

respondents through an online survey, and awareness of the National CLAS paper form or telephone administration. Information that will be collected includes demographic information, specialty, number of years the physician has provided direct patient care, training related to cultural competency and the National CLAS Standards, provision of CLAS to patients, organizational characteristics that helped or prevented provision of CLAS,

as the basis to provide regional and national estimates. Participation in the CLAS survey is voluntary. There will be no financial incentive to participate. The CLAS survey will be a self-administered online questionnaire, with paper form and telephone administration as follow-up alternatives for non-respondents. A three-year approval will be requested. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Office-based physicians	NAMCS CLAS Survey	800	1	30/60	400
Total	400

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.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15BEB; Docket No. CDC-2015-0071]

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 efforts 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 information collect project entitled *Balance After Baby Intervention: Phase 2 (BAB12.)* A three-year clearance is requested to conduct a randomized controlled trial of a Web site-based lifestyle program with a racially diverse population of

postpartum women who had recent Gestational diabetes mellitus (GDM). **DATES:** Written comments must be received on or before October 27, 2015. **ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0071 by any of the following methods: *Federal eRulemaking Portal: Regulation.gov.* Follow the instructions for submitting comments. *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., 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 CONTACT: 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 NE., MS-D74, 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 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

Balance After Baby Intervention: Phase 2 (BABi2)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC Division of Reproductive Health (DRH) is focused on understanding and preventing complications due to pregnancy and the development of chronic diseases in reproductive age women. Similarly, the CDC established the National Diabetes Prevention Program (NDPP), administered through the Division of Diabetes Translation (DDT), to make strategies for preventing type 2 diabetes broadly available to individuals at high risk of developing diabetes. Gestational diabetes mellitus (GDM) is one of the most common pregnancy complications in the US, affecting approximately 3–13% of pregnancies, or approximately 200,000 cases annually. As defined by the American Diabetes Association (2003), GDM is glucose intolerance that first presents during pregnancy after the first trimester. Women with a history of GDM have a substantially increased risk of developing type 2 diabetes mellitus (T2DM) within 5 to 16 years after their index pregnancy. It has also been shown that many women with a history of GDM gain weight after pregnancy, increasing their risk for obesity, which

itself is a strong risk factor for repeat GDM and T2DM. Because of this, as obesity prevalence continues to increase, there is a concurrent rise in incidence and prevalence of GDM and T2DM, resulting in a large disease burden on individuals, families, and society. To assist in reducing this national disease burden, it is critical to develop and implement successful interventions that reduce the annual number of newly diagnosed T2DM cases, especially in increased risk populations, such as women with a history of GDM. As part of this Healthy People 2020 objective, the Diabetes Prevention Program (DPP) demonstrated that an intensive lifestyle intervention (16 face-to-face sessions over a 24-week period) promoting physical activity, healthy eating, and weight reduction significantly decreased T2DM incidence by 58% in high risk patients. However, the DPP included predominantly older individuals whose ability to attend group meetings and adopt healthy lifestyle changes is different than younger postpartum women. For this reason, successful adaptations of the DPP that address barriers in postpartum women with recent GDM, such as limited time and resources, fatigue, and childcare demands, must be identified and tested. This BABi2 data collection request aims to address these barriers through the conduct of a randomized, controlled intervention trial of a Web site-based lifestyle program, Balance after Baby (BAB) that is adapted from the DPP and tailored specifically for postpartum women with recent GDM. The project aims to screen 293 (98 annualized over 3 years) women with recent GDM pregnancy for enrollment into the study, followed by assessment

at the following five post-partum time points: 6-weeks, 6-months, 12-months, 18-months, and 24-months. Of the estimated 190 (63 annualized) women who will meet eligibility requirements and attend the first study visit, approximately half will be assigned to the control group and will receive standard postpartum follow-up, while those assigned to the intervention group will have access to the BAB informational Web site and a lifestyle coach. For all participants, the BABi2 study visits will involve the completion of visit-specific questionnaires, laboratory testing, and the collection of physical measurements such as height and weight. Collected data will be used by CDC and BABi2 investigators to assess the impact and effectiveness of the BABi2 intervention as a potential public health weight loss tool for women at increased T2DM risk. For the calculation of the estimated burden hours per study visit detailed in the table below, a constant 5% rate of exclusion and attrition was applied between visits. The burden table provides a participant estimate, which will be evenly distributed across control and intervention groups for each information collection step, annualized over a 3-year collection period. Therefore, of the 190 women (63 annualized) who attend the 6-week visit, the estimated number of participants returning for the 6-month visit is reduced to 180 (60 annualized), followed by 172 (57 annualized), 162 (54 annualized), and 154 (51 annualized) for the 12-, 18-, and 24-month visits respectively. The average burden per questionnaire ranges from 8 minutes for the BABi2 Screener Questionnaire up to 36 minutes for the BABi2 6-month Questionnaire.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Women with a recent history GDM ...	BABi2 Screener Questionnaire	98	1	8/60	13
Women with a recent history GDM ...	BABi2 6-Week Questionnaire	63	1	35/60	37
Women with a recent history GDM ...	BABi2 6-Month Questionnaire	60	1	36/60	36
Women with a recent history GDM ...	BABi2 12-Month Questionnaire	57	1	32/60	31
Women with a recent history GDM ...	BABi2 18-Month Questionnaire	54	1	32/60	29
Women with a recent history GDM ...	BABi2 24-Month Questionnaire	51	1	33/60	28
Total	174

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1643-N]

Medicare Program; Solicitation of Nominations to the Advisory Panel on Hospital Outpatient Payment

AGENCY: Centers for Medicare &
Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice solicits nominations for up to seven new members to the Advisory Panel on Hospital Outpatient Payment (HOP, the Panel). There will be vacancies on the Panel for four-year terms that begin during Calendar Year 2016.

The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (Secretary) and the Administrator of the Centers for Medicare & Medicaid Services on the clinical integrity of the Ambulatory Payment Classification groups and their associated weights, and supervision of employees of hospitals, hospital outpatient therapeutic services, systems, or other Medicare providers that are subject to the OPPS. For supervision deliberations, the Panel shall also include members that represent the interests of Critical Access Hospitals (CAHs), who advise the Centers for Medicare & Medicaid Services (CMS) only regarding the level of supervision for hospital outpatient therapeutic services. (For purposes of the Panel, consultants or independent contractors are not considered to be full-time employees in these organizations.)

The Secretary re-chartered the Panel in 2014 for a 2-year period effective through November 6, 2016.

DATES: *Submission of Nominations:* We will consider nominations if they are received no later than 5 p.m. Eastern Standard Time (E.S.T) October 27, 2015.

ADDRESSES: Please submit nominations electronically to the following email address: APCPanel@cms.hhs.gov.

Web site: For additional information on the Panel and updates to the Panel's activities, we refer readers to our Web site at the following address: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

FOR FURTHER INFORMATION CONTACT:

Persons wishing to nominate individuals to serve on the Panel or to obtain further information may contact Carol Schwartz at the following email address: APCPanel@cms.hhs.gov or call (410) 786-3985.

News Media: Representatives should contact the CMS Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act), and section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside advisory panel regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights that are components of the Medicare Hospital Outpatient Prospective Payment System (OPPS), and the appropriate supervision level for hospital therapeutic outpatient services. The Advisory Panel on Hospital Outpatient Payment (HOP, the Panel) is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels. The Panel may consider data collected or developed by entities and organizations (other than the Department of Health and Human Services) as part of their deliberations.

The Charter provides that the Panel shall meet up to 3 times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the OPPS for the following Calendar Year (CY).

The Panel shall consist of a chair and up to 15 members who are full-time employees of hospitals, hospital outpatient therapeutic services, systems, or other Medicare providers that are subject to the OPPS. For supervision deliberations, the Panel shall also include members that represent the interests of Critical Access Hospitals (CAHs), who advise the Centers for Medicare & Medicaid Services (CMS) only regarding the level of supervision for hospital outpatient therapeutic services. (For purposes of the Panel, consultants or independent contractors are not considered to be full-time employees in these organizations.)

The current Panel members are as follows:

(Note: The asterisk [*] indicates the Panel members whose terms end during CY 2016, along with the month that the term ends.)

- E.L. Hambrick, M.D., J.D., Chair, a CMS Medical Officer.
- Karen Borman, M.D., F.A.C.S.* (July 2016)
- Dawn L. Francis, M.D., M.H.S.
- Ruth Lande
- Jim Nelson, M.B.A., C.P.A., F.H.F.M.A.* (January 2016)
- Leah Osbahr, M.A., M.P.H.* (January 2016)

- Jacqueline Phillips* (February 2016)
- Johnathan Pregler, M.D.
- Traci Rabine* (January 2016)
- Michael Rabovsky, M.D.
- Wendy Resnick, F.H.F.M.A.
- Michael K. Schroyer, R.N.
- Marianna V. Spanaki-Varelas M.D., Ph.D., M.B.A.* (February 2016)
- Norman Thomson, III, M.D.
- Gale Walker* (January 2016)
- Kris Zimmer

Panel members serve on a voluntary basis, without compensation, according to an advance written agreement; however, for the meetings, CMS reimburses travel, meals, lodging, and related expenses in accordance with standard Government travel regulations. CMS has a special interest in ensuring, while taking into account the nominee pool, that the Panel is diverse in all respects of the following: Geography; rural or urban practice; race, ethnicity, sex, and disability; medical or technical specialty; and type of hospital, hospital health system, or other Medicare provider subject to the OPPS.

Based upon either self-nominations or nominations submitted by providers or interested organizations, the Secretary, or her designee, appoints new members to the Panel from among those candidates determined to have the required expertise. New appointments are made in a manner that ensures a balanced membership under the FACA guidelines. For 2016, we anticipate doing one solicitation for nominees. Our appointment schedule will assure that we have the full complement of members for each Panel meeting. Current members' terms expire at different times throughout the year; therefore, we will add new members throughout the year as terms expire.

II. Criteria for Nominees

The Panel must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. Each panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPS (except for the CAH members, since CAHs are not paid under the OPPS). All members must have technical expertise to enable them to participate fully in the Panel's work. Such expertise encompasses hospital payment systems; hospital medical care delivery systems; provider billing systems; APC groups; Current Procedural Terminology codes; and alpha-numeric Health Care Common Procedure Coding System codes; and the use of, and payment for, drugs, medical devices, and other services in