Act (the Act). The Act addresses pediatric device needs by providing financial incentives for development, production, approval and distribution of new devices for rare and unmet pediatric needs; allowing for a pediatric device approval pathway that permits extrapolation of adult effectiveness data to support a pediatric indication based on similar course of the disease or condition or a similar effect of the device; and providing grants to pediatric device consortia that provide technical support and assistance to pediatric device innovators.

FDA held a public workshop on December 5, 2011, to support FDA's efforts to define pathways for approving pediatric device indications by leveraging available scientific research data. An important, but not the only, focus was a discussion of how to determine when it is appropriate to use, and how to use, existing scientific research data to determine pediatric effectiveness based on a similar course of a disease or condition or a similar effect of a device on adults and similar extrapolation between pediatric subpopulations.

The demand by health care professionals and consumers for safe and effective pediatric medical devices continues to steadily increase. Pediatric medical devices treat or diagnose diseases and conditions occurring from birth through the 21st year of life. Some devices are designed specifically for pediatric use, while others are adopted from specific adult device applications or produced for more general use.

Designing pediatric medical devices can be challenging; children are often smaller and more active than adults; body structures and functions change throughout childhood, and children may be long-term device users—bringing new concerns about device longevity and long-term exposure to implanted materials. The current medical device market for children has a higher demand than supply. FDA is committed to supporting the development and availability of safe and effective pediatric medical devices.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments on the topics discussed at the Public Workshop.

II. Topics Discussed at the Public Workshop

The public workshop discussed the following topic areas:

1. The use of existing scientific research data to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance,
2. The scientific and regulatory limitations and issues with the use of existing scientific research data, and
3. The methods to overcome the pitfalls and data gaps, including statistical approaches and modeling.

III. Transcripts

Please be advised that a transcript of the public workshop is available at *http://www.regulations.gov* at FDA docket number FDA–2011–N–0754. The transcript may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript is also available online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm278053.htm*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 19, 2012.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2012–1443 Filed 1–24–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (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.

Proposed Project: The Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs: Forms (OMB No. 0915–0044)—[Extension]

The HPSL Program provides long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL program provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma in nursing, or associate, baccalaureate, or graduate degrees in nursing.

Participating HPSL and NSL schools are responsible for determining the eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The Deferment Form (Deferment-HRSA Form 519) provides the schools with documentation of a borrower's eligibility for deferment. The Annual Operating Report (AOR–HRSA Form 501) provides the Federal Government with information from participating schools (schools that are no longer granting loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due to the Federal Government are returned) relating to HPSL and NSL program operations and financial activities.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Deferment—HRSA Form 519	2,011	1	2,011	0.166	334
AOR—HRSA Form 501	907	1	907	4	3,628
Total	2,918				3,962

Email comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 18, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–1496 Filed 1–24–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Collection; Comment Request: Revision of the National Diabetes Education Program Comprehensive Evaluation Plan

SUMMARY: 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 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval. This is a request for a revision to an existing approved information collection request.

Proposed Collection: Title: The National Diabetes Education Program (NDEP) Comprehensive Evaluation Plan. *Type of Information Collection Request:* Revision of a currently approved collection (#0925–0552). *Need and Use of Information Collection:* The National Diabetes Education Program is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The longterm goal of the NDEP is to reduce the burden of diabetes and pre-diabetes in the United States, and its territories, by facilitating the adoption of proven strategies to prevent or delay the onset of diabetes and its complications. The NDEP objectives are to: (1) Increase awareness and knowledge of the seriousness of diabetes, its risk factors, and effective strategies for preventing type 2 diabetes and complications associated with diabetes; (2) increase the number of people who live well with diabetes and effectively manage their disease to prevent or delay complications and improve quality of life; (3) decrease the number of Americans with undiagnosed diabetes; (4) Among people at risk for type 2 diabetes, increase the number who make and sustain effective lifestyle changes to prevent diabetes; (5) facilitate efforts to improve diabetes-related health care and education, as well as systems for delivering care (6) reduce health disparities in populations disproportionately burdened by diabetes, and (7) facilitate the incorporation of evidence-based research findings into health care practices.

Multiple strategies have been devised to address the NDEP objectives. These have been described in the NDEP Strategic Plan and include: (1) Promoting and implementing culturally and linguistically-appropriate diabetes awareness and education campaigns for a wide variety of audiences; (2) identifying, disseminating, and supporting the adoption of evidence-based, culturally and linguistically-appropriate tools and resources that support behavior change, improved quality of life, and better diabetes outcomes; (3) expanding NDEP reach and visibility through collaborations with public, private, and nontraditional partners, and use of national, state, and local media, traditional and social media, and other relevant channels.; and (4) conducting and supporting the evaluation of NDEP resources, promotions, and other activities to improve future NDEP initiatives.

The NDEP evaluation will document the extent to which the NDEP program has been implemented, and how successful it has been in meeting program objectives. The evaluation relies heavily on data gathered from existing national surveys such as National Health and Nutrition Examination Survey (NHANES), the National Health Interview Survey (NHIS), the Behavioral Risk Factor Surveillance System (BRFSS), among others for this information. This revision request is continued collection of additional primary data from NDEP target audiences on some key process and impact measures that are necessary to effectively evaluate the program. Continued approval and revision to revise and/or add questions is requested for a survey of audiences targeted by the National Diabetes Education Program including people at risk for diabetes, people with diabetes and their families, and the public.

Burden Statement: The burden for the collection of information, conducted every two to three years (2–3 years) is estimated to average 0.03 hours per response screening interview with ineligible persons and 0.25 hours per response for the eligible respondent interview.

Respondents/Affected Entities: Adult individuals.

Estimated Number of Respondents: 3759.

Frequency of Response: Once per respondent.

Estimated Total Annual Hour Burden: 575. There are no Capital Costs, Operating or Maintenance Costs to report.

Changes in the Estimates: There is no change in estimate from the last ICR renewal.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.