substantial impact on prevention program development and monitoring at the local, State, and national levels.

CDC estimates that NHBS will involve, per year in each of the 25 MSAs, eligibility screening of 50 to 200 persons and eligibility screening plus the behavioral assessment with 500 eligible respondents, resulting in a total of 37,500 eligible survey respondents and 7,500 ineligible screened persons during a 3-year period. Data collection will rotate such that interviews will be conducted among one group per year: MSM in year 1, IDU in year 2, and HET in year 3. The type of data collected for each group will vary slightly due to different sampling methods and risk characteristics of the group.

Participation of respondents is voluntary and there is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

| Respondent | Form | Number of respondents | Number of responses per respondent | Average burden per response (hours) | Total burden (in hours) |
|---|---|---|---|---|---|
| Year 1: | | | | | |
| Men Approached at Eligible Venue. | Screener | 17,500 | 1 | 5/60 | 1,458 |
| Eligible Men | Behavioral Assessment | 12,500 | 1 | 60/60 | 12,500 |
| Year 2: | | | | | |
| Injecting Drug Users Referred by Peer Recruiters. | Screener | 13,750 | 1 | 5/60 | 1,146 |
| Eligible Injecting Drug Users | Behavioral Assessment | 12,500 | 1 | 85/60 | 17,708 |
| Year 3: | | | | | |
| Heterosexual Men and Women Referred by Peer Recruiters. | Screener | 13,750 | 1 | 5/60 | 1,146 |
| Eligible Heterosexual Men and Women. | Behavioral Assessment | 12,500 | 1 | 70/60 | 14,583 |
| Total | | 45,000 | 1 | | 48,541 |

Dated: December 2, 2010.

**Carol E. Walker,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2010–30763 Filed 12–7–10; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[CMS–3234–N]**

### Medicare Program; Renewal of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the renewal of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).

**ADDRESSES:** *Copies of the Charter:* To obtain a copy of the Secretary's Charter for the MEDCAC submit a request to: *See* **FOR FURTHER INFORMATION CONTACT.**

**FOR FURTHER INFORMATION CONTACT:** Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410–786–0309) or via e-mail at *Maria.Ellis@cms.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) announcing the establishment of the Medicare Coverage Advisory Committee (MCAC). The Secretary signed the initial charter for the MCAC on November 24, 1998. The MCAC was originally established to provide independent guidance and expert advice to CMS on specific clinical topics. In 2007 the Charter was renewed and the name MCAC was modified to Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) to more accurately reflect the Committee's role. The MEDCAC is advisory, with the final decision on all issues resting with CMS. Under the current charter, the MEDCAC advises the Secretary of the Department of Health and Human Services (DHHS) and the Administrator of the CMS, on the quality of evidence on clinical topics under review by CMS.

The MEDCAC consists of a pool of 100 appointed members. Members are selected from authorities in clinical medicine of all specialties, administrative medicine, public health, biologic and physical sciences, health care data and information management and analysis, patient advocacy, the economics of health care, medical ethics and other related professions such as epidemiology and biostatistics, and methodology of trial design. There are 94 at-large standing voting members. Six of the members are patient advocates and six are nonvoting members representing the industry interest.

## II. Provisions of this Notice

This notice announces the signing of the MEDCAC charter renewal by the Secretary on November 23, 2010. The new charter makes the following changes:

- There are 4–8 meetings per year.
- A period of service for the Chair and Vice-Chair of no more than 4 years.

The MEDCAC functions on a committee basis. The MEDCAC—(1) Hears public testimony; (2) reviews medical literature, technology assessments and other relevant evidence and advises CMS on the strength and weaknesses of that evidence; (3) advises CMS of any evidence gaps that may exist and recommends the types of evidence that should be developed to fill those evidentiary gaps. The Committee may be asked to develop recommendations about specific clinical issues under review and to review and comment upon proposed or existing Medicare coverage policies. The Committee may also be asked to comment on pertinent aspects of

proposals being considered and other policies. The Committee works from an agenda provided by the designated Federal official that lists specific issues.

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

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

Dated: November 16, 2010.

**Barry M. Straube,**

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

[FR Doc. 2010–30761 Filed 12–7–10; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0602]**

## Biologics Price Competition and Innovation Act of 2009; Meetings on User Fee Program for Biosimilar and Interchangeable Biological Product Applications; Request for Notification of Stakeholder Intention To Participate

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

**ACTION:** Notice; request for notification of participation.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this notice to request that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify FDA of their intent to participate in consultation meetings relating to the development of a user fee program for biosimilar and interchangeable biological product applications submitted under the Public Health Service Act (PHS Act). FDA is holding these consultation meetings to satisfy the requirement in the Patient Protection and Affordable Care Act that FDA consult with such public stakeholders regarding the development of recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of biosimilar and interchangeable biological product applications for fiscal years (FYs) 2013 through 2017. To ensure continuity and to support the development of recommendations for establishing a user fee program for biosimilars and interchangeable products, the Agency requests stakeholder representation throughout this consultation process.

**DATES:** Submit notification of intention to participate by January 10, 2011. Stakeholder discussions with FDA will occur during negotiations with the regulated industry.

**ADDRESSES:** Submit notification of intention to participate in stakeholder meetings by e-mail to *Biosimilars UserFeeProgram@fda.hhs.gov*.

**FOR FURTHER INFORMATION CONTACT:** Sunanda Bahl, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 1168, Silver Spring, MD 20993–0002, 301–796–3584, FAX: 301–847–8443, *e-mail: sunanda.bahl@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. Background

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148). The Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the PHS Act and other statutes to create an abbreviated approval pathway for biological products shown to be highly similar (biosimilar) to, or interchangeable with, an FDA-licensed reference biological product. (*See* sections 7001 through 7003 of the BPCI Act.) Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product.

The BPCI Act amends section 735 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379g) to include 351(k) applications for biosimilar or interchangeable biological products in the definition of "human drug application" for the purposes of the prescription drug user fee provisions. (*See* section 7002(f)(3)(A) of the BPCI Act.) The authority conferred by the FD&C Act's prescription drug user fee provisions expires in September 2012. The BPCI Act directs FDA to develop recommendations for a user fee program for biosimilar and biological product applications for FYs 2013 through 2017. (*See* section 7002(f)(1) of the BPCI Act.)

### II. FDA Consultation With Stakeholders

FDA is required to develop recommendations to present to Congress by January 15, 2012, that address the goals, and plans for meeting the goals, for the process for the review of biosimilar and interchangeable biological product applications for FYs 2013 through 2017. (*See* section 7002(f)(1) of the BPCI Act.) In developing such recommendations, FDA must consult with a range of groups, including scientific and academic experts; health care professionals; representatives of patient and consumer advocacy groups; and regulated industry. (*See* section 7002(f)(1) of the BPCI Act.) FDA initiated this consultation process on November 2 and 3, 2010, by holding a public hearing at which stakeholders and other members of the public were given an opportunity to present their views on issues associated with the implementation of the BPCI Act. To facilitate identification of regulated industry, in the **Federal Register** notice that announced the November 2010 public hearing, FDA requested that comments identify companies that would be affected by a user fee program for biosimilar or interchangeable biological products, as well as industry associations representing such companies. (*See* 75 FR 61497, October 5, 2010.)

FDA is issuing this **Federal Register** notice to request that other stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify FDA of their intent to participate in consultation meetings related to the development of recommendations for a user fee program for biosimilar and interchangeable biological product applications. FDA believes that consistent stakeholder representation at these consultation meetings will be important to ensure progress in the discussions. If you wish to participate in this process, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed. Stakeholders who identify themselves through this notice will be included in future stakeholder discussions as FDA negotiates with regulated industry. These discussions will satisfy the requirement for consultation with public stakeholders in section 7002(f)(1) of the BPCI Act.

### III. Additional Information on the BPCI Act

There are several sources of information on FDA's Web site that may serve as useful resources for stakeholders intending to participate in consultation meetings:

- The **Federal Register** notice that announced the November 2 and 3, 2010, public hearing and requested public comments is available at *http://edocket.access.gpo.gov/2010/pdf/2010–24853.pdf*.