reports, (4) the status of concluded postmarketing studies as determined by FDA, and (5) the number of open postmarketing commitments for which FDA did not receive an annual report.

Additional information about postmarketing study commitments made by sponsors to CDER and CBER are provided on FDA's Web site at *http://www.fda.gov/cder*. Like this notice, the site does not list postmarketing study commitments containing proprietary information. It is FDA policy not to post information on the Web site until it has been reviewed for accuracy. The information currently available on the site includes only postmarketing study commitments made since January 1, 1991. The numbers published in this notice cannot be compared with the numbers resulting from searches of the Web site. This notice incorporates totals for all postmarketing study commitments in FDA databases, including those made prior to 1991 as well as those undergoing review for accuracy. The report in this notice will be updated annually while the Web site will be updated quarterly (in April, July, October, and January).

II. Summary of Information From Postmarketing Study Progress Reports

This report summarizes the status of postmarketing commitments as of September 30, 2002. If a commitment did not have a schedule and a postmarketing progress report was not received, the commitment is categorized according to the most recent information available to the agency.

Data in table 1 are numerical summaries generated from FDA databases. The data are broken out according to application type (NDAs/ANDAs or BLAs).

TABLE 1.—SUMMARY OF POSTMARKETING STUDY COMMITMENTS TO CBER AND CDER

(NUMBERS AS OF SEPTEMBER 30, 2002)

	NDAs/ANDAs (% of total)	BLAs (% of total)
Applicants with open postmarketing commitments	126	44
Number of open postmarketing commitments	1,339	223
Status of open postmarketing commitments		
• Pending	820 (61%)	67 (30%)
• Ongoing	285 (21%)	102 (46%)
• Delayed	25 (2%)	17 (8%)
• Terminated	8 (1%)	2 (1%)
• Submitted	201 (15%)	35 (16%)
Concluded studies	349	52
• Commitment met	240 (69%)	47 (90%)
• Commitment not met	0 (0%)	1 (2%)
• Study no longer needed or feasible	109 (31%)	4 (8%)
Open postmarketing commitments with annual report due but not received	289 (22%)	77 (35%)

Dated: May 12, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12720 Filed 5–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA–03–87 Notice of Cooperative Agreement to Plan, Develop, Implement, and Operate a Continuing Clinical Education Program in the Pacific Basin (CPAC) CFDA Number 93.884

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for a Cooperative Agreement for fiscal year (FY) 2003 to Plan, Develop, Implement, and Operate a Continuing Clinical Education Program in the Pacific Basin.

The purpose of this Cooperative Agreement is to plan, develop, implement and operate a continuing clinical education (CCE) program in the U.S-Associated Pacific Islands. Six island jurisdictions comprise the U.S.-Associated Pacific Basin: American Samoa, the Commonwealth of the North Mariana Islands, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands and the Republic of Palau. A cooperative agreement will be awarded to assist the eligible entity to develop, implement and operate a CCE program in the U.S.-Associated Pacific Basin. The goal is to meet the needs of the health care workforce in all six island jurisdictions by providing training to a full range of primary care and allied health providers emphasizing cultural competency and distance learning; developing a needs assessment to identify the specific educational needs and develop curricula and recruit faculty; demonstrate linkages and relationships within all six island jurisdictions; and establish an advisory board with all six island jurisdictions represented.

The Pacific Basin health care workforce is comprised of Pacific Basin Medical Officers and other primary care providers (family physicians, general internists, general pediatricians, dental professionals, physician assistants, nurses, health assistants, and allied health workers). Allied Health professionals include health professionals who have received a certificate, an associate's degree, a

bachelor's degree, a master's degree, a doctoral degree, or post baccalaureate training, in a science relating to health care. Allied health professionals may include, but are not limited to, speech pathologists, physical therapists, physical therapy assistants, nutritionists, dental hygienists, dental assistants, medical technologists, cytotechnologists, laboratory assistants, medical informaticians, respiratory therapists, occupational therapists, ultrasound technicians, sonographists, nuclear medicine technicians, radiography technicians, clinical psychologists, social workers, and counselors. Although these primary care and allied health care providers may have the same title as primary care and allied health care providers in the United States, their skill levels and the roles they perform can be quite different from their U.S. counterparts. This Cooperative Agreement program will support a wide range of objectives to meet the needs of the primary care and allied health care providers in the Pacific Basin.

Eligible entities are required to use funds in collaboration with two or more disciplines Activities conducted under this cooperative should include: (a) The recruitment of representatives from all six jurisdictions that will comprise an Advisory Committee responsible for providing appropriate input to all key aspects of the project and to facilitate conducting the clinical education courses; (b) a needs assessment for all six jurisdictions in the Pacific Basin to identify their specific educational needs; (c) the recruitment of faculty and the development of curricula that will meet the needs of all six jurisdictions; (d) the development, implementation and operation of on-site and distance learning continuing clinical education programs for the primary care and allied health care providers in all six jurisdictions of the Pacific Basin; and (d) cultural competency training that emphasizes sensitivity to cultural differences, socioeconomic factors and geographic issues that impact the population in the Pacific Basin.

Authorizing Legislation

This Cooperative Agreement is solicited under the following authority of Title VII of the Public Health Service (PHS) Act, Sections 747 and 755. Section 747, as amended, that authorizes grants to plan, develop and operate, or participate in an approved professional training program (including an approved residency or internship program) in the field of family medicine, internal medicine, or pediatrics for medical (M.D. and D.O.) students, interns (including interns in internships in osteopathic medicine), residents, or practicing physicians that emphasizes training for the practice of family medicine, general internal medicine, or general pediatrics. Section 755, as amended, authorizes grants to assist allied health programs in meeting the costs associated with expanding or establishing programs that will increase the number of individuals trained in allied health professions, which may include those that provide career advancement training for practicing allied health professionals.

Federal Involvement

The Federal role in the conduct of this cooperative agreement is substantial and will be maintained by HRSA's Bureau of Health Professions (BHPr), Division of Medicine and Dentistry (DMD) staff through technical assistance and guidance to the grantee beyond the normal stewardship responsibilities in the administration of grant awards. The Federal Government will provide technical assistance and advice with respect to the following activities:

1. Planning, development, administration, and evaluation of all phases of the program, including all curricula developed for the program, the content and staffing of faculty training, and the review of the evaluation plan for the project initiated at its inception;

2. Reviewing and approving the plans at the end of the curriculum development phase of the project to assure appropriate direction and redirection of activities, if necessary;

3. Participation in all appropriate meetings, committees, conference calls, and working groups related to the Cooperative Agreement and its projects;

4. Reviewing and approving the curricula vitae documenting the credentials and experience for selection to the Advisory Committee and proposed members; and

5. Reviewing and approving the curriculum development phase to the implementation phase of this work.

Availability of Funds

Up to $400,000 will be available in FY 2003 to fund one award made under this Cooperative Agreement. It is expected that funding will be continued to complete a 4-year total project period. It is expected that awards will be made on or before September 1, 2003. Continuation awards beyond the first year of the project period will be based on the achievement of satisfactory progress and the availability of funds.

Background

HRSA's mission is to improve the Nation's health by assuring equitable access to comprehensive, quality health care for all. In addressing this goal, HRSA's Bureau of Health Professions has responsibility for the education of health professionals.

The Institute of Medicine (IOM) was commissioned by HRSA in the late 1990s to examine the health needs of the populations in the U.S.-Associated Pacific Islands. The IOM made recommendations for improvement of jurisdictional health needs in their report, ''Pacific Partnerships for Health: Charting a Course for the 21st Century,'' January 1998. The four key recommendations were (1) adopt and support a viable system of community-based primary and preventive health care; (2) improve coordination within and between the jurisdictions and the U.S.; (3) increase community involvement and investment in health care; and (4) promote the education and training of the health care workforce.

One of the main focuses for BHPr is to promote continuing clinical education for primary care and allied health care providers. This is consistent with IOM recommendation number four. The goal is to maintain and improve the clinical capacity of primary care and allied health care providers in the Pacific Basin, especially for the Medical Officers trained in the HRSA-supported Pacific Basin Medical Officer Training Program (whose operations terminated on December 31, 1996). BHPr's focus will help improve the health status of Pacific Basin residents and support a viable system of community-based primary care. Furthermore, this will improve the overall system of primary, preventive, and allied health care in the Pacific Basin and lead to overall sustainability of program efforts.

Applicants to this Cooperative Agreement must focus on planning, developing, implementing and operating a continuing clinical education program that will meet the specific needs of all six jurisdictions in the Pacific Basin.

Eligible Applicants

Eligible applicants are public or nonprofit private hospitals, accredited schools of medicine or osteopathic medicine, health professions schools, academic health centers, State or local governments, or public or private nonprofit entities, including faith-based and community-based organizations. Eligible entities are required to use

funds in collaboration with two or more disciplines.

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 applications. As provided in section 791(a) of the PHS Act, a preference will be given to any qualified applicant that meets the criteria for a ''new program'' under this Cooperative Agreement.

For the purposes of this Cooperative Agreement, all proposed CCE programs are eligible to be considered as new programs; however, applicants cannot automatically receive the preference. Preference will be given to those proposed CCE programs that request the preference and that meet at least four of the following criteria:

(1) The mission statement of the program identifies a specific purpose of this program as being the preparation of health professionals to serve underserved populations;

(2) The curriculum of the program includes content which will help to prepare practitioners to serve underserved populations;

(3) Substantial clinical training experience is required under the program in medically underserved communities;

(4) A minimum of 20% of the clinical faculty of the program spend at least 50% of their time providing or supervising care in medically underserved communities;

(5) The entire program or a substantial portion of the program is physically located in a medically underserved community;

(6) Student assistance, which is linked to service in medically underserved communities following graduation, is available to the students in the program; and

(7) The program provides a placement mechanism for deploying graduates to medically underserved communities.

This statutory general preference will only be applied to applications that rank above the 20th percentile of applications recommended for approval by the peer review group.

The term ''medically underserved community (MUC)'' means an urban or rural area or population that:

(a) Is eligible for designation under section 332 as a Health Professional Shortage Area (HPSA);

(b) Is eligible to be served by a Migrant Health Center under section 330 of the PHS Act, a Community Health Center under section 330 of the Act, a grantee under section 330 of the Act (relating to homeless individuals), or a grantee under section 330 of the Act (relating to residents of public housing);

(c) Is eligible for certification under section 1861(aa)(2) of the Social Security Act (relating to rural health clinics); or

(d) Is designated by a State Governor (in consultation with the medical community) as a shortage area or MUC. (Section 799B(6) of the PHS Act.).

Allied Health Funding Priority

A ''funding priority'' is defined as the favorable adjustment of aggregate review scores of individually approved applications. A funding priority will be given to approved applicants who devote resources to educate and train allied health professionals in areas experiencing shortages in the disciplines of medical technology and cytotechnology.

To qualify for the priority, the applicant should satisfactorily demonstrate that this Cooperative Agreement includes the training of allied health professionals in areas experiencing shortages in the disciplines of medical technology and cytotechnology.

Applicants meeting the funding priority will receive an additional 5 points. Peer reviewers will determine which applications receive the funding priority.

Special Considerations

A special consideration is the enhancement of priority scores by individual merit reviewers of approved applications, because the application addresses special areas of concern.

Title VII, section 747(c)(3) provides for a statutory special consideration to be given to projects that prepare practitioners to care for underserved populations and other high risk groups such as the elderly, individuals with HIV/AIDS, substance abusers, homeless and victims of domestic violence.

An administrative special consideration will be given to projects that propose approaches for enhancing current and/or developing new educational opportunities using distance learning methodologies, with the goal of improving access to primary health care for medically and/or dentally underserved communities and/or underserved populations or other high risk groups. The proposed project should focus on educational opportunities for trainees and not on providing clinical services.

Statutory Matching or Cost Sharing Requirement

None.

Review Criteria

The specific review criteria used to review and rank applications are included in the application guidance that will be provided to each potential applicant. Peer reviewers will evaluate applications based on: (1) The quality of the applicants' proposed geographic needs assessment, including addressing the needs of underserved populations and other high risk groups and the incorporation of distance learning methodologies; (2) the quality of the proposed curriculum, including evaluation of curriculum specific to geriatrics, oral health, and diabetes; (3) the applicants' overall management capabilities, including its ability to demonstrate strong partnerships with the U.S.-Associated Pacific Island jurisdictions and its knowledge of ongoing HRSA-funded activities in the Pacific Islands; and (4) the quality of the proposed outcome measures and dissemination strategies, including qualitative and quantitative evaluation plans and the project's impact at multiple levels (local, national, and international). Applicants should pay strict attention to addressing these criteria, as they are the basis upon which applications will be judged by the reviewers.

The following generic review criteria are also applicable to this Cooperative Agreement:

(a) That the estimated cost to the Government of the project is reasonable considering the level and complexity of activity and the anticipated results.

(b) That project personnel are well qualified by training and/or experience for the support sought, that project personnel understand the cultural differences, socioeconomic factors, and geographic issues that impact the population in the Pacific Basin, and that the applicant organization or the organization to provide training has adequate facilities and manpower.

(c) That insofar as practical, the proposed activities, if well executed, are capable of attaining project objectives.

(d) That the project objectives are capable of achieving the specific program objectives defined in the program announcement and the proposed results are measurable.

(e) That the method for evaluating proposed results includes criteria for determining the extent to which the program has achieved its stated objectives and the extent to which the accomplishment of objectives can be attributed to the program.

(f) That, insofar as practical, the proposed activities, when accomplished, are replicable, national

in scope, and include plans for broad dissemination.

Application Requests, Dates and Address

The **Federal Register** notice and the application form for this Cooperative Agreement are available on the HRSA Web site address at *http://bhpr.hrsa.gov/grants.* Applicants may also request a hard copy of these materials from the Division of Grants Management Operations (CPAC), HRSA Grants Application Center (GAC), 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879, telephone number 1–877–477–2123 or 1–877–HRSA–123. The GAC e-mail address is *HRSAGAC@hrsa.gov.* If mailing the application, send the original and two copies of the application to GAC.

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.

Applications for this Cooperative Agreement must be postmarked or submitted by the due date June 30, 2003. Applications postmarked after this due date or sent to any address other than the Gaithersburg, MD address will be returned to the applicant and not reviewed.

National Health Objectives for the Year 2010

The PHS urges applicants to submit their work plans that address specific Federal workforce objectives. These objectives are stated in the DHHS publication Healthy People 2010, dated January 2000. The Internet address for this document is: *http://www.health.gov/healthypeople/,* or you may call 1–800–367–4725 for information. Particular attention should focus on Healthy People 2010 such as Objective 21 (oral health); and Objective 23–8 (incorporating specific competencies in the public health workforce).

Smoke-Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace; to promote the non-use of all tobacco products; and to promote Public Law 103–227, the Pro-Children Act of 1994, which prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Additional Information

Questions concerning programmatic aspects of this Cooperative Agreement may be directed to Ellie Grant, Program Specialist, Primary Care Medical Education Branch, Division of Medicine and Dentistry, Bureau of Health Professions, HRSA. Ms. Grant's e-mail is *egrant@hrsa.gov* and her telephone number is 301–443–5404.

Paperwork Reduction Act

The standard application form HRSA–6025–1, the HRSA Competing Training Grant Application, has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 0915–0060. If the methods for developing the proposed comprehensive outcome evaluation of all efforts delivered through this Cooperative Agreement (as described in the Background section of this notice) fall under the purview of the Paperwork Reduction Act, awardees will assist HRSA in seeking OMB clearance for proposed data collection activities.

This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

Dated: April 23, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–12774 Filed 5–20–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 219–9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 16C–17, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested after the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a list of petitions received by HRSA on October 1, 2002, through December 31, 2002.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the