

suppliers on a capitated basis. The local unit of government could select all willing suppliers or use a limited number of suppliers and use savings from efficiencies to provide added services.

The demonstration offers the selected units of government a great deal of flexibility, as long as the government entity establishes a delivery system that ensures access to care and quality services under a budget neutral capitated payment rate.

We will select up to three units of local government, using a competitive application process. A qualifying unit of local government is defined as a city, county, or incorporated town. A demonstration project can only exclude beneficiaries enrolled in Medicare Part B who reside within the unit if geographic features make coverage impractical for a specified area. In such case, up to 20 percent of the unit's Part B enrollees may be excluded.

An independent panel will review proposals. Areas that will be examined include: Statement of the Problem; Organizational Capability; Service Delivery, Operations, and Quality Assurance; Payment Methodology and Implementation.

#### IV. Final Selection

The final selection of up to three demonstration projects will be made by our Administrator from among the most highly qualified applicants. The Administrator will make the selection giving greater emphasis to proposals that have strong evidence of service delivery, operations, and quality assurance; the implementation plan; organizational capability; and payment methodology. The operational protocols for the payment system, coverage process, eligibility determination, and claims payment must be approved by us prior to implementation. We reserve the right to conduct site visits to the awardees' location prior to making awards. An independent contractor, selected and funded by us, will design and conduct an evaluation of the demonstration after its conclusion. The awardee will be required to cooperate with the contractor conducting the evaluation.

**Authority:** Section 4532 of the Balanced Budget Act of 1997, (Pub. L. 105-33); and Section 225 of the Balanced Budget Refinement Act of 1999, (Pub. L. 106-113). (Catalog of Federal Domestic Assistance Program No. 93.779, Health Care Financing Research, Demonstrations and Evaluations)

Dated: October 17, 2000.

**Michael M. Hash,**

*Acting Administrator, Health Care Financing Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration [HCFA-1157-N]

#### Medicare Program; December 12, 2000, Meeting of the Competitive Pricing Advisory Committee

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Competitive Pricing Advisory Committee (the CPAC) on December 12, 2000. The Balanced Budget Act of 1997 (BBA) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. The BBA requires the Secretary to create the CPAC to make recommendations on demonstration area designation and appropriate research designs for the project. The CPAC meetings are open to the public.

**DATES:** The meeting is scheduled for December 12, 2000, from 9 a.m. until 12 noon, e.s.t.

**ADDRESSES:** The meeting will be held at the Marriott Wardman Park Hotel, 2660 Woodley Road N.W., Washington, D.C. 20008.

**FOR FURTHER INFORMATION CONTACT:** Sharon Arnold, Ph.D., Executive Director, Competitive Pricing Advisory Committee, Health Care Financing Administration, 7500 Security Boulevard C4-14-17, Baltimore, Maryland 21244-1850, (410) 786-6451. Please refer to the HCFA Advisory Committees Information Line (1-877-449-5659 toll free) / (410-786-9379 local) or the Internet (<http://www/hcfa.gov/fac>) for additional information and updates on committee activities.

**SUPPLEMENTARY INFORMATION:** Section 4011 of the Balanced Budget Act of 1997 (BBA), Public Law 105-33, requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under

which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. Section 4012(a) of the BBA requires the Secretary to appoint a Competitive Pricing Advisory Committee (the CPAC) to meet periodically and make recommendations to the Secretary concerning the designation of areas for inclusion in the project and appropriate research design for implementing the project. The CPAC has previously met on May 7, 1998, June 24 and 25, 1998, September 23 and 24, 1998, October 28, 1998, January 6, 1999, May 13, 1999, July 22, 1999, September 16, 1999, October 29, 1999, January 12, 2000, and May 23, 2000.

The CPAC consists of 15 individuals who are independent actuaries; experts in competitive pricing and the administration of the Federal Employees Health Benefit Program; and representatives of health plans, insurers, employers, unions, and beneficiaries. The CPAC members are: James Cubbin, Executive Director, General Motors Health Care Initiative; Robert Berenson, M.D., Director, Center for Health Plans and Providers, HCFA; John Bertko, Actuary Principal, Humana Inc.; David Durenberger, Vice President, Public Policy Partners; Gary Goldstein, M.D., Chief Medical Officer-Health Plans, Humana Inc.; Samuel Havens, Healthcare Consultant; Margaret Jordan, Executive Vice President, Texas Health Resources; Chip Kahn, President, The Health Insurance Association of America; Cleve Killingsworth, President and CEO, Health Alliance Plan; Nancy Kichak, Director, Office of Actuaries, Office of Personnel Management; Len Nichols, Principal Research Associate, The Urban Institute; Robert Reischauer, President, The Urban Institute; John Rother, Director, Legislation and Public Policy, American Association of Retired Persons; Andrew Stern, President, Service Employees International Union, AFL-CIO; and Jay Wolfson, Director, The Florida Information Center, University of South Florida. The Chairperson is James Cubbin and the Co-Chairperson is Robert Berenson, M.D. In accordance with section 4012(a)(5) of the BBA, the CPAC will terminate on December 31, 2004.

The agenda for the December 12, 2000, meeting will include a continuing discussion on the components of a Report to Congress being prepared by the CPAC. Section 533 of the Medicare, Medicaid, and State Child Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999, Public Law 106-113, revised section 4011 of

the BBA to require the CPAC to submit a report on the following topics:

- Incorporation of original Medicare fee-for-service into the demonstration.
- Requirements of quality activities under the demonstration.
- Inclusion of a rural area in the demonstration.
- Requirements of a benefit structure under the demonstration.

The CPAC will also develop recommendations for how it should proceed in the future to carry out its responsibilities under the BBA.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director, by 12 noon, December 7, 2000, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director, no later than 12 noon, December 11, 2000. Anyone who is not scheduled to speak, may submit written comments to the Executive Director, by 12 noon, December 11, 2000.

The meeting is open to the public, but attendance is limited to the space available. Individuals requiring sign language interpretation for the hearing impaired or other special accommodation should contact the Executive Director at least 10 days before the meeting.

(Section 4012 of the Balanced Budget Act of 1997, Public Law 105-33 (42 U.S.C.1395w-23 note) and section 10(a) of Public Law 92-463 (5 U.S.C. App.2, section 10(a))

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

Dated: November 6, 2000.

**Michael M. Hash,**

*Acting Administrator, Health Care Financing Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) Collaboration in the Identification, Characterization and Development of Inhibitors of the Smad3 Signaling Protein for Use in the Treatment of Wounds and Fibrotic Diseases Characterized by Chronic Inflammation**

**AGENCY:** National Institutes of Health, PHS, DHHS.

#### **ACTION:** Notice.

The National Cancer Institute's Laboratory of Cell Regulation and Carcinogenesis (LCRC) has characterized the role of the Smad3 signaling molecule in wound healing and has developed several mouse models of fibrosis. NCI would like to use its expertise of Smad3 biology in a collaboration with an outside party to identify and characterize inhibitors of Smad3 activity.

**SUMMARY:** The National Cancer Institute (NCI) seeks a Cooperative Research and Development Agreement (CRADA) Collaborator to aid NCI in the identification and development of inhibitors of the function of the Smad3 signaling protein. Smad3 and a closely related gene, Smad2, act as nuclear transcriptional activators in response to intracellular signals from the transforming growth factor betas (TGF-betas) and activin molecules (1,2). The existence of these genes was first proposed after a screen for developmental mutations in the nematode led to the identification of three genes, *sma-2*, *sma-3*, and *sma-4*, that were homologs of *Drosophila* MAD, a protein with a role in the signaling of a TGF-beta superfamily ligand (3). The Smad2 and Smad3 signaling pathways play important roles in the cellular proliferation, differentiation and migration crucial to cutaneous wound healing and the induction of fibrosis in diseases characterized by chronic inflammation (4).

NCI has generated a line of mice that are homozygously deleted in the Smad3 gene (Smad3<sup>ex8/ex8</sup> mice). These mice have made it possible for NCI to examine the contribution of Smad3 in cutaneous wound healing. Smad3<sup>ex8/ex8</sup> mice survive into adulthood and show accelerated cutaneous wound healing characterized by an increased rate of re-epithelialization and a reduced local inflammatory infiltrate of monocytes and neutrophils. Thus, Smad3 appears to mediate in vivo signaling pathways that mediate key aspects of wound healing including influx of inflammatory cells and control of epithelial cell proliferation and migration. NCI's studies indicate that inhibitors of Smad3 function, such as specific, small molecule or antisense-related compounds, may accelerate cutaneous wound healing and may even be beneficial to other processes such as the treatment of extensive burns, the suppression of radiation-induced scarring, the growth of autologous skin grafts and the treatment of fibrotic diseases characterized by chronic inflammation.

NCI is looking for a CRADA Collaborator with a demonstrated record of success in the isolation and characterization of small molecule protein inhibitors. The proposed term of the CRADA can be up to five (5) years.

**DATES:** Interested parties should notify this office in writing of their interest in filing a formal proposal no later than January 22, 2001. Potential CRADA Collaborators will then have an additional thirty (30) days to submit a formal proposal. CRADA proposals submitted thereafter may be considered if a suitable CRADA Collaborator has not been selected.

**ADDRESSES:** Inquiries and proposals regarding this opportunity should be addressed to Holly Symonds Clark, Ph.D., Technology Development Specialist (Tel. #301-496-0477, FAX #301-402-2117), Technology Development and Commercialization Branch, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852. Inquiries directed to obtaining patent license(s) for the technology NIH reference No. E-070-00/0, filed May 19, 2000 for "Inhibition of Smad3 to Prevent Fibrosis and to Improve Wound Healing" (Roberts and Ashcroft), should be addressed to Marlene Shinn M.S., J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, (Tel. 301-496-7056, ext. 285; FAX 301-402-0220).

**SUPPLEMENTARY INFORMATION:** A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into with NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995. NCI is looking for a CRADA partner to aide NCI in the characterization and development of inhibitors of the function of the Smad3 signaling protein. The expected duration of the CRADA would be from one (1) to five (5) years.

The members of the transforming growth factor-beta (TGF-beta) superfamily are multi-functional growth factors that are responsible for a variety of biological processes in tissue homeostasis, differentiation, morphogenesis and development of multicellular animals (for reviews see 5, 6). They transduce their signals from the plasma membrane to nuclei of target cells through distinct combinations of a family of serine/threonine kinase receptors. Once activated by specific phosphorylation events, these receptors