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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 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." 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.

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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