

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention**

[60Day-05-AC]

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) 498-1210. CDC is requesting an emergency clearance for this data collection with a two week public comment period. CDC is requesting OMB approval of this

package 7 days after the end of the public comment period.

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. Send comments to Seleda M. Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov. Written comments should be received within 14 days of this notice.

Proposed Project

Severe Acute Respiratory Syndrome (SARS) Research—New—National Center for Infectious Diseases (NCID),

Centers for Disease Control and Prevention (CDC).

As part of the effort taken by CDC to learn more about the epidemiology and clinical dynamics of infection with Severe Acute Respiratory Syndrome (SARS) coronavirus, CDC's National Center for Infectious Diseases would like to collect information in the event of a re-emergence of SARS. Protocols have been developed for the study of SARS transmission, dynamics of infection and SARS infection during pregnancy. Information on symptoms of illness, activities during periods of contact with a SARS case or within a SARS-affected area and outcomes of illness will be requested from SARS case-patients, contacts of SARS case-patients, health care professionals and state and local public health providers. Data will be used for research to contribute to the global understanding of SARS illness and refine methods of SARS infection control. Expedited clearance is necessary so that data may be collected immediately in the event of SARS re-emergence this fall. There is no cost to the respondents.

Form	Respondents	No. of Respondents	Estimated No. of responses/respondent	Avg. burden per response (in hours)	Total burden (hours)
1. Transmission protocol: Clinical Baseline Questionnaire for SARS Cases.	Health departments, clinicians ...	100	1	1	100
2. Transmission protocol: Follow-up Questionnaire	SARS cases and contacts	500	5	10/60	417
3. Transmission protocol: Characterization of SARS Tool for Data Collection.	Health departments, clinicians ...	50	1	1	50
4. Transmission protocol: Baseline Questionnaire for Contacts	Health departments	300	1	15/60	75
5. Transmission protocol: Questionnaire for Household Information.	Health departments	300	1	10/60	50
6. Transmission protocol: Questionnaire for Close Household Contacts.	Health departments, clinicians ...	300	1	15/60	75
7. Transmission protocol: Questionnaire for Airline Contacts	Quarantine officers, health dept.	1,000	1	30/60	500
8. Transmission protocol: Questionnaire for Health Care Worker Contacts.	Health departments, clinicians ...	300	1	15/60	75
9. Pregnancy protocol: Pregnancy, Delivery and Follow-up Data Collection Tools.	Health departments, clinicians ...	50	1	40/60	33
Total	2900			1375

Dated: October 8, 2004.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention**

[30Day-04-040W]

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) 498-1210 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

National Healthcare Safety Network (NHSN)—New—National Center for Infectious Disease (NCID), Centers for Disease Control and Prevention (CDC).

OMB first approved the information collection now known as the “National Nosocomial Infections Surveillance (NNIS) System” (OMB No.0920–0012) in 1970; it approved the “National Surveillance System for Healthcare Workers(NaSH)” (OMB 0920–0417) in 1997, and the “Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers” (OMB No. 0920–0442) in 1999. These three data collections have been modified and are being merged to create

the NHSN. The NHSN will evolve with the addition of modules and participating healthcare institutions from a wide spectrum of settings.

The NHSN is a knowledge system for accumulating, exchanging, and integrating relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and to promote healthcare safety. Specifically, the data will be used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare workers with similar risks. They will be used to detect changes in the epidemiology of adverse events resulting from new and

current medical therapies and changing risks.

Healthcare institutions that participate in NHSN voluntarily report their data to the Division of Healthcare Quality Promotion in the National Center for Infectious Diseases at the Centers for Disease Control and Prevention through the National Electronic Disease Surveillance System that uses a web browser-based technology for data entry and data management. Data are collected by trained surveillance personnel using written standardized protocols. The table below shows the estimated annual burden in hours to collect and report data. The total burden hours are 65,817.

Title	No. of respondents	No. of responses/respondent	Burden per response (in hrs.)
Facility Contact Information	350	1	10/60
Patient Safety Component Facility Characteristics	350	1	30/60
Agreement To Participate and Consent	350	1	15/60
Group Contact Information	350	1	5/60
Patient Safety Monthly Reporting Plan	350	9	25/60
Healthcare Personnel Safety Reporting Plan	90	2	10/60
Patient Data*			
Primary Bloodstream Infection (BSI)**	200	36	25/60
Pneumonia (PNEU)	200	72	25/60
Urinary Tract Infection (UTI)	200	27	25/60
Surgical Site Infection (SSI)	200	27	25/60
Dialysis Incident (DI)	80	90	12/60
Custom Event (not reported to CDC)			
Antimicrobial Use and Resistance (AUR)—Microbiology Laboratory Data**	20	45	3
Antimicrobial Use and Resistance (AUR)—Pharmacy Data**	20	36	2
Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU or SCA)	245	18	5
Denominators for Specialty Care Area (SCA)	75	9	5
Denominators for Neonatal Intensive Care Unit (NICU)	100	9	4
Denominators for Procedure	200	540	5/60
Dialysis Log Form (Not reported to CDC)			
Denominators for Outpatient Dialysis	80	9	5/60
Patient Safety Component—Hemodialysis Center Practices Survey	80	1	1
List of Blood Isolates+	350	1	1
Manual Categorization of Positive Blood Cultures+	350	1	1
Exposures to Blood/Body Fluids	90	42	1
Healthcare Personnel Post Exposure Prophylaxis	90	6	15/60
Healthcare Personnel Demographic Data	90	42	10/60
Healthcare Personnel Vaccination History	90	42	15/60
Annual Facility Survey	90	1	5.5
Implementation of Engineering Controls	90	1	30/60
Healthcare Personnel Survey	90	10	10/60

* Data on Patient Data Form are entered as part of an adverse event (AE), so the burden of these data are included under each AE form's burden estimate.

** Burden will be eliminated when reporting these data once an HHSN institution implements electronic data capture.

+ Burden during Validation phase only, then eliminated.

Dated: October 12, 2004.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Occupational Health and Safety Research, Program Announcement (PA) 04038

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Occupational Health and Safety Research, Program Announcement (PA) 04038.

Times and Dates: 7 p.m.-7:30 p.m., November 4, 2004 (Open); 7:30 p.m.-9 p.m., November 4, 2004 (Closed); 8 a.m.-5 p.m., November 5, 2004 (Closed).

Place: Courtyard by Marriott Louisville Downtown, 100 South Second Street, Louisville, KY 40202, phone (502) 562-0200.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include a site visit and the review, discussion, and evaluation of an application received in response to Program Announcement Number 04038.

Contact Person for More Information: Chuck Rafferty, Ph.D., Research Grants Program Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE., MS-E74, Atlanta, GA 30333, Telephone (404) 498-2530.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 12, 2004.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of California's Medicaid State Plan Amendment 03-028B

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on California's Medicaid State Plan Amendment (SPA) 03-28B to be held on December 2, 2004, 10 a.m., 75 Hawthorne Street; 4th Floor Conference Room, San Francisco, California 94105-3901 to reconsider our decision to disapprove SPA 03-028B.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by November 2, 2004.

FOR FURTHER INFORMATION CONTACT:

Kathleen Scully-Hayes, Presiding Officer, CMS, LB-23-20, Lord Baltimore Drive, Baltimore, Maryland 21244, Telephone: (410) 786-2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove California's Medicaid State Plan Amendment (SPA) 03-28B.

California submitted SPA 03-28B on September 18, 2003. In this SPA, California proposed to provide targeted case management (TCM) services in several counties for two populations: persons on probation, and individuals with a public guardian. By letter dated July 6, 2004, the Centers for Medicare & Medicaid Services (CMS) disapproved the SPA.

At issue in this reconsideration is whether SPA 03-28B is consistent with the requirements contained in sections 1902(a)(10) and 1902(a)(23), of the Social Security Act (the Act), as described in more detail below. In general, CMS found that the SPA had three fundamental problems: (1) The proposed TCM services duplicate services that are integral components of the State's adult probation program and the State's public guardian program; (2) the amendment would result in charges to Medicaid for services available

without charge to individuals on probation; and (3) the provider qualifications limit providers of services for these groups to the probation officers employed by the county probation departments and to court-appointed guardians under county public guardian agencies.

More specifically, at issue is whether the SPA complies with the requirement in section 1902(a)(10) of the Act which authorizes State Medicaid plans to provide for "medical assistance." In the definition of that term, at section 1905(a)(19) of the Act, case management services are authorized "as defined in section 1915 (g)(2)." That section defines case management as services that assist beneficiaries in gaining access to needed services. The Congressional Conference committee report accompanying Pub. L. 99-272, which added section 1915(g) to the Act, emphasized that payment for case management services must not duplicate payments made to public agencies or private entities under other program authorities for the same purpose. CMS uses the term "duplication of required coverage to refer to this situation. In this instance, Medicaid payment for services provided by the adult probation program and the public guardian program would duplicate payments under other programs that are the responsibility of the State government. Because the congressional definition of Medicaid TCM excluded duplicate coverage, CMS determined that the proposed case management services are not within the scope of the definition of "medical assistance" that is authorized to be included in a State Medicaid plan by section 1902(a)(10).

The CMS' reading of the term "medical assistance" to exclude "duplication of required coverage" is also consistent with the language of section 8435 of Pub. L. 100-647, which states that the Medicaid case management benefit is not to be construed as to require the Secretary of Health and Human Services to make payment for case management services that are provided without charge to the users of such services. Approval of SPA 03-028B would be contrary to this provision, because the proposed adult population services are available without charge.

In addition, at issue is whether the proposed SPA is consistent with the requirements at section 1902(a)(23) of the Act that a state plan must provide that beneficiaries may obtain services from any qualified entity or person who undertakes to provide such services. The proposed SPA restricts providers of