

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

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

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.

There are no costs to respondents except their time to participate in the survey.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hours)
Grantees	Annual Application	61	1	25	1525
	Annual Report	61	1	30	1830
Total	3355

Dated: July 20, 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

Advisory Committee for Injury Prevention and Control (ACIPC), Science and Program Review Subcommittee

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 for the aforementioned committee and subcommittee:

Name: Science and Program Review Subcommittee (SPRS).

Times and Date: 11:30 a.m.–11:35 a.m., August 20, 2007 (Open). 11:35 a.m.–12:30 p.m., August 20, 2007 (Closed).

Place: CDC, Koger Center, Vanderbilt Building, Room 1006, 2939 Flowers Road, Atlanta, Georgia 30341-3724.

Purpose: The subcommittee provides advice on the needs, structure, progress, and performance of programs in the National Center for Injury Prevention and Control (NCIPC).

Matters To Be Discussed: The subcommittee will have a secondary review, discussion, and evaluation on the individual research grant and cooperative agreement applications submitted in response to the two Fiscal Year 2007 Requests for Applications (RFAs) related to the following individual research announcements: RFA-CE-05-020, Youth Violence Prevention through Community-Level Change; and RFA-CE-07-011, Multi-Level Parent Training Effectiveness Trial—Phase II (U49).

Following this meeting, the voting members of ACIPC will meet via teleconference to vote on the recommendations of the SPRS regarding the RFAs.

Name: Advisory Committee for Injury Prevention and Control.

Times and Date: 12:30 p.m.–12:55 p.m., August 20, 2007 (Open). 12:55 p.m.–1:30 p.m., August 20, 2007 (Closed).

Place: CDC, Koger Center, Vanderbilt Building, Room 1006, 2939 Flowers Road, Atlanta, Georgia 30341-3724.

Purpose: The committee advises and makes recommendations to the Secretary, Department of Health and Human Services, the Director, CDC, and the Director, NCIPC regarding feasible goals for the prevention and control of injury. The committee makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention and control.

Matters To Be Discussed: Agenda items for the open portion include the call to order and introductions and request for public comments. The committee will vote on the results of the secondary review. This portion of the meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and (b), title 5 U.S.C., and the Determination of the Acting Director, Management Analysis and Services Office, CDC pursuant to Public Law 92-463.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Ms. Amy Harris, Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE., M/S K61, Atlanta, Georgia 30341-3724, Telephone (770) 488-4936.

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: July 17, 2007.

Elaine L. Baker,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0290]

Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)” dated July 2007. The draft guidance document discusses certain cell selection devices that minimally manipulate autologous PBSCs at the point of care for specific clinical indications, and the applicability of the requirements to such PBSCs. The guidance also discusses the submission of data intended to support approval of cell selection devices.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance submit written or electronic comments on the draft guidance by October 24, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-