

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-10-09AI]

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) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of the Action Plan for the National Public Health Initiative on Diabetes and Women’s Health—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Diabetes can have unique and profound effects on women’s lives and health. For instance, diabetes is a more common cause of coronary heart disease

among women than men, and the prognosis of heart disease is worse for women with diabetes than men with diabetes. The burden of diabetes for women is also unique because the disease can affect both mothers and their unborn children. It is projected that from 2000 to 2025, women will represent more than half of all cases of diabetes in the United States.

The National Public Health Initiative on Diabetes and Women’s Health (“The Initiative”) was established to provide support and resources for the creation and implementation of a national public health Action Plan. The Initiative is co-sponsored by the American Diabetes Association (ADA), the American Association of Diabetes Educators (AADE), the American Public Health Association (APHA), the Association of State and Territorial Health Officials (ASTHO), and the Centers for Disease Control and Prevention (CDC).

The Initiative’s Action Plan identifies gaps in diabetes-related research and programmatic activities, and strategic objectives, within the areas of community health, diabetes state programs, education and community outreach, quality of care, research, and surveillance.

CDC proposes to conduct a survey to assess collective progress toward achieving the objectives outlined in the Action Plan. The survey will also request information about the specific strategies, steps, resources and partnerships that have been employed

to meet the objectives. Respondents will be the 4 co-sponsors of The Initiative, 20 CDC-funded, state-based diabetes prevention and control programs (DPCPs), and approximately 100 private-sector public health organizations with a focus on diabetes and/or women’s health. Survey responses will be compiled into a progress report and disseminated to respondents, allowing them to learn about each other’s activities and the steps needed to replicate successful diabetes prevention and control efforts.

Information will be collected once per year for a period of 3 years, and the progress report will be updated annually to reflect recent activities and progress. Private-sector partners and state-based partners will submit one survey response per organization per year. Co-sponsors will receive a modified version of the survey. Due to the size and complexity of the activities managed by co-sponsors, the co-sponsoring organizations will have the option of submitting multiple survey responses from different areas of the organization, in order to capture the full range of activities conducted. It is estimated that each co-sponsor will submit an average of three responses. Participation in the survey is voluntary.

Information will be collected electronically through a web-based survey tool. There are no costs to respondents other than their time. The total estimated annualized burden hours are 66.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)
Co-Sponsors	Co-Sponsor Survey	4	3	.5
State-based DPCPs	Partner Survey	20	1	.5
Private Sector Partners	Partner Survey	100	1	.5

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0533]

Draft Guidance for Industry: Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus; 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 “Draft Guidance for Industry: Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus”. This draft guidance provides recommendations for assessing blood donor suitability and blood product safety and maintaining blood and blood product availability in response to pandemic (H1N1) 2009 virus. It is intended for establishments that manufacture Whole Blood and blood components intended for use in