

Dated: July 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission of Childhood Vaccines; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), as enacted by Public Law (Pub. L.) 99-660 and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

DATES: The agency must receive nominations on or before August 21, 2003.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Office of Special Programs, HRSA, Parklawn Building, Room 16C-17, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl A. Lee, Principal Staff Liaison, Policy Analysis Branch, Division of Vaccine Injury Compensation, at (301) 443-2124 or e-mail: cleeh@hrsa.gov.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and Section 2119 of the Act, 42 U.S.C. 300aa-19, as added by Public Law 99-660 and amended, HRSA is requesting nominations for three voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP. The activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse

reactions; surveying Federal, State, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b); advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; and recommending to the Director of the National Vaccine Program that vaccine safety research be conducted on various vaccine injuries.

The ACCV consists of nine voting members appointed by the Secretary as follows: Three health professionals, who are not employees of the United States Government and have expertise in the health care of children, the epidemiology, etiology and prevention of childhood diseases, and the adverse reactions associated with vaccines, at least two shall be pediatricians; three members from the general public, at least two shall be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and three attorneys, at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and one shall be an attorney whose specialty includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as nonvoting ex officio members.

Specifically, HRSA is requesting nominations for three voting members of the ACCV representing: (1) A pediatrician with special experience in childhood diseases; (2) an attorney whose specialty includes representation of a vaccine manufacturer; and (3) a member from the general public. Nominees will be invited to serve a 3-year term beginning January 1, 2004, and ending December 31, 2006.

Interested persons may nominate one or more qualified persons for membership on the ACCV. Nominations shall state that the nominee is willing to serve as a member of the ACCV and appears to have no conflict of interest that would preclude the ACCV membership. Potential candidates will be asked to provide detailed information concerning consultancies, research grants, or contracts to permit evaluation of possible sources of conflicts of interest. A curriculum vitae or resume

should be submitted with the nomination.

The Department of Health and Human Services has special interest in assuring that women, minority groups, and the physically disabled are adequately represented on advisory committees; and therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or physically disabled candidates.

Dated: July 10, 2003.

Elizabeth M. Duke,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[HRSA-03-039]

Fiscal Year 2003 Competitive Application Cycle for the Healthy Communities Access Program (HCAP); CFDA Number 93.252

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds for new awards.

Legislative Authority: The "Health Care Safety Net Amendments of 2002" (Pub. L. 107-251) amended Part D of Title III of the Public Health Service (PHS) Act by inserting a new Subpart V, Section 340, creating the Healthy Communities Access Program (HCAP). Section 340 of the PHS Act (42 U.S.C. 256) authorizes the award of competitive grants to eligible entities to assist in the development of integrated health care delivery systems to serve communities of individuals who are uninsured and/or underinsured.

Purpose: To provide assistance to communities and consortia of health care providers and others they represent to develop or continue activities to strengthen integrated community health care delivery systems that coordinate health care services for individuals who are uninsured or underinsured, and to develop or strengthen activities related to providing coordinated care for individuals with chronic conditions who are uninsured or underinsured.

Eligibility: Tribal, faith-based and community-based organizations are encouraged to apply. For an entity to be eligible to receive a new HCAP award, the following requirements must be met:

1. The applicant entity must represent a consortium whose principal purpose

is to provide a broad range of coordinated health care services to their defined community's uninsured and underinsured populations.

2. The community-wide consortium represented by the applicant entity must include at least one of each of the following providers that serve the stated community, unless such provider does not exist, declines or refuses to participate, or places unreasonable conditions on its participation:

- A Federally qualified health center (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa));
- A hospital with a low-income utilization rate (as defined in section 1923(b)(3) of the Social Security Act (42 U.S.C. 1396r-4(b)(3))), that is greater than 25 percent;
- A public health department; and
- An interested public or private sector health care provider or an organization that has traditionally served the medically uninsured and underserved.

3. The applicant entity is neither a current nor former Community Access Program (CAP) grantee and is proposing to serve either a service area or target population of uninsured and underinsured individuals that has not been exclusively served by a previous CAP grant.

For an existing CAP grantee to be eligible to receive a completing Continuation HCAP award, the following requirements must be met.

1. The applicant entity must represent a consortium whose principal purpose is to provide a broad range of coordinated health care services to their defined community's uninsured and underinsured populations.

2. The community-wide consortium represented by the applicant entity must include at least one of each of the following providers that serve the stated community, unless such provider does not exist, declines or refuses to participate, or places unreasonable conditions on its participation:

- A Federally qualified health center (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa));
- A hospital with a low-income utilization rate (as defined in section 1923(b)(3) of the Social Security Act (42 U.S.C. 1396r-4(b)(3))), that is greater than 25 percent;
- A public health department; and
- An interested public or private sector health care provider or an organization that has traditionally served the medically uninsured and underserved.

Existing CAP grantees seeking a 4th year if funding must demonstrate extraordinary circumstances, *i.e.*, an event (or events) outside the control of the eligible entity that has prevented the eligible entity from fulfilling the objectives described by such entity in their approved grant application for the budget period for the preceding fiscal year. The event(s) and impact, or impact alone, of any of the extraordinary circumstances noted below must have occurred during the applicant's budget period (September 1, 2002–August 31, 2003) for the preceding fiscal year. Examples include: Natural disasters or other major disruptions to the security or health of the community served by the applicant that directly and adversely affect the applicant; or significant economic deteriorations in the community served by the applicant that directly and adversely affect the applicant.

DATES: The timelines for application submission and award are as follows:

Application Deadline: August 26, 2003.

Grant Awards Announced: September 28, 2003.

Applications will be considered on time if they are received by 5 p.m. eastern standard time on August 26, 2003 or before the established deadline. Applicants should obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service or request a legibly dated U.S. Postal Service postmark. Private metered postmarks will not be accepted as proof of timely mailing. Applicants sent to any address other than that specified below are subject to being returned. Applicants will receive notification of their application receipt. Applicants should note that HRSA will be accepting grant applications online in the last quarter of the fiscal year (July through September). Please refer to the HRSA grants schedule at <http://www.hrsa.gov/grants.htm> for more information.

How To Request and Submit an Application: To obtain a complete application kit (*i.e.*, application instructions, necessary forms, and application review criteria), call toll free 1-877-HRSA-123 (1-877-477-2123). When contacting the HRSA Grants Application Center (GAC) please refer to the program announcement number HRSA-03-39 and the name of this program.

An original and two copies of the application must be sent to: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland 20879; FAX: 1-877-HRSA-

345 (1-877-477-2345); E-mail: hrsagac@hrsa.gov.

Application Review and Funding Criteria: Each application received by the deadline will be screened for eligibility. An application will be considered eligible if it meets all of the specific eligibility requirements listed above. Applications that do not meet the eligibility requirements will not be accepted for processing and will be returned. An Objective Review Committee (ORC) will review all eligible applications. The review criteria used by the Objective Review Committee to assess each application (out of 100 points) will include:

- *Community Health Care Delivery System Needs Assessment (maximum 10 points):* Extent to which the applicant clearly defines the service area and target population of uninsured and underinsured individuals for the project and provides a detailed assessment of the current delivery system for the applicant's uninsured and underinsured populations so as to describe the extent of unmet need for a more coordinated system of care.

- *Consortium Organizational and Functional Structure (Maximum 15 Points):* Extent to which the applicant describes the history, membership, functional structure, accountability, and strategies of the applicant's HCAP consortium in terms of its capacity to implement an efficient, higher quality, comprehensive system of care for the stated target population of uninsured and underinsured individuals.

- *Project Work Plan (Maximum 35 Points):* Extent to which the applicant's work plan demonstrates the clarity, feasibility, and scope of proposed activities, goals, and measurable objectives which are consistent and aligned with stated needs and will develop or strengthen an integrated community health care delivery system that provides more efficient, effective, coordinated, and quality care at a lower cost for the stated population of uninsured or underinsured individuals.

- *Program Performance Plan (Maximum 15 Points):* Extent to which the applicant provides an appropriate plan for evaluation of the activities carried out under the grant that ensures monitoring and measurement of progress towards the corresponding goals and objectives as well as the use of evaluation findings to improve program performance and support sustainability.

- *Sustainability Plan (Maximum 15 Points):* Extent to which the applicant provides an appropriate plan for long-term project sustainability and community-reinvestment for HCAP

activities through decreasing dependence on Federal funds.

- **Budget (Maximum 10 Points):**

Extent to which the applicant presents a detailed, clear and comprehensive budget that is appropriate and reasonable for the scope of proposed activities described in the Project Work Plan and which adequately documents and demonstrate the use of non-Federal contributions to the greatest extent possible for the proposed HCAP project.

Further evaluation/review criteria detail will be listed in the application guidance.

Funding Preference: A funding preference is defined as the funding of a specific category or group of approved applications ahead of other categories or groups of approved applications. There is one preference under this funding opportunity. A preference will be accorded to applicants that demonstrate the greatest extent of unmet need in the community involved for a more coordinated system of care.

Matching or Cost Sharing

Requirement: No match or cost sharing required.

Estimated Amount of Available Funds: \$35,000,000 for New Awards and \$70,000,000 for Competing Continuations.

Estimated Number of Awards: Up to 35 New Awards and 100 Competing Continuations.

Estimated Average Size of Each Award: New awards will range from \$800,000 to \$900,000 and Competing Continuations will range from \$600,000 to \$700,000.

Estimated Project Period: Up to three years for new award. For competing continuations, Cap Grantees that received: (1) Their initial funding in fiscal year 2000 are eligible for a one year project period under Extraordinary Circumstances; (2) their initial funding in fiscal year 2001 are eligible for a one year project period under this announcement; and (3) their initial funding in fiscal year 2002 are eligible for up to a two year project period under this announcement.

FOR FURTHER INFORMATION CONTACT:

Tracy McClintock, phone number: (301) 594-4300, e-mail: tmccclintock@hrsa.gov.

Paperwork Reduction Act: The application for the Healthy Communities Access Program has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 0920-0428.

Public Health System Reporting Requirements: Under these requirements (approved by the Office of

Management and Budget under OMB number 0937-0195), a community-based non-governmental applicant must prepare and submit a Public Health System Impact Statement to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date. This statement must include:

1. A copy of the face page of the application (SF 424) and
2. A summary of the project, not to exceed one page, which provides:
 - a. A description of the population to be served,
 - b. A summary of the services to be provided, and
 - c. A description of the coordination planned with the appropriate State and local health agencies.

Executive Order 12372: This program has been determined to be subject to provisions of Executive Order 12372, as implemented by 45 CFR part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The Form PHS 5161 contains a listing of States that have set up a review system and will provide a State Point of Contact (SPOC) in the State for the review. A list of SPOC contacts is also available at <http://www.whitehouse.gov/omb/grants/spoc.html>. Applicants (other than federally-recognized Indian tribal governments) should contact their SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State.

Except in unusual circumstances, the due date for State process recommendations is at least 60 days from the deadline date established by the Secretary. 45 CFR 100.8(a)(2). In this instance, there are less than 90 days before the end of the 2003 fiscal year (on September 30, 2003). Due to this unusual circumstance, HRSA is establishing a 30-day due date for State process recommendations to assure timely consideration of such recommendations. The HRSA does not guarantee that it will accommodate or explain its responses to State process recommendations received after the due date (See "Intergovernmental Review of Federal Programs" Executive Order 12372, and 45 CFR Part 100, for a description of the review process and requirements).

Dated: July 15, 2003.

Elizabeth M. Duke,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the Teleconference meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Prevention (CSAP) National Advisory Council in July 2003.

The agenda will include the review, discussion, and evaluation of individual grant applications. Therefore the Teleconference meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App.2, 10(d).

A roster of committee members and substantive program information may be obtained from Carol Watkins, Executive Secretary, Rockwall II Building, Suite 900, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-9542.

Committee Name: SAMHSA Center for Substance Abuse Prevention National Advisory Council.

Meeting Dates: Monday, July 21, 2003, 3-5 p.m. (Closed Session).

Meeting Place: Center for Substance Abuse Prevention, 5515 Security Lane, Rockwall II Building, Conference Room I, Room 900, Rockville, Maryland, Telephone (301) 443-0365.

Contact: Carol D. Watkins, Executive Secretary, 5600 Fishers Lane, Rockwall II Building, Suite 900, Rockville, Maryland 20857, Telephone: (301) 443-9542.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: July 16, 2003.

Toian Vaughn,

Executive Secretary/Committee Management Officer, Substance Abuse and Mental Health Services Administration.

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