

medical ethics or other relevant professions.

The MEDCAC works from an agenda provided by the Designated Federal Official. The MEDCAC reviews and evaluates medical literature, technology assessments, and hears public testimony on the evidence available to address the impact of medical items and services on health outcomes of Medicare beneficiaries. The MEDCAC may also advise Centers for Medicare and Medicaid Services (CMS) as part of Medicare's "coverage with evidence development" initiative.

## II. Provisions of the Notice

As of June 2014, there will be 30 membership terms expiring. Of the 30 memberships expiring, 1 is nonvoting industry representative, 3 are voting patient advocates and the remaining 26 membership openings are for the general MEDCAC voting membership.

Accordingly, we are requesting nominations for both voting and nonvoting members to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies. We wish to ensure adequate representation of the interests of both women and men, members of all ethnic groups and physically challenged individuals. Therefore, we encourage nominations of qualified candidates from these groups.

All nominations must be accompanied by *curricula vitae*. Nomination packages must be sent to Maria Ellis at the address listed in the **ADDRESSES** section of this notice. Nominees for voting membership must also have expertise and experience in one or more of the following fields:

- Clinical medicine including subspecialties
- Administrative medicine
- Public health
- Biological and physical sciences
- Epidemiology and biostatistics
- Clinical trial design
- Health care data management and analysis
- Patient advocacy
- Health care economics
- Medical ethics
- Other relevant professions

We are looking particularly for experts in a number of fields. These include cancer screening, genetic testing, clinical epidemiology; psychopharmacology; screening and

diagnostic testing analysis; and vascular surgery. We also need experts in biostatistics in clinical settings, dementia treatment, minority health, observational research design, stroke epidemiology, and women's health.

The nomination letter must include a statement that the nominee is willing to serve as a member of the MEDCAC and appears to have no conflict of interest that would preclude membership. We are requesting that all *curricula vitae* include the following:

- Date of birth
- Place of birth
- Social security number
- Title and current position
- Professional affiliation
- Home and business address
- Telephone and fax numbers
- Email address
- List of areas of expertise

In the nomination letter, we are requesting that the nominee specify whether they are applying for a voting patient advocate position, for another voting position or a nonvoting industry representative. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.

Members are invited to serve for overlapping 2-year terms. A member may serve after the expiration of the member's term until a successor is named. Any interested person may nominate one or more qualified persons. Self-nominations are also accepted. The current Secretary's Charter for the MEDCAC is available on the CMS Web site at: <http://www.cms.hhs.gov/FACA/Downloads/medcaccharter.pdf>, or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

**Authority:** 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: October 18, 2013.

**Patrick Conway,**

*CMS Chief Medical Officer and Director, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* Parents and Children Together (PACT) Evaluation.

*OMB No.:* 0970-0403.

*Description:* The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing data collection activity as part of the Parents and Children Together (PACT) Evaluation. The objective of the PACT evaluation is to document and provide initial assessment of selected Responsible Fatherhood and Healthy Marriage grant programs that were authorized under the 2010 Claims Resolution Act. This information will be critical to informing decisions related to future investments in programming as well as the design and operation of such services.

PACT is utilizing three major, interrelated evaluation strategies: Impact evaluation; implementation evaluation; and qualitative evaluation. To collect data for these strategies, eighteen instruments have been approved to-date. This 30-Day **Federal Register** Notice covers two new instruments:

- (19) Follow-up Survey (for Responsible Fatherhood study participants)
- (20) Follow-up Survey (for Healthy Marriage study participants)

A more thorough description of the study and instruments was provided in a 60 Day **Federal Register** Notice posted in Vol. 78, No. 102, p. 31942 on May 28, 2013.

*Respondents:* Program applicants, program participants, program staff, and staff at referral agencies.

#### Annual Burden Estimates

This current 30-Day **Federal Register** Notice covers two new instruments:

ANNUAL BURDEN: CURRENT REQUEST

Activity/respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (hours)	Total annual burden hours
<b>Responsible Fatherhood Grantee Impact Evaluation</b>				
(19) RF Follow-up survey Study participants .....	1,600	1	0.75	1,200
<b>Healthy Marriage Grantee Impact Evaluation</b>				
(20) HM Follow-up survey Study participants .....	3,200	1	0.75	2,400
Total .....				3,600

*Estimated Total Annual Burden Hours (for instruments previously approved and currently in use, and those associated with this 30-Day Notice): 16,716.*

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Steven M. Hanmer,**  
*OPRE Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-1214]

**Clinical Investigator Training Course**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research/Office of Medical Policy and the Duke University Office of Continuing Medical Education are cosponsoring a 3-day training course for clinical investigators on scientific, ethical, and regulatory aspects of clinical trials. This training course is intended to provide clinical investigators with expertise in the design, conduct, and analysis of clinical trials; improve the quality of clinical trials; and enhance the safety of trial participants. Senior FDA staff will communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

*Date and Time:* The training course will be held on November 12 and 13, 2013, from 8 a.m. to 5 p.m., and on November 14, 2013, from 8 a.m. to 4 p.m.

*Location:* The course will be held at the Holiday Inn College Park, 10000 Baltimore Ave., College Park, MD 20740.

*Contact Person:* Connie Wisner, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6360, Silver Spring, MD 20993, 301-796-8509.

*Registration:* Register by November 1, 2013. The registration fee is \$400 per person. The fee includes course materials and onsite lunch. Early registration is recommended because seating is limited. There will be no onsite registration.

Register online for the training course at the registration Web site: <http://continuingeducation.dcri.duke.edu/fda-clinical-investigators-training-course-registration> or download a full-size copy of the registration form from the registration site and mail a check and completed form to: Duke University

Conference and Event Services, FDA Investigator Course, Box 90841, 101 Bryan Center, Durham, NC 27708. You will receive an email that confirms your registration. (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Attendees are responsible for their own accommodations. A block of rooms has been reserved under "FDA Clinical Investigator Course" at the Holiday Inn College Park at a reduced conference rate. Reservations for these accommodations can be made online using the course registration Web site mentioned previously. Click on "registration form." You will see a direct link to the hotel.

Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at the registration/information Web site mentioned previously.

If you need special accommodations due to a disability, please contact Connie Wisner (see *Contact Person*) at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Clinical trial investigators play a critical role in the development of medical products. They bear the responsibility for ensuring the safe and ethical treatment of study subjects and for acquiring adequate and reliable data to support regulatory decisions. This course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct