BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-0904]

[Docket No. CDC-2016-0117]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revision of the "SEARCH for Diabetes in Youth Study," a national multi-center

study aimed at understanding more about diabetes among children and young adults in the United States.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0117 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

SEARCH for Diabetes in Youth Study (OMB Control No. 0920-0904, Expires 8/31/2017) - 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 1361 incident cases of diabetes among youth under 20 years each year of the study and completed an average of 1088 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 1511 cases during this incident year. Of these cases, CDC anticipants 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 will no longer be collected. The total estimated annualized burden for this information collection is 1,371 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 130 hours. This is a new data collection instrument.

The SEARCH for Diabetes in Youth Study was initially approved with 4,248 annualized burden hours. In this Revision, we request approval for 1,878 annualized burden hours (a net reduction of 2,369 annualized burden hours). 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 1,878.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response	Total Burden (in hours)
Incident cases	Medical Inventory	1,511	1	5/60	126
	Initial Participant Survey	1,511	1	10/60	252
Incident cases in 2016 who complete the survey	Physical exam	823	1	80/60	1,097
	Specimen collection	823	1	20/60	274
Prevalent cases	Initial Participant Survey	776	1	10/60	129
Total					1,878

_____

Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

[FR Doc. 2016-29428 Filed: 12/7/2016 8:45 am; Publication Date: 12/8/2016]