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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-0904]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond,

including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

SEARCH for Diabetes in Youth Study (OMB Control Number 0920-0904, Expiration Date 08/31/2017) - Revision - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Diabetes is one of the most common chronic diseases among children in the United States. When diabetes strikes during childhood, it is routinely assumed to be type 1, or juvenile-

onset, diabetes. Type 1 diabetes (T1D) develops when the body's immune system destroys pancreatic cells that make the hormone insulin. Type 2 diabetes begins when the body develops a resistance to insulin and no longer uses it properly. As the need for insulin rises, the pancreas gradually loses its ability to produce sufficient amounts of insulin to regulate blood sugar. Reports of increasing frequency of both type 1 and type 2 diabetes in youth have been among the most concerning aspects of the evolving diabetes epidemic. In response to this growing public health concern, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) funded the SEARCH for Diabetes in Youth Study.

The SEARCH for Diabetes in Youth Study began in 2000 as a multi-center, epidemiological study, conducted in six geographically dispersed Study Centers that reflected the racial and ethnic diversity of the U.S. Phases 1 (2000-2005) and 2 (2005-2010) produced estimates of the prevalence and incidence of diabetes among youth age < 20 years, according to diabetes type, age, sex, and race/ethnicity, and characterized selected acute and chronic complications of diabetes and their risk factors, as well as the quality of life and quality of health care. Phase 3 (2010-2015) built upon the activities in Phase 1 and 2 and added a cohort component to collect information on estimate the prevalence and incidence of risk factors and

complications, including chronic microvascular (retinopathy, nephropathy, and autonomic neuropathy) and selected markers of macrovascular complications (hypertension, arterial stiffness) of diabetes.

SEARCH Phase 4 (2015-2020) continues the activities of the SEARCH Registry Study via cooperative agreements with the clinical sites, data coordinating center, and CDC. Respondents will be youth < 20 years of age who have been diagnosed with diabetes. Information will be collected from the study participants by five clinical sites and transmitted to the Coordinating Center for the study, each funded through a cooperative agreement. Information collection will support a case registry that can be used to estimate the incidence and prevalence of diabetes in youth in the U.S. The registry study will continue to collect information from participants related to diabetes diagnosis and will ask participants identified with incident diabetes in 2016 to complete an in-person study examination. CDC is no longer funding the cohort component of the SEARCH for Diabetes in Youth Study.

SEARCH Phase 3 identified an average of 1,361 incident cases of diabetes among youth under 20 years each year of the study and completed an average of 1,088 participant surveys each year (80% participation rate among registry study participants).

Respondents will be the Population-based Diabetes in Youth (SEARCH for Diabetes in Youth Phase 4) study participants. The information collection will include:

1. Incident diabetes cases:

- Collection of information on newly diagnosed incident diabetes cases in youth age < 20 years. CDC estimates that each clinical site will identify and register an average of 302 to 303 cases per year, for a total of 1,511 cases across all sites. There are no changes for the Medication Inventory Form. The Initial Participant Survey form has been revised to eliminate questions that were not useful to the researchers and to improve readability and understanding for the participants. The overall burden for the form has not changed. The total estimated annualized burden for this information collection is 378 hours.
- Physical exam and specimen collection for the 2016 incident cases. CDC estimates that each clinical site will identify and register 1,511 cases during this incident year. Of these cases, CDC anticipates 80% will complete the Initial Participant Survey and be invited for an in-person visit. Of those, we anticipate a 65 to 70% response rate and complete 823 in-person visits. The Physical Exam Form has not changed. There was a change to the Specimen Collection Form since a spot urine sample will no longer be collected.

The total estimated annualized burden for this information collection is 1,509 hours.

2. Prevalent diabetes cases:

- Collection of information on prevalent cases of diagnosed diabetes among youth < 20 years. CDC estimates that the clinical sites will identify 776 cases. The items collected for each case include an Initial Participant Survey. The total estimated annualized burden for this information collection is 129 hours. This is a new data collection instrument.

The estimated annualized burden per participant respondent is reduced by 3.2 hours since the CDC is no longer funding the cohort component.

The total annualized burden for this study is 2,016 hours. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Form Name	Average Burden per Response
Incident case	1,511	1	Medical Inventory	5/60
		1	Initial Participant Survey Incident case (adult and parent)	10/60

Incident case in 2016 who complete survey	823	1	Physical Exam	1.5
		1	Specimen collection	20/60
Prevalent case	776	1	Initial Participant Survey, Prevalent case (adult and parent)	10/60

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