on data from the previous week. Thus, the recreational exposures were not likely high enough for us to quantify microcystins in blood and the serum samples were all below the LOD for microcystins.

For the new data collection, we will conduct two separate studies in different lakes. In total, we will recruit 200 study participants who are at risk for swallowing water or inhaling spray (i.e., water skiers, jet skiers, people sailing small boats) and who would

normally be doing these activities, even in the presence of a bloom. We may recruit people who train for organized swimming events (e.g., triathlons) in lakes. In addition, we will recruit 50 study participants from lakes with no blooms as a comparison group to assess the health effects associated with recreational activities on “clean” lakes. Study participants will be asked to sign a consent form, complete a symptom survey before and after doing their recreational water activities, provide one 10-ml whole blood sample after their recreational activities, and complete a telephone symptom survey 8–10 days after doing study activities.

The purpose of the new data collection is to continue assessing the public health impact of exposure to the cyanobacterial toxins, microcystins, during recreational activities. We will examine the extent of human exposure to microcystins present in recreational waters and associated aerosols and whether serum levels of microcystins can be used as a biomarker of exposure.

There is no cost to the respondents other than their time. The total estimated annualized burden hours are 69.

ESTIMATED ANNUALIZED BURDEN HOURS

| Forms | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|--|-----------------------|------------------------------------|--|
| Screening questionnaire | 125 | 1 | 5/60 |
| Consent and pre-exposure questionnaire | 100 | 1 | 10/60 |
| Post-exposure questionnaire | 100 | 1 | 15/60 |
| 10-day post exposure questionnaire | 100 | 1 | 10/60 |

Dated: September 6, 2007.

Maryam I. Daneshvar,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of New System of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of a New System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, CMS is proposing to establish a new system of records (SOR) titled, “Performance Measurement and Reporting System (PMRS),” System No. 09-70-0584. PMRS will serve as a master system of records to assist in projects that provide transparency in health care on a broad-scale enabling consumers to compare the quality and price of health care services so that they can make informed choices among individual physicians, practitioners and providers of services. In cooperation with local or regional public-private collaborative stakeholders; individuals assigned to provider groups; insurance and provider associations; government agencies; employers; accrediting and quality organizations; Chartered Value Exchanges (CVE), data aggregators, and other community leaders who are

committed to improving the quality of services, CMS is laying the foundation for pooling and analyzing information about the quality of medical services and performance provided by physicians and health care providers. PMRS will further assist in developing existing strategies to improve health care quality including transparency of cost and/or price information, quality and utilization information; and patient safety for Medicare beneficiaries by collecting and aggregating data, by measuring performance at the individual physician level, and by reporting meaningful information to Medicare beneficiaries in order to make informed choices and improve outcomes.

Pursuant to the “routine use” promulgated under this system of records notice, CMS or a non-Quality Improvement Organization (non-QIO)