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For the above-stated reasons, and after consulting with the Secretary as required by 42 CFR 430.15(c)(2), CMS disapproved Virginia SPA 02-09 because CMS concluded that the State had failed to demonstrate that it fulfilled the conditions as specified in section 1902(a)(30)(A) of the Act to ensure that payments are "consistent with efficiency, economy, and quality of care."

Section 1116 of the Act and 42 CFR Part 430 establish Departmental procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. CMS is required to publish a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Virginia announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. Patrick W. Finnerty, Director,
Virginia Department of Medical Assistance
Services,
600 East Broad Street, Suite 1300,
Richmond, VA 23119.

Dear Mr. Finnerty:

I am responding to your request for reconsideration of my decision, dated June 16, 2003, to disapprove Virginia State Plan Amendment (SPA) 02-09. This SPA proposes to provide supplemental payment for services rendered by a newly created class of physicians and other health professionals who are State employees affiliated with a State academic medical center. There are two supplemental payment methodologies described in the SPA. The first, effective July 2, 2002, until August 12, 2002, would provide payment equal to the difference between the amount indicated on the Medical Assistance (Medicaid) fee schedule

applicable to other providers of the same type, and the lower of Medicare-allowed amount or billed charges. The second method, effective August 13, 2002, would be equal to the difference between the Medicaid fee schedule and providers' usual and customary charges. There is no ceiling on charges during the second period.

At issue is whether the State has documented that its proposed supplemental payment methodology is consistent with efficiency, economy, and quality of care when the supplemental payment methodology: (1) Is not justified by any increased costs to the State to ensure access to services for Medicaid beneficiaries; (2) pays significantly more than other third party payers for the same services; (3) is not a usual and customary payment methodology; and (4) would unduly complicate tracking and audit processes.

Section 1902(a)(30)(A) of the Social Security Act (the Act) requires that states have methods and procedures to ensure that payments are consistent with efficiency, economy, and quality of care. The State was unable to document that other third party payers pay an amount equal to billed charges. In addition, the State did not document that the providers affected by this amendment have higher costs than other providers of the same type in the State, nor did it demonstrate that any portion of the increased payment would be required to pay actual costs incurred in order to ensure access to the Medicaid services at issue. Virginia also failed to justify why the supplemental payment is warranted for public providers only.

The supplemental payment methodology proposed by the State is not a customary method for paying physicians and other health professionals. The methodology would make it difficult to track payments for specific services and would complicate auditing processes.

For the above stated reasons, and after consulting with the Secretary as required by 42 CFR 430.15(c)(2), CMS disapproved Virginia SPA 02-09 because CMS concluded that it fulfilled the conditions as specified in section 1902(a)(30)(A) of the Act to ensure that payments are "consistent with efficiency, economy, and quality of care." Therefore, based on the reasoning set forth above, and after consultation with the Secretary as required under 42 CFR 430.15(c)(2), CMS disapproved Virginia SPA 02-09.

I am scheduling a hearing on your request for reconsideration to be held on September 25, 2003, at 10 a.m., Room 217; Second Floor; Suite 216; The Public Ledger Building; 150 South Independence Mall West; Philadelphia, Pennsylvania 19106 to reconsider our decision to disapprove Virginia SPA 02-09. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to

facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786-2055.

Sincerely,

Thomas A. Scully.

Section 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 430.18) (Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: July 28, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03-20672 Filed 8-12-03; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute: Licensing Opportunity and Cooperative Research and Development Agreement (CRADA) Opportunity to Develop Therapeutic Uses for the Newly Identified Cardiac Precursor Cells Named "SPOC" Cells

AGENCY: National Heart, Lung, and Blood Institute.

ACTION: Notice.

SUMMARY: The National Heart Lung and Blood Institute is seeking licensees and/or CRADA partners to further develop, evaluate, and commercialize therapeutic uses for the newly identified cardiac precursor cells named "spoc" cells. The U.S government-owned technology is encompassed within PCT Patent Application No. PCT/US02/33860, entitled, "Stem Cells that Transform to Beating Cardiomyocytes".

The NHLBI seeks potential Collaborator(s) wishing to provide expertise in (1) genomics/proteomics and analysis; (2) animal models of heart disease; (3) high throughput drug screening.

Prospective collaborators need only be interested in pursuing a focused aspect of the potential applications.

DATES: Only written CRADA capability statements received by the NHLBI on or before September 29, 2003, 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.

Inventions described in the patent application(s) are available for either exclusive or non-exclusive licensing in accordance with 35 U.S.C. 207 and 37 CFR part 404. Respondees interested in licensing the invention(s) should submit an "Application for License to Public Health Service Inventions."

FOR FURTHER INFORMATION AND

QUESTIONS: Questions about licensing opportunities should be addressed to Fatima Sayyid, M.H.P.M., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, Tel: 301-435-4521; Fax: 301-402-0220; E-mail: sayyidf@mail.nih.gov. Information about Patent Applications and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement.

Capability statements and questions about this CRADA opportunity should be submitted to Dr. Vincent Kolesnitchenko, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 6018, MSC 7992, Bethesda, MD 20892-7992; Tel: 301-594-4115; Fax: 301-594-3080; E-mail: kolesniv@nhlbi.nih.gov.

SUPPLEMENTARY INFORMATION: A CRADA is an agreement designed to enable certain collaborations between the Government laboratories and non-Government laboratories. It is not a grant, and is not a contract for the procurement of goods/services. The NHLBI is prohibited from transferring funds to a CRADA collaborator. Under a CRADA, NHLBI can contribute facilities, staff, materials, and expertise to the effort. The collaborator typically contributes facilities, staff, materials, expertise, and funding to the collaboration. The CRADA collaborator may elect an option to negotiate an exclusive or non-exclusive license to Government intellectual property rights arising under the CRADA in a predetermined field of use and may qualify as a co-inventor of new technology developed under the CRADA.

Respondees interested in licensing the technology will be required to submit an Application for License to Public Health Service Inventions. Inventions described in the patent application(s) are available for either exclusive or non-

exclusive licensing in accordance with 35 U.S.C. 207 and 37 CFR part 404. Information about patent application(s) and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement.

Technology Description: Spoc cells are a previously unknown subpopulation of stem cells in adult murine skeletal muscle that can be transformed into beating cardiomyocytes in primary tissue culture. These cells are not satellite cells, myofibroblasts or myoblasts or hematopoietic stem cells. A portion of these marked freshly isolated spoc cells, injected into the tail vein of a mouse with an acute myocardial infarct populates the infarct in 2 weeks time; by 3 months they differentiate into cardiac myocytes in the region of the infarct. Spoc cells can be used to isolate orthologue human cells that may be useful in treating chronic and acute heart failure. These cells may also be used to produce cell lines from transgenic animals with targeted genes that are important to cardiac function. Such cell lines will be useful in high throughput pharmaceutical screening projects.

Capability Statements: A Selection Committee will use the information provided in the "Collaborator Capability Statements" received in response to this announcement to help 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 criteria:

(1) The ability to collaborate with NHLBI on further research and development of this technology. This ability can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to on-going research and development.

(2) Expertise and experience in the following area: genomics/proteomics and analysis; animal models of heart disease; high throughput drug screening. Prospective collaborators need only be interested in pursuing a focused aspect of the potential applications.

(3) The demonstration of adequate resources to perform the research, development and commercialization of this technology (e.g., facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

(4) The willingness to cooperate with the NHLBI in the timely publication of research results and to accept the legal provisions and language of the CRADA with only minor modifications, if any.

Dated: July 24, 2003.

Lili Portilla,

Director, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute.

Dated: August 4, 2003.

Steven M. Ferguson,

Acting Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 03-20561 Filed 8-12-03; 8:45 am]

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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 agencies 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.

Microscopy Imaging System, Filter, and Method for Controlling the Illuminating Light Path of a Fluorescence Microscope

Bechara Kachar (NIDCD)

U.S. Provisional Application Serial No. 60/463,318 filed 17 Apr 2003 (DHHS Reference No. E-172-2003/0-US-01)

Licensing Contact: Michael Shmilovich; 301/435-5019; shmilovm@mail.nih.gov