

respondents through an online survey, 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,

and awareness of the National CLAS Standards.

The target universe of the CLAS survey includes non-federally employed physicians who were classified by the American Medical Association or the American Osteopathic Association as providing “office-based, patient care.” The target universe excludes physicians in the specialties of anesthesiology, radiology, and pathology. The survey sample of 2,400 physicians will be used

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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 BILLING CODE 4163–18–P

**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 (BABI2.)* 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: 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 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 US obesity prevalence continues to increase, there is a concurrent rise in the 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 a recent GDM pregnancy for enrollment into the study, followed by assessments

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  
hospital outpatient therapeutic services.

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](mailto: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/Advisory  
PanelonAmbulatoryPayment  
ClassificationGroups.html](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](mailto: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(i)(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  
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