

delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Clinical Laboratory Improvement Advisory Committee (CLIAC)**

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

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Clinical Laboratory Improvement Advisory Committee (CLIAC). This meeting is open to the public, limited only by the webcast lines available. Check the CLIAC website on the day of the meeting for the web conference link [www.cdc.gov/cliac](http://www.cdc.gov/cliac).

**DATES:** The meeting will be held on November 3, 2021, from 11:00 a.m. to 6:00 p.m., EDT, and November 4, 2021, from 11:00 a.m. to 6:00 p.m., EDT.

**ADDRESSES:** This is a virtual meeting. Meeting times are tentative and subject to change. The confirmed meeting times, agenda items, and meeting materials including instructions for accessing the live meeting broadcast will be available on the CLIAC website at [www.cdc.gov/cliac](http://www.cdc.gov/cliac).

**FOR FURTHER INFORMATION CONTACT:** Nancy Anderson, MMSc, MT(ASCP), Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24–3, Atlanta, Georgia 30329–4027, Telephone: (404) 498–2741; [NAnderson@cdc.gov](mailto:NAnderson@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

**Purpose:** This Committee is charged with providing scientific and technical advice and guidance to the Secretary, HHS; the Assistant Secretary for Health;

the Director, CDC; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

**Matters To Be Considered:** The agenda will include agency updates from CDC, CMS, and FDA. In addition to the general updates, agency presentations will include an overview of the FDA's Center for Biologics Evaluation and Research, a laboratory safety update, and a status report on the new CLIA regulations assessment workgroup. Presentations and CLIAC discussion will focus on next generation sequencing in clinical and public health laboratories and laboratory data exchange and harmonization. Agenda items are subject to change as priorities dictate.

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments pertinent to agenda items. Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to present an oral comment will be limited to a total time of five minutes (unless otherwise indicated). Speakers should email [CLIAC@cdc.gov](mailto:CLIAC@cdc.gov) or notify the contact person at least five business days prior to the meeting date. For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least five business days prior to the meeting date so that the comments may be made available to the Committee for their consideration and public

distribution. All written comments will be included in the meeting Summary Report posted on the CLIAC website.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day–21–1274; Docket No. CDC–2021–0096]

**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 the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the Million Hearts Hospital & Health System Recognition Program. This program recognizes institutions working systematically to improve the cardiovascular health of the population and communities they serve.

**DATES:** CDC must receive written comments on or before November 16, 2021.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC–2021–0096 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](http://Regulations.gov). Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600

Clifton Road NE, Mailstop H21-8, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

*Please note:* Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21-8, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate 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. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

### Proposed Project

Million Hearts Hospitals & Health Systems Recognition Program (OMB Control No. 0920-1274, Exp. 11/30/2022)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

Heart disease, stroke and other cardiovascular diseases (CVDs) kill over 800,000 Americans each year, accounting for one in every three deaths. CVD is the nation's number one killer among both men and women, and the leading cause of health disparities. Million Hearts, a national, public-private initiative co-led by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS), was established to address this issue. Whether migrating towards value-based reimbursement or simply striving for a significant impact in reducing the devastation of heart attacks and strokes, clinical organizations are positioned to improve the health of the population they serve by implementing high-impact, evidence-based strategies. Achieving a Million Hearts Hospitals & Health Systems designation signals a commitment to not only clinical quality, but population health overall.

Initially launched in 2020, the Program will continue to recognize institutions that are working to systematically improve the cardiovascular health of the population and communities that they serve by implementing strategies under the Million Hearts priority areas of Keeping People Healthy, Optimizing Care, Improving Outcomes for Priority Populations, and Innovating for Health. CDC anticipates that new applicants will range from health systems with multiple hospitals, hospitals with and without ambulatory medical practices, and medical practices not affiliated with hospitals. Any clinical entity whose leaders consider it eligible may apply.

Recognition can be achieved by a robust commitment to implement specific strategies, by implementing specific strategies, and most importantly, by achieving specific outcomes. Applicants will complete the Million Hearts Hospitals & Health Systems Recognition Program application, indicating the areas in which they are committing to implement Million Hearts strategies; areas in which they have implemented key strategies; and those strategies for which they have achieved outcomes/ results.

Applicants must address a minimum of one strategy in at least three of the four priority areas (Keeping People Healthy, Optimizing Care, Improving Outcomes for Priority Populations and Innovating for Health) that are outlined in the application. However, they are encouraged to target as many strategies as is appropriate for their institution. Applicants will be subject to a background check.

The Million Hearts Hospitals and Health Systems designation conveys that the institution is committed to preventing heart attacks and strokes by a combination of efforts that are about Keeping People Healthy, Optimizing Care, Improving Outcomes for Priority Populations and Innovating for Health. All applicants with reported outcomes and a select number of those who are committing to implement, or are implementing Million Hearts strategies, will be asked to participate in a semi-structured, qualitative interview. The purpose of the interview is to obtain in-depth contextual information about the Million Hearts strategies and facilitators used to achieve improved cardiovascular outcomes among the applicant's patient population. Applicants with reported outcomes will receive increased recognition from Million Hearts by having their success stories highlighted by Million Hearts by placement on the Million Hearts website or e-newsletter.

The program's web-based application will stay open throughout the year and applications will be reviewed on a quarterly basis and recognized within six months of acceptable review. CDC estimates that information will be collected from up to 50 applicants per year. The overall goal of the Million Hearts initiative is to prevent one million heart attacks and strokes. Promoting evidence-based strategies that prevent CVD is an additional focus of the initiative.

CDC will use the information collected through the Million Hearts Hospitals & Health Systems Recognition Program to increase widespread attention on successful and sustainable implementation strategies, improve understanding of these strategies at the practice level, bring visibility to organizations that commit, implement, or have implemented Million Hearts strategies and motivate other hospitals and health systems to strengthen their efforts to address CVD.

OMB approval is requested for three years. CDC requests approval for an estimated 149 annual burden hours. Participation is voluntarily, and 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	Avg. burden per response (in hrs.)	Total burden (in hrs.)
Medical & Health Service Manager ..	Recognition Program Application .....	50	1	160/60	134
Medical & Health Service Manager ..	Interview Guide .....	30	1	30/60	15
Total .....	.....	.....	.....	.....	149

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day–21–0314]

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled The National Survey of Family Growth (NSFG) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on June 10, 2021 to obtain comments from the public and affected agencies. CDC received one non-substantive comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

**Proposed Project**

The National Survey of Family Growth (NSFG) (OMB Control No. 0920–0314, Exp. 06/30/2021)—Reinstatement with Change—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on “family formation, growth, and dissolution,” as well as “determinants of health” and “utilization of health care” in the United States. This information collection request includes the data collection in 2022–2024 for the continuous National Survey of Family Growth (NSFG).

The NSFG was conducted periodically between 1973 and 2002, continuously in 2006–2010, and after a break of 15 months, continuously in

2011–2019, by the National Center for Health Statistics, CDC (CDC/NCHS). The response rate during the 2011–2019 data collection period ranged from 64.5–74.0%, and the cumulative response rate for this eight-year fieldwork period was 67.7%.

The NSFG program produces descriptive statistics which document factors associated with birth and pregnancy rates, including contraception, infertility, marriage, cohabitation, and sexual activity, in the US household population 15–49 years (15–44 prior to 2015), as well as behaviors that affect the risk of HIV and other sexually transmitted diseases (STD). The survey also disseminates statistics on the medical care associated with contraception, infertility, pregnancy, and related health conditions.

NSFG data users include the DHHS programs that fund the survey, including CDC/NCHS and 11 others within the Department of Health and Human Services:

- Eunice Kennedy Shriver National Institute for Child Health and Human Development (NIH/NICHD)
- Office of Population Affairs (OPA)
- Children’s Bureau in the Administration for Children and Families (ACF/CB)
- Office of Planning, Research, and Evaluation (ACF/CB)
- Office on Women’s Health (OASH/OWH)
- CDC’s Division of HIV/AIDS Prevention (CDC/NCHHSTP/DHAP)
- CDC’s Division of STD Prevention (CDC/NCHHSTP/DSTDP)
- CDC’s Division of Adolescent and School Health (CDC/NCHHSTP/DASH)
- CDC’s Division of Reproductive Health (CDC/NCCDPHP/DRH)
- CDC’s Division of Cancer Prevention and Control (CDC/NCCDPHP/DCPC)
- CDC’s Division of Violence Prevention (CDC/NCIPC/DVP)

The NSFG is also used by state and local governments (primarily for benchmarking to national data); private research and action organizations focused on men’s and women’s health, child well-being, and marriage and the