

Dated: November 25, 2003.

**Laura Yerdon Martin,**

*Acting Director, Executive Secretariat,  
Centers for Disease Control and Prevention.*

[FR Doc. 03-30257 Filed 12-4-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention (CDC)

#### National Center on Birth Defects and Developmental Disabilities

*Name:* Scientific Workshop on Impact of Maternal Thyroid Disease on the Developing Fetus: Implications for Diagnosis, Treatment, and Screening.

*Times and Dates:* 8 a.m.–7:30 p.m., January 12, 2004. 8 a.m.–4 p.m., January 13, 2004.

*Place:* Renaissance Atlanta Hotel Downtown, 590 West Peachtree Street, NW., Atlanta, Georgia 30308-3586, Telephone (404) 881-6000.

*Status:* Open to the public, limited only by the space available.

*Purpose:* The purpose of the workshop is to summarize the body of scientific evidence, describe the gaps in knowledge, provide direction for future research, and offer guidance for appropriate public health action if warranted.

*Matters To Be Discussed:* The agenda will include an overview of the prevalence of thyroid dysfunction in reproductive-age women and factors associated with abnormal function, outcomes related to thyroid dysfunction during pregnancy, detection and treatment of thyroid dysfunction, and considerations for public health practice.

Agenda items may be subject to change as priority dictates.

#### FOR FURTHER INFORMATION CONTACT:

Micah H. Milton, Health Scientist, National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, NE., m/s E-87, Atlanta, Georgia 30333. Telephone 404/498-3082.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: December 1, 2003.

**Joseph E. Salter,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-R-53; CMS-10102]

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

*Agency:* Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Imposition of Cost Sharing Charges Under Medicaid and Supporting Regulations contained in 42 CFR 447.53; *Form No.:* CMS-R-53 (OMB# 0938-0429); *Use:* The information collection requirements contained in 42 CFR 447.53 require the States to include in their Medicaid State Plan their cost sharing provisions for the medically and categorically needy. The State Plan is the method in which States inform staff of State policies, standards, procedures and instructions; *Frequency:* Occasionally; *Affected Public:* State, local or tribal government; *Number of Respondents:* 54; *Total Annual*

*Responses:* 20; *Total Annual Hours:* 2,700.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* National Implementation of Hospital CAHPS (HCAHPS); *Form No.:* CMS-10102 (OMB# 0938-NEW); *Use:* The HCAHPS survey instrument, developed under the CAHPS umbrella, is a reliable and valid instrument that any organization can use (at no cost) to obtain patient data about hospital experiences. This tool will be adopted by the Quality Initiative: A Public Resource on Hospital Performance. Though the main purposes of this survey are consumer choice and hospital accountability, we intend and expect that the collection and reporting of these data will stimulate quality improvements. A standardized hospital survey from the patient's perspective will generate both universal measures and comparative data for consumers who need to select a hospital, and a new incentive for hospitals to further improve quality of care and accountability. This standardized instrument will allow consumers to make "apples to apples" comparisons among hospitals, allow hospitals and hospital chains to self compare, and provide state oversight officials with useful data; *Frequency:* Annually; *Affected Public:* Individuals or households; *Number of Respondents:* 2,212,000; *Total Annual Responses:* 2,212,000; *Total Annual Hours:* 368,367.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://cms.hhs.gov/regulations/pr/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 26, 2003.

**Julie Brown,**

*Acting, Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 03-30200 Filed 12-4-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute (NHLBI): Opportunity for Cooperative Research and Development Agreements (CRADAs) To Develop Novel Mechanical and Biological Treatments in Interventional Cardiovascular Medicine Using X-Ray Fluoroscopy and/or Real-Time Magnetic Resonance Imaging

**ACTION:** Notice.

**SUMMARY:** The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) announces the opportunity for Cooperative Research and Development Agreements (CRADAs) to develop novel mechanical and biological treatments in interventional cardiovascular medicine using x-ray fluoroscopy and real-time magnetic resonance imaging. The NHLBI seeks potential Collaborators wishing to provide expertise in (1) novel biological treatments for cardiovascular disease, including agents to facilitate mobilization of bone-marrow-derived stem and progenitor cells, (2) novel agents for therapeutic angiogenesis for myocardial or peripheral artery applications, (3) novel immune-modulating agents to treat to prevent manifestations of atherosclerosis, coronary artery occlusion, or myocardial ischemia/infarction, (4) novel mechanisms of drug, gene, or cell delivery to the myocardium or skeletal muscle to treat manifestations of coronary or peripheral artery atherosclerosis, and (5) intravascular devices for real-time magnetic resonance imaging-guided treatments including but not limited to angioplasty balloons, recanalization systems, percutaneous cardiac valves, stents, endografts, and bypass grafts.

The NHLBI seeks capability statements from parties interested in entering into a potential CRADA to manufacture, prototype, and test the above-specified agents or devices leading to early clinical testing and development. The availability of private sector support may increase the feasibility of particular aspects of the

final design, but the primary criterion for selecting potential collaborators is the scientific merit of proposals for developing a plan to identify novel putative therapeutic agents and devices.

The NHLBI can provide extensive preclinical and clinical support in the development of Collaborator deliverables, including animal experiments, advanced x-ray fluoroscopic and magnetic resonance imaging laboratories, and investigations conducted in the Warren G. Magnuson Clinical Center at the Bethesda campus of the National Institutes of Health.

The control of clinical trials shall reside entirely with the Institute and the scientific participants of the trial. In the event that any adverse effects are encountered which, for legal or ethical reasons, may require communication with the U.S. Food and Drug Administration, the relevant collaborating institutions will be notified. Neither the conduct of the trial nor the results should be represented as an NHLBI endorsement of the agent, drug, or device under study.

**DATES:** Only written CRADA capability statements received by the NHLBI within 21 days of publication of this notice will be considered during the initial design phase. Confidential information must be clearly labeled. Potential collaborators may be invited to meet with the Selection Committee at the Collaborators' expense to provide additional information. The Institute may issue an additional notice of CRADA opportunity during the design phase if circumstances change or if the design alters substantially.

*For Additional Information and Questions:* Capability statements should be submitted to Ms. Peg Koelble, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 6018, Bethesda, MD 20892-7992; Tel: 301-594-4095; Fax: 301-594-3080; email: [koelblep@nhlbi.nih.gov](mailto:koelblep@nhlbi.nih.gov).

*Capability Statements:* A Selection Committee will use the information provided in the "Collaborator Capability Statements" received in response to this announcement to help in its deliberations. It is the intention of the NHLBI that all qualified Collaborators have the opportunity to provide information to the Selection Committee through their capability statements. The Capability Statement should not exceed 10 pages and should address the following selection criteria:

1. The statement should provide specific details of the method to be used in the development of novel candidate

biological treatments, delivery systems, or real-time MRI-guided mechanical treatments for cardiovascular disease.

2. The statement should include a detailed plan demonstrating the ability to provide sufficient capacity in drug, gene, or stem cell development and manufacturing or in mechanical device prototyping, testing, development, and manufacturing.

3. The statement may include outline measures of interest to the Collaborator. The specifics of the proposed outcome measures and the proposed support should include but not be limited to: expertise in the proposed field, specific personnel allocation to the proposed collaboration, specific internal or external funding commitment to support the advancement of scientific research, services, facilities, equipment, or other resources that would contribute to the conduct of the commercial development.

4. The statement must address willingness promptly to publish research results and ability to be bound by PHS intellectual property policies (see CRADA: <http://ott.od.nih.gov/newpages/crada.pdf>).

Dated: November 26, 2003.

**Carl Roth,**

*Associate Director for Scientific Program Operation, National Heart, Lung, and Blood Institute.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**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