

programs? Are States likely to consider a CHIP-like approach or other options? What are the pros and cons of these various options?

4. How can eligibility and enrollment be effectively coordinated between the Basic Health Program and other State programs to reduce churning between programs and promote continuity of care?

5. How could establishing a Basic Health Program affect the ability of an entire family to be covered by the same plan?

6. Are standard health plans likely to also participate in other coverage programs, such as the Exchanges, Medicaid, or CHIP? Should this be encouraged, and if so, how could CMS and States encourage it?

E. Amount of Payment

1. The statute specifies that amounts in the trust fund may only be used to reduce the premiums and cost-sharing of, or to provide additional benefits for, eligible individuals enrolled in standard health plans within a Basic Health Program. What options are States considering for reducing premiums and cost-sharing, or providing additional benefits? What, if any, guidance is needed on this provision?

2. What are the likely administrative costs for a Basic Health Program? What factors, especially in terms of resources, are likely to affect a State's ability to establish a Basic Health Program? How are States likely to fund the costs associated with establishing and administering a Basic Health Program?

3. The statute specifies that in developing the financial methodology for the Basic Health Program, the determination of the value of the premium tax credits and cost-sharing reductions should take into consideration the experience of other States. What information would be most helpful to inform this methodology? Should implementation of the Basic Health Program be postponed until other States' experiences are available?

4. Other than those listed in the statute, what factors should be considered when establishing the methodology for determining the amount of Basic Health Program funding to States? How should the Federal government implement this calculation?

5. The statute specifies that the funding calculation is on a per-enrollee basis. How should the Federal government acquire the detailed information necessary to perform this calculation?

6. What are the best State-specific data sources to use in estimating the

availability of affordable employer-sponsored insurance?

7. What methods should be considered to measure and monitor compliance with the 95 percent cap on funding? How should CMS implement the provisions in Section 1331(d)(3)(B) of the Affordable Care Act regarding corrections to overpayments made in any year?

F. Eligibility

1. What education and outreach will be necessary to facilitate a helpful consumer experience?

G. Secretarial Oversight

1. What process should the Secretary use to certify or recertify Basic Health Programs? How should this process be similar to or different from Exchange certification?

2. What should be considered when developing an oversight process for the Basic Health Program?

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

Dated: July 27, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011-23388 Filed 9-9-11; 11:15 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Food and Drug Administration/Xavier University Global Outsourcing Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled "FDA/Xavier University Global Outsourcing Conference." This 2.5-day public conference for the pharmaceutical industry is in direct alignment with the "FDA Strategic Priorities 2011–2015," and includes presentations from key FDA officials, global regulators, and industry experts. This conference drives collaboration on the topic of global outsourcing compliance by bringing pharmaceutical/biotechnology companies and contract partners to the

same event to address the issues that reside on both sides of the contract. Expert presentations address the "how to" aspects of improving outsourced product quality through topics such as Strategic Procurement, End-to-End lifecycle product management, Managing Global Complex Supply Chains, and other topics. The experience level of our audience has fostered engaged dialog that has lead to innovative initiatives.

Dates and Times: The public conference will be held on October 3, 2011, from 8:30 a.m. to 5 p.m., October 4, 2011, from 8:30 a.m. to 5 p.m., and October 5, 2011, from 8:30 a.m. to 1 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

Contact Persons:

For information regarding this document: Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East Seventh Street, Cincinnati, OH 45202, 513-246-4134, e-mail: steven.eastham@fda.hhs.gov.

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, e-mail: phillipsm4@xavier.edu.

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, dinners, and dinner speakers for the 2.5 days of the conference. Prior online registration or registration by mail must be done by October 3, 2011. There will also be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES¹

Attendee	Fee
Industry	\$1,495
Small Business (<100 employees)	1,000
Consultants	700
Startup Manufacturer	300
Academic/Government	300
Media	Free

¹ The fourth registration from the same company is free.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the "Register Now" link on the conference Web site at <http://www.XavierGOC.com>. FDA has verified the Web site address, but is not responsible for subsequent changes to

the Web site after this document publishes in the **Federal Register**.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, e-mail, and payment information for the fee to Xavier University, *Attention: Sue Bensman*, 3800 Victory Pkwy., Cincinnati, OH 45207. An e-mail will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West Fifth Street, Cincinnati, OH 45202, 513-421-9100. To make reservations online, please visit the "Venue & Logistics" link at <http://www.XavierGOC.com>. The hotel is expected to sell-out during this timeframe; so, early reservation in the conference room-block is encouraged.

If you need special accommodations due to a disability, please contact Marla Phillips (see *Contact Persons*) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA's important mission to protect the public health. The conference will provide those engaged in FDA-regulated outsourcing with information on the following topics:

- Regulatory Expectations for Outsourcing Roles and Responsibilities, Supply Chain Quality, and Challenges Observed,
- Price Versus Total Cost of Ownership,
- Strategic Procurement,
- Development and Commercial Contracts,
- Functional Quality Agreements,
- Meaningful Metrics,
- FDA and the Medicines and Healthcare Products Regulatory Agency Inspection Trends and Enforcement,
- McNeil Case Study and Living Under Consent Decree,
- Practical Risk Management and Case Studies of Litigation,
- Supplier Qualification Program,
- Third Party Initiatives and Impact,
- Operationalizing Quality-by-Design,
- Audit Panel to Cover Focus Areas for Due Diligence Audits, Ongoing Audit/Oversight, and Supply Chain Audits,
- The Power of Integrated Supply Chains—By Design. Drive to the Source of the Frustrations,
- End-to-End Planning for Successful Launch,
- Pharma Case Study on How to Manage a Global Complex Supply Chain,
- USP <1079>: Good Storage and Distribution Practices, and USP <1083>

Pedigree and Track and Trace Presented By the Author, and

- Next Steps for the Industry.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121) by providing outreach activities by Government Agencies to small businesses.

Dated: September 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-23482 Filed 9-13-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Gastrointestinal/Kidney Pathophysiology, Toxicology/Pharmacology AREA Grant Applications.

Date: October 5, 2011.

Time: 3 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 1 Metro Center, Bethesda, MD 20814.

Contact Person: Patricia Greenwel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301-435-1169, greenwel@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Special Topic: Enabling Bioanalytical and Imaging Technologies.

Date: October 6-7, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Four Points by Sheraton Washington DC Downtown, 1201 K Street, NW., Washington, DC 20005.

Contact Person: Ross D Shonat, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6172, MSC 7892, Bethesda, MD 20892, 301-435-2786, ross.shonat@nih.hhs.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Molecular Neuroscience.

Date: October 6, 2011.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol Hamelink, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213-9887, hamelinc@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 7, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-23530 Filed 9-13-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Center for Scientific Review Special Emphasis Panel, October 5, 2011, 3:30 p.m. to October 5, 2011, 6:30 p.m., Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814 which was published in the **Federal Register** on September 6, 2011, 76 FR 55076-55077.

The meeting is cancelled due to the reassignment of applications.

Dated: September 7, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-23536 Filed 9-13-11; 8:45 am]

BILLING CODE 4140-01-P