

rulemaking consistent with the recommendations of the Task Force. As also recommended by the Task Force, FDA intends, within 1 year, to initiate notice-and-comment rulemaking to establish scientific review criteria and procedures for qualified health claim petitions. By that time, FDA expects to complete the consumer studies research as described in the Task Force report (attachment D). The results of this research, together with further evaluation of the regulatory alternatives identified by the Task Force, with the benefit of public comment, and evaluation of any additional alternatives that stakeholders suggest in response to the advance notice of proposed rulemaking, will inform the rulemaking FDA intends to initiate.

Dated: July 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2003 Competitive Application Cycle for Operational Health Center Networks (OHCN) CFDA Number 93.224, HRSA-03-105

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of up to \$2,100,000 to support costs associated with the operation of a practice management or managed care network or plan, including the purchase or lease of equipment (including the costs of amortizing the principal of, and paying the interest on, loans for equipment).

Authorizing Legislation: Section 330(e)(1)(C) of the Public Health Service Act, as amended authorizes support to health centers that receive assistance under section 330, or at the request of the health centers, directly to a managed care or practice management network or plan that is at least majority controlled and, as applicable, at least majority owned by such health centers receiving assistance under section 330 for the costs associated with the operation of such network or plan, including the purchase or lease of equipment (including the costs of amortizing the principal of, and paying the interest on, loans for equipment). Operational

networks are defined as a group of three or more health centers that can demonstrate that an essential, mission-critical function is performed at the network level for the network members, enabling the member centers to perform their business and clinical operations more efficiently and effectively.

DATES: The intended time lines for application submission, review, and award are as follows:

Application Deadline: August 11, 2003.

Grant awards announced: September 30, 2003.

Applications will be considered on time if they are: (1) received by 5 p.m. Eastern Standard Time on August 11, 2003; or (2) postmarked on or before the deadline date given in the **Federal Register** notice and received in time for orderly processing. Applications submitted after the deadline date will be returned to the applicant and not processed. 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 shall not be accepted as proof of timely mailing. Applications sent to any address other than that specified below are subject to being returned. Applicants should note that HRSA anticipates 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.

Where to request and send an application: To obtain a complete application kit, (i.e., application instructions, necessary forms, and application review criteria), contact the HRSA Grants Application Center (GAC) at: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland 20879, Phone: 1-877-HRSA-123 (1-877-477-2123), Fax: 1-877-HRSA-345 (1-877-477-2345), Email: hrsagac@hrsa.gov.

When contacting the HRSA GAC please use the following program announcement when requesting application materials: HRSA-03-105, citing "Operational Health Center Networks." Send the original and two copies of the application to the HRSA GAC. Applicants will receive a letter acknowledging the receipt of their application.

Eligible applicants: The following entities are eligible to apply for funding under this announcement:

1. A health center, as defined and funded under section 330 of the Public Health Service Act, acting on behalf of

the member health centers and the network.

(A) A health center applying on behalf of a managed care network or plan must have received Federal grants under subsection (e)(1)(A) of section 330 for at least the two consecutive preceding years.

(B) A health center (Community Health Center, Migrant Health Center, Health Care for the Homeless, Public Housing Primary Care and Healthy Schools, Healthy Communities) applying on behalf of a practice management network must have received Federal grants under section 330 for at least the two consecutive preceding years.

2. Operational networks, controlled by and acting on behalf of the health center(s) as defined and funded under section 330 of the Public Health Service Act. At the request of all the member health centers, a network may apply for direct funds if it is at least majority controlled and, as applicable, at least majority owned, by such health centers.

3. Eligibility is limited to public and non-profit organizations, including faith-based and community organizations.

Matching or cost sharing requirement: Grantees must provide at least 60 percent of the total approved cost of the project. The total approved cost of the project is the sum of the HRSA share and the non-Federal share. Applicants must demonstrate that at least 30 percent of the cost sharing requirement is met through cash contributions. The remaining non-Federal share may be met by cash or in-kind contributions.

Application review and funding criteria: Each application submitted by the deadline will be reviewed initially for completeness and eligibility. Applications that are determined to be ineligible, incomplete, or non-responsive will be returned to the applicant without further consideration. Those applications that are determined to be eligible and responsive to the requirements will be reviewed by a panel of reviewers comprised of non-Federal experts using the following objective review criteria:

1. Appropriateness in meeting expectations of the Integrated Shared Development Initiative—extent to which the application effectively demonstrates the integration and coordination of primary care across business and clinical functions of network members.

2. Appropriateness to State Environment and Marketplace—extent to which the application demonstrates both the (a) appropriateness of the network to the State marketplace and/or

environment, and (b) strengthened position (*i.e.*, financial condition, competitive position) of its member health centers in the State marketplace and/or environment.

3. Strength of Collaboration—extent to which commitment (as evidenced by the contribution of time, resources, cash, *etc.*) by each network member is demonstrated in the business plan, implementation plan, strategic plan, budget spreadsheet and accompanying narrative, and operational agreement.

4. Network Operation: Core Strength and Competencies—extent to which the network design is suited to the organizational/administrative capacity of the network members based on operational history of the network.

5. Capacity of the Network to Support Shared/Integrated Operations—extent to which network members have shared and/or integrated functions or components of their systems.

Funding preference: A funding preference is defined as the funding of a specific category or group of approved applications ahead of other categories of applications. A preference will be given to applicants proposing to serve sparsely populated rural or frontier areas.

Estimated amount of available funds: For fiscal year 2003, up to \$2,100,000 will be available for this program.

Estimated project period: 3 years.

Estimated number of awards: This is a new program; the estimated number of awards may range from 5 to 7 in fiscal year 2003.

Estimated or average size of each award: This is a new grant program; the estimated costs are expected to vary considerably with a range from \$150,000 to \$300,000.

Information contact: Applicants may contact Christie Brown by phone at 301-594-4314 or by email at CBrown1@hrsa.gov.

Paperwork Reduction Act: The application for Operational Health Center Networks 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 a program that is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, 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 application packages pursuant to this notice will contain a listing of States with review systems and will provide a single point of contact (SPOC) in the State for review. A SPOC list 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. The due date for State process recommendations is 60 days after the applicable Federal application receipt due date. The granting agency does not guarantee to “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: June 25, 2003.

Elizabeth M. Duke,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Indian Health Service Contract Health Service; Purchase-Delivery Order for Health Service

AGENCY: Indian Health Service, HHS.

ACTION: Request for public comment: 30-day proposed information collection:

Indian Health Service Contract Health Service Purchase-Delivery Order for Health Service.

SUMMARY: The Indian Health Service, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. As required by section 3507(a)(1)(D) of the Act, the proposed information collection has been submitted to the Office of Management and Budget (OMB) for review and approval.

The IHS received no comments in response to the 60-day **Federal Register** notice (67 FR 77800) published on December 19, 2002. The purpose of this notice is to allow an additional 30 days for public comment to be submitted directly to OMB.

Proposed Collection

Title: 0917-0002, re-titled “Indian Health Service Contract Health Service Purchase-Delivery Order for Health Service.” **Type of Information Collection Request:** Reinstatement, without change, of a previously approved collection for which approval has expired. **Form number:** IHS-843-1A. **Need and Use of Information Collection:** Respondents certify that they have performed the health care services authorized by the IHS. Information is used to manage, administer and plan for the provisions of health care services to eligible American Indians, process payments to providers, obtain program data, provide program statistics, and serve as a legal document for health care services rendered. **Affected Public:** Businesses or other for-profit, Individuals or Households, Not-for-profit institutions, and State, local or Tribal Government. **Type of Respondents:** Health care providers.

The table below provides the following: types of data collection instructions, estimated number of respondents, number of responses per respondent, annual number of responses, average burden hour per response, and total annual burden hours.