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*.

• Comments submitted in response to the November 2010 public hearing notice can be found at *http://www.regulations.gov* using Docket No. FDA–2010–N–0477.

• Additional information regarding implementation of the BPCI Act is available at: *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/UCM215031*.

**IV. Notification of Intent To Participate in Consultation Meetings**

If you intend to participate in stakeholder consultation meetings regarding the development of recommendations for a user fee program for biosimilar and interchangeable biological product applications for FYs 2013 through 2017, please provide notification by e-mail to *BiosimilarsUserFeeProgram@fda.hhs.gov* by January 10, 2011. Your e-mail should contain complete contact information, including name, title, affiliation, address, e-mail address, telephone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification.

Dated: December 2, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–30713 Filed 12–7–10; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency; (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; and (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.

**Proposed Project: Data Collection Tool for Rural Health Community-Based Grant Programs (OMB No. 0915–0319)—[Revision]**

On May 20, 2008, OMB approved the Agency's request for the collection of data related to program and clinical measures (OMB No. 0915–0319) and set an expiration date of May 31, 2011. The Agency is now proceeding to submit a revised package which will include program specific measures that are further aligned with the agency's updated clinical measures. These measures were modified based on the feedback received from grantees and to reflect ORHP and HRSA's current priorities and clarify certain measures across all 330A programs. In addition, these revisions will enhance data collection and analysis in an effort to strengthen the value of the data collection tool.

There are currently six rural health grant programs that operate under the authority of Section 301 of the Public Health Service (PHS) Act. These programs include: (1) Rural Health Care Services Outreach Grant Program (Outreach); (2) Rural Health Network Development Grant Program (Network Development); (3) Small Healthcare Provider Quality Grant Program (Quality); (4) Delta States Rural Development Network Grant Program (Delta); (5) Network Planning Grant Program and (6) Rural Health Workforce Development Grant Program. These grants are to provide for the expanded delivery of health care services, the planning and implementation of integrated health care networks, and the planning and implementation of quality improvement and workforce activities—all in rural areas.

For these programs, performance measures were drafted to provide data useful to the programs and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to ORHP, including: (a) Access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development, and (g) health related clinical measures. Several measures will be used for all six programs. All measures will speak to the Office's progress toward meeting the goals set.

The annual estimate of burden is as follows:

| Instrument | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| Rural Health Care Services Outreach Grant Program | 111 | 1 | 111 | 2.75 | 305.25 |
| Rural Health Network Development | 49 | 1 | 49 | 2 | 98 |
| Delta States Rural Development Network Grant Program | 12 | 1 | 12 | 3 | 36 |
| Small Health Care Provider Quality Improvement Grant Program | 59 | 1 | 59 | 6 | 354 |
| Network Development Planning Grant Program | 30 | 1 | 30 | 1 | 30 |
| Rural Health Workforce Development Program | 20 | 1 | 20 | 1.75 | 35 |
| Total | 281 | | 281 | | 858.25 |

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.