

the NTP BSC on the agenda topics. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the NTP BSC chair. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to send a copy of their statement to the Executive Secretary for the NTP BSC (see **ADDRESSES** above) by November 21, 2007, to enable review by the NTP BSC prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the NTP BSC and NIEHS/NTP staff and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site and persons identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), phone, e-mail, and sponsoring organization (if any) with the document. Public comments submitted on NTP study nominations in response to a March 29, 2007, **Federal Register** notice (72 FR 14816) are posted on the NTP Web site (<http://ntp.niehs.nih.gov/go/29306>). These submissions will be part of the materials provided to the BSC and do not need to be resubmitted.

#### **Background Information on the NTP Board of Scientific Counselors**

The NTP BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the overall program and its centers. Specifically, the NTP BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping

terms of up to four years. NTP BSC meetings are held annually or biannually.

Dated: October 10, 2007.

**Samuel H. Wilson,**

*Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.*

[FR Doc. E7-20519 Filed 10-16-07; 8:45 am]

**BILLING CODE 4140-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Meeting of the President's Council on Physical Fitness and Sports**

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the President's Council on Physical Fitness and Sports will hold a meeting. This meeting is open to the public. A description of the Council's functions is included also with this notice.

**DATES:** November 7, 2007, from 8 a.m. to 3 p.m.

**ADDRESSES:** Mayo Clinic, Dan Abraham Healthy Living Center, Subway Level, Room 200, 200 First Street, SW., Rochester, Minnesota 55905.

**FOR FURTHER INFORMATION CONTACT:** Melissa Johnson, Executive Director, President's Council on Physical Fitness and Sports, 200 Independence Avenue, Room 738H, SW., Washington, DC 20201, (202) 690-5187.

**SUPPLEMENTARY INFORMATION:** The President's Council on Physical Fitness and Sports (PCPFS) was established originally by Executive Order 10673, dated July 16, 1956. PCPFS was established by President Eisenhower after published reports indicated that American boys and girls were unfit compared to the children of Western Europe. Authorization to continue Council operations was given at appropriate intervals by subsequent Executive Orders. The Council has undergone two name changes and several reorganizations. Presently, the PCPFS is a program office located organizationally in the Office of Public Health and Science within the Office of the Secretary in the U.S. Department of Health and Human Services.

On September 28, 2007, President Bush signed Executive Order 13265 to reestablish the PCPFS. Executive Order 13265 was established to expand the

focus of the Council. This directive instructed the Secretary to develop and coordinate a national program to enhance physical activity and sports participation. The Council currently operates under the stipulations of the new directive. The primary functions of the Council include: (1) To advise the President, through the Secretary, on the progress made in carrying out the provisions of the enacted directive and recommend actions to accelerate progress; (2) to advise the Secretary on ways and means to enhance opportunities for participation in physical fitness and sports and, where possible, to promote and assist in the facilitation and/or implementation of such measures; (3) to advise the Secretary regarding opportunities to extend and improve physical activity/fitness and sports programs and services at the national, State, and local levels; and (4) to monitor the need for the enhancement of programs and educational and promotional materials sponsored, overseen, or disseminated by the Council and advise the Secretary, as necessary, concerning such needs.

The PCPFS holds at a minimum, one meeting in the calendar year to (1) Assess ongoing Council activities and (2) discuss and plan future projects and programs.

Dated: October 10, 2007.

**Melissa Johnson,**

*Executive Director, President's Council on Physical Fitness and Sports.*

[FR Doc. E7-20473 Filed 10-16-07; 8:45 am]

**BILLING CODE 4150-35-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Centers for Disease Control and Prevention**

##### **Notice of Establishment**

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Secretary, Department of Health and Human Services (HHS), announces the establishment of the Board of Scientific Counselors, National Center for Public Health Informatics (NCPHI).

This board is established to ensure that the national center has access to external viewpoints, the capacity to conduct peer review of scientific programs, and perform second level peer-review of research applications.

The Board of Scientific Counselors, NCPHI will advise the Secretary, HHS, and the Director, Centers for Disease Control and Prevention; concerning strategies and goals for the programs

and research within the national centers; shall conduct peer-review of scientific programs; and monitor the overall strategic direction and focus of the national centers. The board, after conducting its periodic reviews, shall submit a written description of the results of the review and its recommendations to the Director, CDC. The board shall also perform second-level peer review of applications for grants-in-aid for research and research training activities, cooperative agreements, and research contract proposals relating to the broad areas within the national centers.

For information, contact Dr. Tom Savel, Executive Secretary, Centers for Disease Control and Prevention, of the Department of Health and Human Services, 1600 Clifton Road, NE., Mailstop E78, Atlanta, Georgia 30333, telephone 404/498-3081 or fax 404/498-6570. The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 9, 2007.

**Elaine L. Baker,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. E7-20475 Filed 10-16-07; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-5045-N]

#### Medicare Program: Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the first demonstration site for the Medicare Clinical Laboratory Services Competitive Bidding Demonstration project and the date for the Bidder's Conference. The Medicare Clinical Laboratory Competitive Bidding Demonstration was mandated by the Congress. Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) requires the Centers for Medicare & Medicaid Services (CMS) to conduct a

demonstration project on the application of competitive acquisition for clinical laboratory services that would otherwise be paid under the Medicare Part B fee schedule. The objective of the demonstration is to determine whether competitive bidding can be used to provide Part B clinical laboratory services at fees below current Medicare payment rates while maintaining quality and access to care.

The MMA specifically requires that the demonstration: (1) Includes tests paid under the Medicare Part B Clinical Laboratory Fee Schedule; (2) excludes entities that have a "face-to-face encounter" with the patient; (3) excludes Pap smears and colorectal cancer screening tests; and, (4) includes requirements under the Clinical Laboratory Improvement Amendments (CLIA) program. An initial Report to the Congress was submitted April 2006.

*Site(S):* The fundamental criteria for selecting demonstration sites require that each Metropolitan Statistical Area (MSA) allows for potential Medicare program savings from the demonstration, is administratively feasible, represents the laboratory market, and will yield demonstration results that can be generalized to other MSAs.

The first demonstration site will be the San Diego-Carlsbad-San Marcos, California MSA.

A Bidders Conference is planned for October 31, 2007 in the San Diego-Carlsbad-San Marcos, California MSA.

The demonstration covers tests provided to beneficiaries enrolled in the traditional fee-for-service (FFS) Medicare program who reside in the area of the demonstration site or competitive bid area (CBA) during the 3 year demonstration period. Beneficiaries who travel outside the CBA during the demonstration period and require laboratory services will be able to access services from most laboratories in the United States. We will not directly pay, however, for services furnished by a required bidder that did not bid or bid and did not win or a non-required bidder that bid and did not win. (The terms "required bidder" and "non-required bidder" are explained in section II below.) Laboratories may not bill beneficiaries for laboratory services covered under the Medicare program.

#### **FOR FURTHER INFORMATION CONTACT:**

Linda Lebovic at (410) 786-3402 or [lab\\_bid\\_demo@cms.hhs.gov](mailto:lab_bid_demo@cms.hhs.gov). Interested parties can obtain information about the demonstration project on the CMS Web site at [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/2004\\_Demonstration\\_Competitive\\_Bidding\\_Clinical\\_Laboratory\\_Services.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/2004_Demonstration_Competitive_Bidding_Clinical_Laboratory_Services.pdf).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amends section 1847(e) of the Social Security Act (the Act) (42 U.S.C. 1395w-3) —"Competitive Acquisition of Certain Items and Services," to include a demonstration project for clinical laboratory services. The statute requires the Secretary of Health and Human Services to conduct a demonstration project on the application of competitive acquisition for payment of clinical laboratory services that would otherwise be made under Medicare Part B Clinical Laboratory Fee Schedule.

##### **II. Provisions of the Notice**

Under section 1847(e) of the Act, Pap smears and colorectal cancer screening tests are excluded from this demonstration. Requirements under CLIA as mandated in section 353 of the Public Health Service Act apply. The aggregate amounts to be paid to contractors in a competitive acquisition area are expected to be less than the aggregate amounts that would otherwise be paid under the laboratory fee schedule. The payment basis determined for each competitive acquisition area will be substituted for payment under the existing Medicare Part B Clinical Laboratory Fee Schedule. The demonstration period is 3 years for each demonstration site or "competitive bid area" (CBA). The competitively set demonstration fee schedule will be used to pay for laboratory services in the CBA for the duration of the 3-year demonstration period. Multiple winners are expected in each CBA.

*Required bidders* are defined as those organizations that will supply, or expect to supply, at least \$100,000 annually in demonstration tests to Medicare beneficiaries residing in the CBA during any year of the demonstration. Required bidders that bid and win will be paid under one demonstration fee schedule for services provided to beneficiaries residing in the CBA for the duration of the demonstration.

*Non-required bidders* are defined as laboratories that are not exempt from the demonstration, but have the option of participating in the bidding process. Non-required bidders that do not bid as well as those that bid and win, will be paid under the demonstration fee schedule for the duration of the demonstration. These laboratories will be paid under the same fee schedule as the winning required bidders. Non-required bidders that choose to bid and