

online at <http://www.fda.gov/MedicalDevices/NewsEvents/MeetingsConferences/ucm187406.htm> by close of business on February 15, 2010. Those without Internet access may register by contacting Christine Kellerman at 301-796-5711. When registering, you must provide your name, title, company or organization (if applicable), address, phone number, and e-mail address. There is no fee to register for the public meeting and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Registration on the day of the public meeting will be permitted on a space-available basis beginning at 8:45 a.m.

If you need special accommodations due to a disability, please contact the hotel at 301-977-8900 at least 7 days prior to the meeting.

Directions to the hotel and other information about the meeting may be found at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm187406.htm>.

**Comments:** FDA is holding this public meeting to raise public awareness about the accuracy and clinical use of blood glucose meters, to share ideas on the challenges associated with their use, to seek public comments on this topic and to work towards identifying solutions. The deadline for submitting comments regarding this public meeting is April 20, 2010, by 5 p.m. EST.

Regardless of attendance at the meeting, interested persons may submit written or electronic comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**SUPPLEMENTARY INFORMATION:** The workshop will include 3 sessions on the following: (1) Clinical accuracy for blood glucose meters, (2) tight glycemic control in clinical settings, and (3) medications and other substances that interfere with the technologies the devices employ. Each session will include presentations from physicians, laboratories, government and industry representatives, and patient advocates who are experts in each area. Presentations will be followed by panel

discussions of session topics and questions from the audience.

Glucose meters are used by millions of people with diabetes every day. These devices have become smaller, faster, and more accurate over the past 3 decades and now allow for better glycemic control by diabetics than in the past. Glucose meters are not only used by diabetics at home, they are also used by health care providers in a variety of settings such as hospitals, emergency response units, nursing homes, and physicians' offices.

Some in the clinical and patient communities have questioned whether the current FDA-recognized accuracy standards for blood glucose meters are acceptable and have challenged FDA to require tighter performance standards. Blood glucose meters are being used in clinical settings and at home in ways that are not within the intended use of the devices as evaluated by FDA. For example, glucose meters are increasingly being used to achieve tight glycemic control despite the fact that these devices have not been cleared for this use. There is currently no consensus that blood glucose meters currently on the market are accurate enough to be used in this way. Still, other stakeholders believe the current analytical performance of glucose meters is adequate and that there is no evidence to support the need for higher standards. Other factors affecting the performance of blood glucose meters include administered drugs, common physiological conditions (such as diabetic ketoacidosis), and user-interface issues. For example, the administration of therapies containing maltose, which are commonly prescribed to patients in the hospital, have resulted in falsely elevated glucose results. (FDA issued a Public Health Notification about this risk. See <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm176992.htm> and <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm177189.htm> for more information.)

In response to the issues identified previously, FDA is reconsidering the current FDA-recognized glucose meter accuracy standards, and is considering whether FDA review criteria for these devices should be changed for reasons of public health. FDA is interested in hearing from clinical experts about the clinical requirements for blood glucose meter accuracy and precision, and the benefits and risks of using glucose meters to achieve and maintain tight glycemic control. The appropriate analytical and clinical accuracy requirements for blood glucose meters

will be discussed during this meeting, as well as the potential benefits and challenges of meeting those requirements. We are seeking participation from all stakeholders including, but not limited to: Physicians, nurses, health care providers who work in intensive care settings, industry, diabetes educators, professional societies, consumers, and patient advocate groups.

**Transcripts:** Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm187406.htm>.

Dated: January 8, 2010.

**Jeffrey Shuren,**

*Acting Director, Center for Devices and Radiological Health.*

[FR Doc. 2010-742 Filed 1-14-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health: 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:** National Institute of Mental Health Special Emphasis Panel; ITVA Conflicts.

**Date:** February 24, 2010.

**Time:** 1:30 p.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

**Contact Person:** Francois Bollor, MD, PhD, Scientific Review Officer, Division of

Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6142, MSC 9606, Bethesda, MD 20892-9606, 301-443-1513, [bolleff@mail.nih.gov](mailto:bolleff@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel, Review of NIMH Research Education Applications.

*Date:* March 2, 2010.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

*Contact Person:* Rebecca C. Steiner, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, [steinerr@mail.nih.gov](mailto:steinerr@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: January 11, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-677 Filed 1-14-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

The Health Resources and Services Administration (HRSA) is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

Section 100.2 of the VICP's implementing regulation (42 CFR Part 100) states that the revised amounts of an average cost of a health insurance policy, as determined by the Secretary, are to be published periodically in a notice in the **Federal Register**. This figure is calculated using the most recent Medical Expenditure Panel Survey-Insurance Component (MEPS-IC) data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family

Foundation and Health Research and Educational Trust (KFF/HRET) Employer Health Benefits survey or other authoritative source that may be more accurate or appropriate.

In 2009, MEPS-IC, available at <http://www.meps.ahrq.gov>, published the annual 2008 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was \$4,386. This figure is divided by 12-months to determine the cost per month of \$365.50. The \$365.50 shall be increased or decreased by the percentage change reported by the most recent KFF/HRET, available at <http://www.kff.org>. The percentage increase was published at 5 percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for 12-month period is \$383.78.

The Department will periodically (generally on an annual basis) recalculate the average cost of a health insurance policy by obtaining a new figure from the latest MEPS-IC data and updating this figure using the percentage change(s) reported by the most recent data from KFF/HRET or other authoritative source that may be more accurate or appropriate in the future. The updated calculation will be published as a notice in the **Federal Register** and filed with the Court.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is \$383.78 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the Secretary to the United States Court of Federal Claims. Such notice was delivered to the Court on January 4, 2010.

Dated: January 11, 2010.

**Mary K. Wakefield,**  
*Administrator.*

[FR Doc. 2010-675 Filed 1-14-10; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### NIH Consensus Development Conference: Lactose Intolerance and Health; Notice

Notice is hereby given by the National Institutes of Health (NIH) of the "NIH Consensus Development Conference: Lactose Intolerance and Health" to be held February 22-24, 2010, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The

conference will begin at 8:30 a.m. on February 22 and 23 and at 9 a.m. on February 24, and it will be open to the public.

Lactose intolerance is the inability to digest significant amounts of lactose, a sugar found in milk and other dairy products. Lactose intolerance is caused by a shortage of the enzyme lactase, which is produced by expression of the lactase-phlorizin hydrolase gene by the cells that line the small intestine. Lactase breaks milk sugar down into two simpler forms of sugar called glucose and galactose, which are then absorbed into the bloodstream. Infants of every racial and ethnic group worldwide produce lactase and successfully digest lactose provided by human milk or by infant formulas. However, by the time many of the world's children reach the age of 3-4 years, expression of intestinal lactase ceases. Most affected individuals, referred to as lactase nonpersisters, in the United States belong to minority groups, especially Asians, African Americans, Hispanics, Native Americans, Alaskan Natives, and Pacific Islanders.

Consumption of lactose-containing products by lactase nonpersisters may cause gas production, bloating, abdominal pain, and diarrhea. These symptoms of lactose intolerance are caused by intestinal bacteria's fermentation of undigested lactose and often cause individuals to avoid lactose-containing products. Lactose intolerance can be diagnosed by drinking one to two large glasses of milk after fasting and measuring breath hydrogen levels a few hours later. Other diagnostic tools include analyzing an intestinal biopsy sample or determining the genetic makeup of the chromosomal region coding for lactase. However, many individuals mistakenly ascribe symptoms of a variety of intestinal disorders to lactose intolerance without undergoing testing. This becomes intergenerational when self-diagnosed lactose-intolerant parents place their children on lactose-restricted diets in the belief that the condition is hereditary.

Healthcare providers are concerned that many lactose-intolerant individuals are avoiding dairy products, which constitute a readily accessible source of calcium and are fortified with vitamin D and other nutrients. Therefore, these individuals may not be meeting recommended intakes of these essential nutrients. Insufficient intakes of calcium carry a risk of decreased bone mineral density. This may have effects on bone health and increase the risk of fracture throughout the lifecycle, especially in