

“grants to States and public and other organizations and agencies for paying part of the cost of research or demonstration projects such as those \* \* \* which will help improve the administration and effectiveness of programs carried on or assisted under the Social Security Act and programs related thereto \* \* \*.” CMS has restructured its efforts under § 1110 into eight themes. The Aging and Disability Resource Center Grants are part of CMS’s Research and Demonstration efforts under Theme 5: Strengthening Medicaid, State Children’s Health Insurance Program (SCHIP), and State Programs. This effort includes research and demonstrations on ways to improve access to and delivery of health care to the persons served by Medicaid. These Resource Center grants, to be awarded as cooperative agreements, are a part of the President’s New Freedom Initiative. The New Freedom Initiative calls for the removal of barriers to community living for people with disabilities. CMS is the designated HHS agency with administrative responsibility for the Real Choice Systems Change Grant program. Because funding for this program appears as part of the agency’s FY 2003 budget, all awards will be made to eligible entities before October 1, 2003.

We will not fund through these grants those efforts or activities that are already being funded under an existing Real Choice Systems Change Grant (funded in FY 2001 or FY 2002) or other grant funds. If a Grantee proposes to significantly expand an earlier-funded project, the applicant must specifically describe this expansion in its application. We also encourage states to seek private sector grant opportunities (e.g., grants from foundations) to augment or coordinate with the Real Choice Systems Change Grants for Community Living.

*Information Collection Requirements.* The information collection requirements associated with this program announcement are under review by the Office of Management and Budget (OMB). A separate notice will be published in the **Federal Register** to solicit comments on this collection.

**FOR FURTHER INFORMATION CONTACT:** Kari Benson, U.S. Department of Health and Human Services, Administration on Aging, Center for Planning and Policy Development, Washington, DC, 20201, telephone: (202) 357-3461 or *Kari.Benson@aoa.gov*. Questions about the Real Choice Systems Change Grants for Community Living Program, and this notice, may also be directed to: Mary Guy, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, DEHPG/DCSI, Mail Stop: S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, (410) 786-2772, E-mail: *RealChoiceFY03@cms.hhs.gov*.

Dated: May 22, 2003.

**Josefina G. Carbonell,**  
*Assistant Secretary for Aging.*  
[FR Doc. 03-13442 Filed 5-28-03; 8:45 am]  
**BILLING CODE 4154-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30DAY-42-03]

**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**

Clinician’s Management Approach to Children with Pharyngitis—New—National Center for Infectious Diseases (NCID), Centers for Disease control and Prevention (CDC). The purpose of this

study is to determine factors associated with appropriate management of children with pharyngitis. We will characterize office laboratory methods currently used by clinicians to diagnose pharyngitis caused by group A streptococcus (GAS), including rapid antigen detection test (RADT) and throat cultures, and also assess clinicians’ treatment approaches for pharyngitis.

The specific goals for this study on children with pharyngitis are:

1. To evaluate current diagnostic methods and treatment approaches for children with pharyngitis by primary care practitioners (pediatricians and family practitioners).
2. To identify factors associated with the use of appropriate laboratory methods by primary care practitioners.
3. To assess the treatment regimen including antimicrobial choices, length and goals of therapy.
4. To determine the impact of full implementation of CLIA on the performance of these tests in office settings.

The investigators will send out an eight-page questionnaire to a sample of 1000 members in each, the American Academy of Pediatrics and the American Academy of Family Practitioners. The survey includes questions on demographics; diagnostic approaches (including types of RADTs and cultures used); logistics in using the diagnostics (such as level of training of the personnel performing the tests, nature of quality control); clinicians’ perception and understanding of the RADTs, including published sensitivity and specificity figures; and impact of CLIA (such as any change on the use of RADTs and culture). One month after the first mailing, each individual will be sent a second mailing to maximize the opportunity to complete the survey.

The study population consists of primary care physicians from pediatrics and family practice. These physicians will be from all areas of the United States and, therefore, from diverse geographic locations. The total burden is estimated to be approximately 400 hours.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hours)
Physicians .....	2,000	1	12/60

**Thomas A. Bartenfeld,**  
*Acting Deputy Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.*  
 [FR Doc. 03-13373 Filed 5-28-03; 8:45 am]  
**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30DAY-44-03]

**Agency Forms Undergoing Paperwork Reduction Act Review**

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**Proposed Project**

**Antineoplastic Drug Exposure: Effectiveness of Guidelines—New—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).** Antineoplastic, chemotherapeutic, or cytostatic drugs are widely used in the treatment of cancer. These drugs possess mutagenic, teratogenic, and carcinogenic properties, cause organ damage, and affect reproductive function. Healthcare workers such as pharmacists and nurses who handle, prepare, and administer these drugs are at increased risk of adverse health effects from these agents, if exposed. The Occupational Safety and Health

Administration (OSHA) developed guidelines for healthcare workers for the safe handling of antineoplastic drugs in 1986 and revised those guidelines again in 1995. However, recent studies suggest that the guidelines have not been effective in preventing exposure. A 1999 industrial hygiene evaluation of six cancer centers in the U.S. and Canada reported that 75% of the wipe test samples in the pharmacy were found to have detectable levels of antineoplastic drugs. Similar findings were reported in the Netherlands, which has similar guidelines. In addition, healthcare workers may assume that gloves designed for bloodborne pathogen protection will also prevent drug exposure which is often not the case. Since air concentrations of antineoplastic drugs in many of the studies have been low to non-detectable, it appears that the dermal route may be an important consideration for internal absorption.

Numerous studies, including those after the OSHA guidelines were revised in 1995, have demonstrated adverse health effects from healthcare workers' exposure to antineoplastic agents. The most common endpoints have been either markers of exposure, such as metabolites in the urine, or genotoxic markers, such as micronuclei, sister chromatid exchange, and chromosomal aberrations. Female reproductive adverse effects have also been shown to occur with healthcare workers' exposure to antineoplastic drugs. Not only have spontaneous abortion and miscarriage been reported, but changes in the menstrual cycle have been demonstrated as well. Based upon animal and human data, one study estimated that exposure to cyclophosphamide by healthcare workers increases the risk of leukemia cases by 17-100 new cases/million workers/10 years.

This project addresses the continuing concern of healthcare workers' exposure

to antineoplastic agents. This is a multifaceted project that involves environmental sampling of the workplace and the collection of biological samples to determine how much of the agent is absorbed and if there are any early biological effects from that exposure. Biological measurements or biomarkers can detect effects of exposure long before a disease can be diagnosed. A questionnaire will be administered to determine confounders and other conditions that might affect exposure such as work history and work practices. This project will recruit oncology nurses, pharmacists, and pharmacy technicians and will be conducted in collaboration with the University of Maryland, the University of North Carolina, and the M.D. Anderson Cancer Center.

In the biological effects part of the study, the participant, after informed consent, will voluntarily provide blood and urine samples and respond to a questionnaire concerning medical history, work history, and work practices to identify study eligibility, past exposures, and confounders.

In the reproductive health part of the study and after informed consent, women will be asked to voluntarily give a daily urine sample for approximately 45 days and keep track of their menstrual cycle by entries into a diary. In addition, a short questionnaire will be given to each participant to determine eligibility for inclusion into the study and confounders of hormone analysis. By utilizing a battery of sensitive biomarkers, the effects of low-level chronic exposure to antineoplastic agents can be determined. Using the results of the proposed study, exposures can be minimized or eliminated before adverse health effects occur. Ultimately, the study will contribute to the prevention of occupational disease from antineoplastic drug exposure. The total annual burden for this data collection is 863 hours.

Survey	Number of respondents	Number of responses/respondent	Average burden/response (in hours)
Antineoplastic Handling Diary .....	75	1	10/60
Biological Effects Study Questionnaire .....	150	1	45/60
Reproductive Health Study Questionnaire .....	100	1	15/60
Reproductive Health Diary .....	100	42	5/60