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*. Interested parties can obtain information about the demonstration project on the CMS Web site at *http://www.cms.hhs.gov/ Demo ProjectsEvalRpts/ 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

do not win will not receive payment for services provided to beneficiaries residing in the CBA for the duration of the demonstration period.

A non-required bidder is:

• A small business laboratory, which we are defining as one that will supply less than $100,000 annually in demonstration tests to Medicare FFS beneficiaries residing in the CBA during each year of the demonstration. These laboratories may choose to be a ''passive'' laboratory. A passive-small business laboratory will have a $100,000 ceiling on annual payment from Medicare for demonstration tests for the duration of the demonstration.

• A laboratory that exclusively serves beneficiaries entitled to Medicare because they have end-stage renal disease (ESRD) residing in the CBA may choose to be a ''passive'' laboratory under the demonstration. A passive-ESRD laboratory may continue to provide services to ESRD beneficiaries residing in the CBA and receive payment from Medicare for demonstration tests paid under the competitively set Part B Clinical Laboratory Fee Schedule (demonstration fee schedule) for the duration of the demonstration.

• A laboratory that exclusively serves beneficiaries residing in nursing homes or receiving home health services in the CBA may choose to be a ''passive'' laboratory under the demonstration. A passive-nursing home laboratory may continue to provide services to beneficiaries residing in nursing homes or receiving home health services in the CBA and receive payment from Medicare for demonstration tests paid under the demonstration fee schedule for the duration of the demonstration.

This notice announces a ''Bidder's Conference'' to be held in the San Diego-Carlsbad-San Marcos, California MSA on October 31, 2007 for potential bidders to learn about the demonstration rules and ask questions about the bidding process. A Bidder's Package provides information about the demonstration project and is available to the public on the CMS project Web site. There will be a single bidding competition covering demonstration tests for each CBA. Bidders will be required to submit a bid price for each Health Care Procedure Coding System (HCPCS) code in the demonstration test menu. Bidding laboratories will be asked to identify demonstration tests that they do not perform, and will be asked to explain their plans for responding to requests for demonstration tests that they do not perform in house (for example, subcontracting and referrals). As part of their bid, laboratories will provide information on ownership, location of affiliated laboratories and specimen collection sites, CLIA certification, laboratory finances, and quality.

III. Collection of Information Requirements

This information collection requirement is subject to the Paperwork Reduction Act of 1995 (PRA). The collection is currently approved under OMB control number 0938–1008 entitled ''Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project Application Form'' with a current expiration date of January 31, 2009.

Authority: Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

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

Dated: October 4, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–20499 Filed 10–16–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Novel Roles of a DNA Repair Protein, DNA-PKcs, in Obesity, Neurological Function, and Aging

Description of Technology: The catalytic subunit of the DNA-dependent protein kinase complex (DNA-PKcs) has been shown to be important in DNA repair and VDJ recombination in lymphocytes. The inventors have discovered that DNA-PKcs also plays novel, important roles in energy regulation and neurological function. The inventors observed that mature DNA-PKcs-deficient mice (also known as SCID mice) have a lower proportion of fat, resist obesity, and have significantly greater physical endurance than wild-type control mice, particularly with increasing age. The inventors also observed that DNA-PKcs-deficient mice have better memory and less anxiety. One potential explanation for this is that they express higher levels of brain-derived neurotrophic factor (BDNF), which is associated with neurogenesis, memory formation and suppression of anxiety and depression. Moreover, DNA-PKcs-deficient cells produce less oxidative stress. Thus, inhibition of DNA-PKcs may have unexpected utility in the treatment of a wide range of diseases and conditions.

The invention discloses methods of inhibiting DNA-PKcs activity to decrease adiposity, improve physical endurance and increase insulin sensitivity and the number of mitochondria. Also claimed are methods directed to improved neurological function, such as methods for protection from neurodegenerative disease, improving memory and learning ability, and for reducing depression and anxiety. Additionally, the invention discloses methods for reducing inflammation and for treating heart disease.

Applications:

Development of therapeutics targeting obesity, insulin-resistant diabetes, and age-related loss of physical endurance.

Development of therapeutics to treat neurological disorders such as depression and memory loss.

Market:

Obesity is a large and growing therapeutic market; over thirty percent of Americans are obese, and over sixty percent are overweight.

Similarly, the market for therapeutics directed to insulin-resistant, or Type 2, diabetes is rapidly expanding; the market for such drugs is expected to top $12 billion in 2012.

Loss of endurance and muscle mass is common in the elderly; the average