

Dated: August 27, 1998.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 98-24200 Filed 9-9-98; 8:45 am]

BILLING CODE 4150-04-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Department of Health and Human Services (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320 and is essential to the mission of the Department. Section 502 of the Agriculture Research and Reform Act of 1998 (Pub. L. 105-185) requires the Secretary of DHHS, within 180 days of the enactment date of June 23, 1998, to make determinations regarding administrative costs, under Section 403(a)(3) of the Social Security Act, common to determining eligibility for the AFDC, Food Stamp and Medicaid programs. Following the normal clearance procedures would cause this statutory deadline to be missed.

Without emergency approval of the proposed information collections described below, the Department could not comply with the Congressional mandate in section 502 of the Pub. L. 105-185.

DHHS is requesting the OMB grant emergency approval as soon as possible for 180-days.

Title and Description of Information Collection: Cost Allocation

Determination Under the Agriculture Research Act—NEW—Section 502 of the Agriculture research, Extension, and Education Reform Act of 1998 (Public Law 105-185) requires the Secretary of Health and Human Services to determine, for each state, the annualized amount the state received under section 403(a)(3), of the Social Security Act for administrative costs common to determining the eligibility of individuals, families, or households that could be allocated to the Food Stamp and Medicaid programs, that were allocated to the AFDC program. The

purpose of this information collection is to enable the Secretary to make this determination. The States will be requested to provide cost information. *Respondents: States; Number of Respondents: 51; Number of Responses per Respondent: one; Average Burden per Response: 132 hours; Total Burden on Respondents: 6,732 hours.*

To request more information please contact Joe Cook on 202-401-2804. The proposed information collection is posted on the internet at <http://www.gov/progorg/grantsnet>.

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 and recommendations for the proposed information collections should be sent immediately directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt or Laura Oliven, New Executive Office Building, Room 10235, Washington, DC 20503.

Comments may be faxed to Ms. Eydt or Ms. Oliven at 202-395-5167.

Please send a copy of your comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW, Washington DC, 20201.

Dated: September 2, 1998.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 98-24201 Filed 9-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Community/Tribal Subcommittee of the Board of Scientific Counselors, Agency for Toxic Substances and Disease Registry; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry

(ATSDR) announces the following subcommittee meeting.

Name: Community/Tribal Subcommittee.

Times and dates: 8:30 a.m.-4:30 p.m., September 28, 1998; 8:30 a.m.-4:45 p.m., September 29, 1998.

Place: ATSDR, 35 Executive Park Drive, Training Room, Atlanta, Georgia 30329.

Status: Open to the public, limited by the space available. The meeting room accommodates approximately 60 people.

Purpose: This subcommittee will bring to the Board advice, citizen input, and recommendations on community and tribal programs, practices, and policies of the Agency. The subcommittee will report directly to the Board of Scientific Counselors.

Matters To Be Discussed: Agenda items include a group discussion of the role of the Subcommittee; presentation and discussion of ATSDR community involvement mission, roles, and activities (including the role, mission, activities of the Office of Urban Affairs, and the Office of the Ombudsman).

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Stephen D. Von Allmen, Science Policy Analyst, BSC, ATSDR, M/S E-28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-0708.

Dated: September 3, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-24259 Filed 9-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99013]

Notice of Availability of Funds; Economic and Outcome Analysis of Antimicrobial Resistance in Hospital-Acquired Infections Among Intensive Care Unit Patients

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for economic and outcome analysis of antimicrobial resistance in hospital-acquired infections among intensive care unit (ICU) patients. This program addresses the "Healthy People 2000" priority area(s) of Immunization and Infectious Diseases.

The purpose of the program is to provide assistance to the National Nosocomial Infections Surveillance

(NNIS) system hospitals to quantify the impact of antimicrobial resistance on their institution and their patients. Understanding the economic costs and patient outcomes associated with such resistant infections will aid the infection control community in their efforts to justify the allocation of resources to improve efforts at preventing the emergence and spread of antimicrobial resistant pathogens. This data will originate from several institutions and allow generalizable estimates of the economic impact and patient outcomes associated with antimicrobial resistance at U.S. hospitals.

The specific objectives of this cooperative agreement are:

1. Assess the impact of antimicrobial resistance, specifically methicillin resistant *S. aureus* and vancomycin-resistant enterococci, causing nosocomial infections, specifically primary bloodstream infections, both in terms of poor patient outcomes (e.g., morbidity and mortality) and economic cost, at participating hospitals.
2. Disseminate information regarding economic costs incurred from antimicrobial resistant organisms.

B. Eligible Applicants

Limited Competition

Assistance will be provided only to U.S. hospitals actively participating in the Intensive Care Unit (ICU) component of CDC's NNIS System, and have used NNIS definitions and methodology for surveillance of nosocomial infections to identify ≥ 60 ICU patients with nosocomial primary bloodstream infection, ≥ 20 of which were associated with methicillin resistant *Staphylococcus aureus*, and 15 of which were associated with vancomycin resistant enterococci over the past 5 years.

Competition is limited to hospitals actively participating in the NNIS System, currently the only source of national data on risk-adjusted, nosocomial infection rates in the United States using standardized methodology.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$130,000 is available in FY 1999 to fund approximately 5 awards. It is expected that the average award will be \$25,000, ranging from \$15,000 to \$30,000 depending on the number of case- and control-patients included in the applicant's proposal. It

is expected that the awards will begin on or about December 15, 1998 and will be made for a 12-month budget period within a 12-month project period. Funding estimates may change.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for conducting activities under A., below, and CDC shall be responsible for conducting activities under B. below.

A. Recipient Activities

1. Design a matched case-control study, where case-patients (i.e., those infected with the antimicrobial resistant pathogen) will be compared to matched control-patients (i.e., those infected with the respective antimicrobial susceptible pathogen). Factors that may influence patient outcome, costs of hospitalization, and adaptability of criteria to other recipients should be considered. Examples of matching criteria may include location of patient, month or year of infection, APACHE II score (± 5 points), comorbid conditions, or a combination of these characteristics. A published example includes that performed by D. Pittet, et al. when determining extra costs of nosocomial bloodstream infection in critically ill patients (JAMA. 1994;271:1598-1601).

2. Collect limited existing data from medical records of all potential case- and control-patients eligible for matching algorithm.

3. Collect detailed data on case- and control-patients of two types: financial and clinical (i.e., descriptive and patient outcome). Determining excess costs may require recording total costs of hospitalization per study patient and costs by each day of hospitalization. In addition, it would be desirable to record costs by category (i.e., laboratory or diagnostic tests, pharmaceuticals, bed occupancy, physician, extra nursing, materials). Patient outcome data must include, but not limited to, mortality, length of stay, response to therapy, and relapse or recurrent infection.

4. Publish results through collaboration with other recipients of this cooperative agreement and CDC.

B. CDC Activities

1. Provide technical assistance in the design and conduct of a pair wise-matched case-control study which may include data collection forms and designing innovative approaches to matching controls to cases.

2. Provide assistance to recipients regarding development of study

protocols, data collection methods, and analyses, as necessary.

3. Assist in the development of data management processes, materials, and protocols.

4. Coordinate pooling data from each site and participate in the analysis of study information and dissemination of study findings.

5. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 10 double-spaced pages (excluding budget and appendixes), printed on one side, with one inch margins, and un-reduced font. Unless indicated otherwise, all information requested below must appear in the narrative. Materials or information that should be part of the narrative will not be accepted if placed in the appendixes. The application narrative must contain the following sections in the order presented below:

1. Abstract: Provide a brief (two pages maximum) abstract of the project. State the length of the project period (maximum is 1 year) for which assistance is being requested (see "Availability of Funds" for additional information).

2. Background and Need: Discuss the background and need for the proposed project. Illustrate and justify the need for the proposed project that is consistent with the purpose and objectives of this cooperative agreement program.

3. Capacity and Personnel:

- a. Describe past experience in conducting projects/studies similar to that being proposed.

- b. Describe resources, facilities, and professional personnel that will be involved in conducting the project. Include in an appendix, curriculum vitae for all professional personnel directly involved with the project.

- c. Because award size should reflect the number of patients on which data will be collected, provide in an appendix a list of all patients, void of personal identifiers, identified by infection control staff using standard NNIS definitions as having a nosocomial primary bloodstream infection while in an intensive care unit for at least the past 5 years. This list

must include, but not be limited to, infections associated with *S. aureus* (both methicillin-susceptible and methicillin-resistant), and *enterococcus* spp. (both vancomycin-susceptible and vancomycin-resistant). Other organisms of interest, and highly desirable to study if present in sufficient quantity, include *Klebsiella pneumoniae* not-susceptible to ceftazidime or aztreonam, *Candida albicans*, and *C. krusei*. For each patient, the list must document the organism(s) associated with the nosocomial bloodstream infection, susceptibility status to the antimicrobial of interest (e.g., pathogens stated above), date of admission to hospital, date of infection, and location of patient at time of infection.

d. Provide in an appendix letters of support from all key participating non-applicant Departments (i.e., medical informatics, medical records), individuals, etc., which clearly indicate their commitment to participate as described in the operational plan. Do not include letters of support from CDC personnel.

4. Objectives and Technical Approach: a. Describe specific objectives for the proposed project which are measurable and time-phased and are consistent with the purpose and goals of this cooperative agreement.

b. Present a detailed operational plan for initiating and conducting the project which clearly and appropriately addresses all Recipient Activities, including the approach to collecting financial data.

c. Clearly identify specific assigned responsibilities for all key professional personnel.

d. Describe the nature and extent of collaboration with CDC and/or others during various phases of the study.

e. Describe in detail a plan for evaluating progress toward achieving project objectives.

5. Budget: Provide in an appendix, a budget and accompanying detailed justification for the project that is consistent with the purpose and objectives of this program. If requesting funds for contracts, provide the following information for each proposed contract: (1) Name of proposed contractor, (2) breakdown and justification for estimated costs, (3) description and scope of activities to be performed by contractor, (4) period of performance, and (5) method of contractor selection (e.g., sole-source or competitive solicitation).

6. Human Subjects: Whether or not exempt from DHHS regulations, if the proposed project involves human subjects, document in an appendix that

the principal investigator has obtained human subjects clearance.

F. Submission and Deadline

Application

Submit the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit. On or before November 1, 1998 submit the application to: Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement #99013, Centers for Disease Control and Prevention, Room 300, 255 East Paces Ferry Road, NE, MS E-18, Atlanta, Georgia 30305-2209.

If your application does not arrive in time for submission to the independent review group, it will not be considered in the current competition unless you can provide proof that you mailed it on or before the deadline (i.e., receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

G. Evaluation Criteria

Applications will be reviewed and evaluated based on the following weighted criteria.

1. Background and Need (10 Points)

Extent to which applicant's discussion of the background for the proposed project demonstrates a clear understanding of the purpose and objectives of this cooperative agreement program. Extent to which applicant illustrates and justifies the need for the proposed project that is consistent with the purpose and objectives of this cooperative agreement.

2. Capacity (50 Points Total)

A. The extent to which applicant has the appropriate organizational structure, administrative support, and ability to access the defined target population, and that this access will ensure an adequate sample size and representation so that epidemiologic analysis of patient outcomes and excess costs will be appropriate and statistically valid. Considerable attention will be given to the quantity of patients having had nosocomial bloodstream infections caused by the targeted antimicrobial resistant pathogens (i.e., potential cases) and those caused by the corresponding susceptible pathogen (i.e., potential controls) documented by the recipient. Considerable attention will be given to the recipient's capacity to access cost data for potential cases and matched controls, and the ability to link cost data to specific categories of costs and/or

date of costs during patient's hospitalization. (40 points)

b. Extent to which applicant documents that professional personnel involved in the project are qualified, by training and experience (i.e., NNIS hospital personnel must have the essential understanding of definitions of nosocomial infections used in the NNIS system); and have an appropriate projected level of effort directed toward accomplishment of the proposed objectives. (10 points)

3. Objectives and Technical Approach (i.e., Plan) (40 Points Total)

a. Extent to which applicant describes specific objectives of the proposed project which are consistent with the purpose and goals of this cooperative agreement program and which are measurable and time-phased. (10 points)

b. Extent to which applicant presents a detailed operational plan for performing the matching process to pick controls for the case-control study. (10 points)

The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research.

This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

c. Extent to which applicant clearly identifies specific assigned responsibilities for all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the proposed studies and extent to which the plan is adequate to accomplish the objectives. (20 points)

4. Budget (Not Scored)

The extent to which the budget is reasonable (i.e., in proportion to the number of patients for which data will be collected), clearly justified, and consistent with the intended use of cooperative agreement funds.

5. Does the application adequately address the requirements of 45 CFR Part 46 for the protection of human subjects?

_____ YES _____ No

Comments: _____

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress reports. Narrative progress reports are required every 6 months. An original and two copies of reports are due within 30 days after first 6 months and 90 days following end of project period. Progress reports should address progress toward overall objectives as represented in the Purpose and Recipient Activities sections of this announcement including status report of case and control selection, enrollment, and progress of data abstraction.

2. Financial status report, no more than 90 days after the end of the budget period. Send all reports to: Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 300, 255 East Paces Ferry Road, NE, M/S E-18, Atlanta, GA 30305-2209.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 (included in the application kit).

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-10 Smoke-Free Workplace Requirements
- AR-7 Executive Order 12372 Review
- AR-11 Healthy People 2000
- AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act Section(s) 301(a)[42 U.S.C. 241(a)], 317(k)(2)[42 U.S.C. 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where to Obtain Additional Information

Please refer to Program Announcement 99013 when you request information. For a complete program description, information on application procedures, an application package, and business management technical assistance, contact: Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement [99013], Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, N.E., [E-18], Atlanta, GA 30305-2209, telephone (404) 842-6872, Email address vxm7@cdc.gov.

See also the CDC homepage on the Internet: <http://www.cdc.gov>

For program technical assistance, contact Scott K. Fridkin, Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mailstop E-55, Atlanta, Georgia 30333. Facsimile: (404) 639-6436. E-mail address: skf0@CDC.GOV

John L. Williams,

Director, Procurement and Grants, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-24257 Filed 9-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project

Title: Early Head Start Evaluation Father Study.

OMB No.: 0970-0169.

Description: The Head Start Reauthorization Act of 1994 established a special initiative creating funding for services for families with infants and toddlers. In response the Administration on Children, Youth and Families

(ACYF) designed the Early Head Start (EHS) program. In September 1995, ACYF awarded grants to 68 local programs to serve families with infants and toddlers. ACYF has awarded grants to additional programs, totaling more than 290.

EHS programs are designed to produce outcomes in four domains: (1) child development, (2) family development, (3) staff development, and (4) community development. The Reauthorization required that his new initiative be evaluated. To study the effect of the initiative, ACYF awarded a contract through a competitive procurement to Mathematica Policy Research, Inc. (MPR) with a subcontract to Columbia University's Center for Young Children and Families. The evaluation will be carried out from October 1, 1995 through March 30, 2002. Data collection activities that are the subject of this **Federal Register** notice are intended for the fourth phase of the EHS evaluation. The sample for the assessments will be approximately 1,144 fathers from the 3,000 EHS sample families, whose mothers and infants/toddlers are participating in the study (see OMB #0970-0143) in 13 of the EHS study sites. Each family will be randomly assigned to a treatment group or a control group. The 36-month father assessments will be conducted through personal interviewing, structured observations and videotaping. All data collection instruments have been designed to minimize the burden on respondents by minimizing interviewing and assessment time. Participation in the study is voluntary and confidential.

The information will be used by government managers, Congress and others to better understand the roles of fathers and father-figures with their children and in the EHS program.

Respondents: Fathers or father-figures of children whose families are in the EHS national evaluation sample (both program and control group families).

ANNUAL BURDEN ESTIMATES

Instrument	Estimated number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
36-month father interview	89	1	1.0	89
36-month interview and videotaping protocol	74	1	1.3	96
36-month abbreviated interview and videotaping protocol	30	1	1.05	32

Estimated Total Annual Burden: 217.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the

Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and