

relevant to this determination shall include but will not be limited to:

- (i) The existence of separate personnel, management, and governance;
- (ii) The existence of separate accounts, accounting records, and timekeeping records;
- (iii) The degree of separation from facilities, equipment and supplies used by the affiliated organization to conduct restricted activities, and the extent of such restricted activities by the affiliate;
- (iv) The extent to which signs and other forms of identification which distinguish the Recipient from the affiliated organization are present, and signs and materials that could be associated with the affiliated organization or restricted activities are absent; and
- (v) The extent to which HHS, the U.S. Government and the project name are protected from public association with the affiliated organization and its restricted activities in materials such as publications, conference and press or public statements.

EFFECTIVE DATE: This guidance is effective on the final date of publication.

Dated: July 23, 2007.

William R. Steiger,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-07-0666]

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 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

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 should be received within 60 days of this notice.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666)—Revision—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Healthcare Safety Network (NHSN) is a system designed to accumulate, exchange, and integrate 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 is 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. The data 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 CDC using a web browser-based technology for data entry and data management. Data are collected by trained surveillance personnel using written standardized protocols. This application to OMB includes a significant increase in the number of burden hours to the previously approved data collection. The increase is due to inclusion of new forms and an increased number of respondents.

NHSN was first approved by OMB in 2005 and CDC proposes to revise this data collection by adding new modules to the NHSN as well as modifying currently approved forms. Four new forms are proposed: (1) Healthcare Worker Influenza Vaccination form; (2) Healthcare Worker Influenza Antiviral Medication Administration form; (3) Pre-season survey on Influenza Vaccination Programs for Healthcare Workers; and (4) Post-season Survey on Influenza Vaccination Programs for

Healthcare Workers. The purpose of these new forms is to help participating healthcare institutions and CDC to: (1) Monitor influenza vaccination coverage among healthcare personnel at individual facilities and to provide aggregate coverage estimates for all participating facilities; (2) monitor progress towards attaining the Healthy People 2010 goal of 60% vaccination coverage among healthcare personnel; (3) monitor influenza vaccination coverage by ward/unit of the facility or occupational group so that areas or groups with low vaccination rates can be targeted for interventions; (4) monitor adverse reactions related to receipt of the vaccine or receipt of antiviral medications; and (5) assess the characteristics of influenza vaccination programs pre- and post-influenza season to identify practices associated with high immunization rates. The total estimated annual burden for these forms is 13,800 hours.

CDC is proposing to add an additional form, Central Line Insertion Practices Monitoring Form, to the Patient Safety Component Device Associated Module. This new form will enable participating facilities and CDC to (1) monitor central line insertion practices in individual patient care units and facilities and provide aggregate data for all participating facilities (facilities have the option of recording inserter-specific adherence data); (2) link gaps in recommended practice with the clinical outcome both in individual facilities and for all participating facilities; (3) facilitate quality improvement by identifying specific gaps in adherence to recommended prevention practices, thereby helping to target intervention strategies for reducing central line infection rates. The total estimated annual burden for this form is 12,500 hours.

CDC proposes to add the Multi-Drug Resistant Organism (MDRO) Prevention Process Monitoring Module to the Patient Safety Component. This module consists of four forms: (1) MDRO Prevention Process Monitoring Form; (2) MDRO Infection Event Form; (3) Laboratory-identified MDRO Event Form; and (4) Laboratory-identified MDRO Event Summary Form. The purpose of these forms is to: (1) Monitor processes and practices in individual patient care units and facilities and to provide aggregate adherence data for all participating facilities; (2) link gaps in recommended practice with the clinical outcome (i.e., MDRO infection) both in individual facilities and for all participating facilities; (3) facilitate quality improvement by identifying specific gaps in adherence to

recommended prevention practices, thereby helping to target intervention strategies for reducing MDRO infection rates. The total estimated annual burden for these forms is 244,500 hours.

The fourth new proposed collection to the NHSN is the High Risk Inpatient Influenza Vaccination Module. This module consists of four forms: (1) Influenza High Risk Inpatient Influenza Vaccine Summary Form—Method A; (2) Influenza High Risk Inpatient Influenza Vaccine Summary Form—Numerator Data Form Method B; (3) Influenza High Risk Inpatient Influenza Vaccine Summary Form—Method B; and (4) Influenza High Risk Inpatient Influenza Vaccine—Denominator Form Method B. The purpose of these forms is to: (1) Monitor influenza vaccination practices for high risk patients and provide aggregate data in regard to the number of high risk patients receiving

vaccination, those already vaccinated, and those who decline due to medical contraindications or other reasons; and (2) to identify reasons that high risk patients are not receiving influenza vaccination. The total estimated annual burden of these forms is 161,250 hours.

CDC is also proposing to open enrollment to any healthcare facility; therefore this submission includes a registration form (Registration Form) to collect necessary registration information. The total estimated annual burden for this form is 125 hours.

A Long Term Acute Care Hospital (LTACH) survey form is included in this submission. This survey will allow long term acute care hospitals and CDC to collect information on LTACH characteristics, infection control practices, and microbiology laboratory practices. This data will provide CDC with more comprehensive information

on all of the types of facilities that utilize the NHSN. The total estimated annual burden for this form is 38 hours.

Finally, CDC also proposes to make minor edits and modifications to currently approved forms.

CDC is also adding an increased number of participating healthcare institutions from a wide spectrum of settings. Part of this increase in burden hours is due to the passage of legislation in many states requiring mandatory reporting of healthcare-associated infections. Some states plan to use or are using NHSN as their data collection system to meet this mandate.

Participating institutions must have a computer capable of supporting an Internet service provider (ISP) and access to an ISP. The only other cost to respondents is their time to complete the appropriate forms.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Form	Number of respondents	Average number of responses per respondent	Average burden per response (in hours)	Total burden hours
Facility Contact Information	1,500	1	10/60	250
Patient Safety Component Hospital Survey	1,500	1	30/60	750
Agreement to Participate and Consent	1,500	1	15/60	375
Group Contact Information	1,500	1	5/60	125
Patient Safety Monthly Reporting Plan	1,500	9	35/60	7,875
Healthcare Personnel Safety Reporting Plan	150	9	10/60	225
Primary Bloodstream Infection (BSI)	1,500	36	30/60	27,000
Pneumonia (PNEU)—also includes Any Patient Pneumonia Flow Diagram and Infant and Children Pneumonia Flow Diagram	1,500	72	30/60	54,000
Urinary Tract Infection (UTI)	1,500	27	30/60	20,250
Surgical Site Infection (SSI)	1,500	27	30/60	20,250
Dialysis (DI)	80	90	15/60	1,800
Antimicrobial Use and Resistance (AUR)—Microbiology Laboratory Data	1,500	45	3	202,500
Antimicrobial Use and Resistance—Pharmacy Data	1,500	36	2	108,000
Denominators for Intensive Care Unit (ICU)/Other locations (Not NICU or SCA)	1,500	18	5	135,000
Denominators for Specialty Care Area (SCA)	1,500	9	5	67,500
Denominators for Neonatal Intensive Care Unit (NICU)	1,500	9	4	54,000
Denominator for Procedure	1,500	540	8/60	108,000
Denominator for Outpatient Dialysis	80	9	5/60	60
Patient Safety Component—Outpatient Dialysis Center Practices Survey	80	1	1	80
List of Blood Isolates	1,500	1	1	1,500
Manual Categorization of Positive Blood Cultures	1,500	1	1	1,500
Exposures to Blood/Body Fluids	150	50	1	7,500
Healthcare Personnel Post-exposure Prophylaxis	150	10	15/60	375
Healthcare Personnel Demographic Data	150	200	20/60	10,000
Healthcare Personnel Vaccination History	150	300	10/60	7,500
Annual Facility Survey	150	1	8	1,200
Implementation of Engineering Controls	150	1	30/60	75
Healthcare Worker Survey	150	100	10/60	2,500
Healthcare Personnel Influenza Vaccination Form	150	500	10/60	12,500
Healthcare Personnel Influenza Antiviral Medication Administration Form	150	50	10/60	1,250
Pre-season Survey on Influenza Vaccination Programs for Healthcare Workers	150	1	10/60	25
Post-Season Survey on Influenza Vaccination Programs for Healthcare Workers	150	1	10/60	25
Central Line Insertion Practices Adherence Monitoring Form (CLIP)	1,500	100	5/60	12,500
Laboratory Testing	150	100	15/60	3,750
MDRO Prevention Process and Outcome Measures Monthly Monitoring Form	1,500	24	10/60	6,000
MDRO Infection Event Form	1,500	72	30/60	54,000
Laboratory Identified MDRO Event Form (LIME)	1,500	240	30/60	180,000
Registration Form	1,500	1	5/60	125

ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

Form	Number of respondents	Average number of responses per respondent	Average burden per response (in hours)	Total burden hours
High Risk Inpatient Influenza Vaccine—Summary Form Method A	1,500	5	16	120,000
High Risk Inpatient Influenza Vaccine-Numerator Data Form Method B	500	250	10/60	20,833
High Risk Inpatient Influenza Vaccine—Summary Form Method B	500	5	4	10,000
High Risk Inpatient Influenza Vaccine—Denominator Data Form Method B	500	250	5/60	10,417
Laboratory Identified MDRO Event—Summary Form	1,500	3	1	4,500
Long-term Acute Care Hospital Survey	75	1	30/60	38
Total				1,276,153

Dated: July 19, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-07-0106]

Proposed Data Collections Submitted for Public Comment and Recommendations

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be received within 60 days of this notice.

Proposed Project

Preventive Health and Health Services Block Grant, Annual Application and Reports—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 1994, OMB approved the collection of information provided in the grant applications and annual reports for the Preventive Health and Health Services Block Grant (OMB #0920-0106). This approval expires on October 31, 2008. * * * CDC is requesting OMB clearance for this legislatively mandated information collection until January 31, 2011. The request is to approve the development and adherence to *Healthy People 2010*, the Nation's Health Objectives which was released the Spring of 2000. The PHHS block grant is mandated according to section 1904 to adhere to the Healthy People framework, therefore, the current application and report format was restructured to coincide with 2010.

This information collected through the applications from the official State health agencies is required from section 1905 of the Public Health Service Act. The information collected from the annual reports is required by section 1906. * * * The data collection tool is being moved from software that is installed to each user's desktop to a web-based system. The following changes will be incorporated into the web-based system: (1) Applications are referred to as Work Plans, (2) Grantees are asked to submit Work Plans within recommended page ranges based on the amount of funding with the objective of reducing the number of pages submitted per grantee, (3) Review functions have been added to the Work Plan, Success Stories, and Annual Report sections, (4) The rationale that was used by the Preventive Health and Health Services

Block Grant (PHHSBG) Advisory Committee to prioritize use of PHHSBG funds is identified via check boxes versus a free form text field, (5) Information is captured relative to the percent of time dedicated to the PHHSBG by the Block Grant Coordinator and other Full Time Equivalents (FTEs) that are paid for in whole or in part with Block Grant dollars, (6) Grantees select the Evidence Based Guideline or Best Practice that is used as the basis for interventions from a pre-defined list, (7) Grantees select the CDC Goals that are being addressed with Block Grant Funds from a pre-defined list and identify the location wherein the funds are being applied, (8) Information items are broken down into discrete fields, for example, specific begin and end dates are entered for objectives and activities, and the components for a SMART (Specific Measurable Achievable, Realistic and Time based) objective are entered individually versus via free form text fields, (9) Grantees select a percent from a pre-defined list in the Annual Report section to identify the extent to which objectives and activities have been accomplished. Written detail is provided only for those items that are 'exceptions' to projected outcomes, (10) A Compliance Review section has been added to provide grantees with general information regarding the Compliance Review process and specific information that pertains to past reviews of their state/territory/tribe.

The total burden hours is estimated at 3355 hours, a reduction of 915 hours below the previous data collection estimate (4270). The number of hours is equal to 61 grantees × 25 hours (1525 hrs) for completion of the application and 61 grantees × 30 hours (1830 hrs) for completion of the annual report. Respondent burden is based upon experience with the Grant Application and Reporting system that is used to complete applications and annual reports.