

injection) may be approved by the agency.

Dated: May 15, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-12874 Filed 5-22-02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00D-1563]

#### Guidance for Industry on Carcinogenicity Study Protocol Submissions; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Carcinogenicity Study Protocol Submissions." This document is intended to provide guidance on the types of information the Center for Drug Evaluation and Research (CDER) relies on when evaluating protocols for animal carcinogenicity studies.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Robert E. Osterberg, Center for Drug Evaluation and Research (HFD-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5476.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Carcinogenicity Study Protocol

Submissions." In conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA), FDA agreed to specific performance goals (PDUFA goals) for activities associated with the development and review of products in human drug applications. The PDUFA goals related to special protocol assessment and agreement provide that, upon request, FDA will evaluate within 45 calendar days certain protocols and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. Protocols for animal carcinogenicity studies are eligible for this special protocol assessment. This guidance is intended to facilitate the agency's review of protocols for animal carcinogenicity studies by informing sponsors of the types of information the agency relies on during its evaluation of such protocols. A draft guidance of the same name was made available for public comment in a notice published in the **Federal Register** of November 7, 2000 (65 FR 66757). This guidance contains only minor changes for clarification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on carcinogenicity study protocol submissions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

##### III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 15, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Availability of Funds

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** General Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year 2002 competitive Cooperative Agreements for health workforce research.

#### Purpose

The purpose of these Cooperative Agreements is to conduct research that will contribute to: (1) The development of information describing the current status of the health professions workforce and (2) the analysis of fundamental health workforce related issues. These Cooperative Agreements will support a wide range of projects designed to address health workforce issues at the National, Regional and State levels.

#### Authorizing Legislation

These Cooperative Agreements are governed by section 761 of Title VII of the Public Health Service Act, as amended, which authorizes the development of information describing the health professions workforce and analysis of workforce related issues and necessary information for decision-making regarding future direction in health professions and nursing programs in response to societal and professional needs. Section 761 also authorizes the development of a non-Federal analytic and research infrastructure for health workforce data collection and analysis.

#### Federal Role

The Federal role in the conduct of these cooperative agreements allow for substantial Federal programmatic involvement in the planning and development of and the reports resulting from these studies. The Bureau of Health Professions (BHP) program officer may be assisted in this effort by program staff of the BHP divisions. The Federal Government involvement will include:

(a) Participation in the approval of study protocols and methodologies;

(b) Providing information about issues that are relevant to Federal policy makers or issues of particular national interest;

(c) Consultation regarding sub-contracts awarded under these cooperative agreements;

(d) Assistance in supplying data relevant to the studies or in identifying sources of such data, including other Federal agencies, or other public and private organizations; and

(e) Assistance in the dissemination of the results and, if appropriate, participation in their publication in peer-reviewed journals.

### Eligible Applicants

Eligible applicants are State or local governments, health professions schools, schools of nursing, academic health centers, community-based health facilities, and other appropriate public or private non-profit entities, including faith-based organizations.

### Review Criteria

The specific review criteria used to review and rank applications are included in the individual guidance material provided with the application kits and are listed below. Applicants should pay strict attention to addressing these criteria, as they are the basis upon which their applications will be judged by the reviewers and are as follows:

1. The degree to which an applicant specializes in health workforce research. An applicant will be considered as specializing in health workforce research through identification of its mission, health workforce research accomplishments, and dedicated staff to health workforce research.

2. The degree to which the applicant demonstrates State and National experience and accomplishments in health workforce issues and research directly supporting the BHP National Center for Health Workforce Analysis and the BHP priorities: Health workforce distribution, racial/ethnic diversity of the health workforce, geriatrics, and genetics. Experience and accomplishments can be demonstrated through past or currently funded research.

3. The degree to which the applicant has health workforce research experience relevant to the proposed research project. For example, for a proposed research project that focuses on a given geographic area such as the US-Mexico border, the applicant should demonstrate experience in conducting US-Mexico border health workforce research. In terms of workforce

discipline-specific studies, the applicant should demonstrate experience in conducting research on the given discipline.

4. The degree to which the applicant's proposed research includes:

a. A well-developed background statement

b. Clearly stated research objectives

c. Clearly stated project activities and methodology

d. A well-developed, reasonable management plan that will enable the successful completion of the project.

### Application Requests, Availability, Dates and Addresses

Application kits will be available upon request on May 1, 2002.

Applicants may request the application kits by contacting the HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland, 20879, by calling at 1-877-477-2123, by fax at 1-877-477-2345, or by e-mail at [hrsaga@hrsa.gov](mailto:hrsaga@hrsa.gov).

Application materials will also be available for downloading via the World Wide Web at: <http://www.hrsa.gov/grants.htm>. In order to be considered for competition, applications must be received by mail or delivered to the HRSA Grants Application Center by no later than June 19, 2002. Applications received after the deadline or sent to any address other than the address above, will be returned to the applicant and not processed.

### Estimated Project Period

The estimated project period for each of the Cooperative Agreements is one year with an approximate award date of September 30, 2002.

### Project Descriptions

#### *Understanding International Medical Graduates (IMGs) 93.900*

The purpose of this cooperative agreement is to collect data and information that will describe IMGs—who they are, where they came from, their visa status, role in addressing needs for healthcare providers in HPSA's and how long they stay in underserved areas. It will also study the impact of September 11 on the number of J-1 waivers.

*Estimated award: \$250,000.*

#### *Role and Limitations of Telemedicine in Improving "Access" 93.900*

The purpose of this cooperative agreement is to conduct a comprehensive analysis of telemedicine in rural and other underserved areas. It will also identify the issues and barriers in the implementation of telemedicine

and evaluate and research successful models to identify best practices.

*Estimated award: \$200,000.*

#### *Supply, Demand and Workforce Issues for 25 Allied Health Occupations 93.900*

The purpose of this cooperative agreement is to provide projections of supply and demand for and an analysis of allied health occupations, including Diagnostic Medical Sonographer, Dietetic Technician, EMT-Paramedics, Medical Assistant, Nuclear Medicine Technologist, and Surgical Technologist. Applicant may propose and justify additional disciplines to be included.

*Estimated award: \$275,000.*

#### *Clinical Laboratory Sciences Workers Shortage Study 93.900*

The purpose of this cooperative agreement is to analyze data on medical laboratory personnel including demographics, employment, education, employment issues, and assess supply and demand for shortages. The study will define the magnitude of laboratory personnel shortage and identify major contributing factors influencing the supply and demand of laboratory personnel. The study will describe impact of shortage on the health care system.

*Estimated award: \$160,000.*

#### *Supply, Demand, Use of Licensed Practical Nurses (LPNs) 93.900*

The purpose of this cooperative agreement is to provide a better understanding of the supply, demand, distribution and utilization of LPNs (including their ability to substitute for registered nurses) and to develop recommendations for the education and utilization of LPNs.

*Estimated award: \$275,000.*

#### *Develop National Database on Nurse Practitioners 93.900*

The purpose of this cooperative agreement is to design and promote the development of a national nurse practitioner database that documents the number and characteristics of nurse practitioners, including demographic, job activity, and work-setting data. The database should be designed to provide the basic research information needed to analyze the nurse practitioner workforce.

*Estimated award: \$125,000.*

#### *Adequacy of Current and Future Dental Workforce 93.900*

The purpose of this cooperative agreement is to: (1) assess the adequacy of the current dental workforce supply and expected demand and (2) project the demand of dental workforce.

*Estimated award: \$100,000.*

*Assessing Variations in Retirement Plans of Physicians by Gender, Race, Specialty, Age and Other Factors 93.900*

The purpose of this cooperative agreement is to assess variations in the retirement plans of physicians by: gender, race specialty, age, practice location (urban, suburban and rural) and by location of medical school (International Medical Graduate versus U.S. Medical Graduate).

*Estimated award: \$50,000.*

*Assessing Disparities of the Health Workforce Distribution in Underserved Areas of Texas and New Mexico Border Regions 93.900*

The purpose of this cooperative agreement is to determine the applicability of recent developments in Geographic Information Systems (GIS) technology and studies to more clearly assess and monitor shortages and health workforce needs in underserved areas of the U.S./Mexico Border region of Texas and New Mexico. Estimated award: \$148,000.

*Genetic Issues of the Hispanic Border Population 93.900*

The purpose of this cooperative agreement is to: (1) Characterize testable genetic issues along the border, (2) characterize genetic services in rural and underserved areas of the Texas and U.S./Mexico border region, and (3) identify the roles of health professionals in providing genetic services in rural areas of Texas and border regions.

*Estimated award: \$100,000.*

*Improving Health Professions Education Programs Planning in New York 93.900*

The purpose of this cooperative agreement is to develop a model collaboration between a Regional Workforce Study Center and a university to better plan health professions/nursing education programs. The Regional Workforce Center will use its knowledge about health workforce supply, demand and issues to advise educational program planners.

*Estimated award: \$50,000.*

*The Workforce Investment Act of 1998: Are States Targeting the Health Workforce? 93.900*

The purpose of this cooperative agreement is to identify and enumerate the goals and strategies that State Workforce Reinvestment Boards have identified or employed in an effort to develop the health care workforce. The analysis should include all States and Territories.

*Estimated award: \$100,000.*

*Health Workforce Needs in the U.S. Virgin Islands 93.900*

The purpose of this cooperative agreement is to evaluate the health workforce needs in the U.S. Virgin Islands as a first step in assuring access to high quality health care.

*Estimated award: \$50,000.*

**Additional Information**

For programmatic information, please contact Sarah Richards (phone 301-443-5452 or via email at [srichards@hrsa.gov](mailto:srichards@hrsa.gov)) or Lou Kuta (phone 301-443-6634 or via e-mail at [lkuta@hrsa.gov](mailto:lkuta@hrsa.gov)).

**Paperwork Reduction Act**

The Standard application form PHS 398, PHS Grant Application, has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 0925-0001.

The Cooperative agreements described in this announcement will not involve data collection activities that fall under the purview of the Paperwork Reduction Act of 1995.

Dated: May 17, 2002.

**Elizabeth M. Duke,**  
*Administrator.*

[FR Doc. 02-12928 Filed 5-22-02; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Rural Access to Emergency Devices Grant Program**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of availability of funds.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that approximately \$12,500,000 will be available for fiscal year (FY) 2002 grants, technical assistance, and program evaluation for the purchase, placement and training in the use of automated external defibrillators (AEDs) and related activities in eligible rural areas. HRSA estimates that approximately 50 awards will be made to community partnerships, in collaboration with State Offices of Emergency Medical Services, for FY 2002. These grants will be awarded under the authority of Public Law 106-505, Title IV—Cardiac Arrest Survival, Subtitle B—Rural Access to

Emergency Devices, 42 U.S.C. 254c note. The Office of Rural Health Policy will administer the Rural Access to Emergency Devices Grant Program.

**DATES:** All applicants interested in applying for funding under this program are to fax or mail a letter of intent to the Office of Rural Health Policy by May 27, 2002, at fax number (301) 443-2803. A copy of this letter of intent must also be faxed or mailed to the State Office of Emergency Medical Services by this same date. The letter of intent need only include the lead applicant's organizational name, proposed number of AEDs requested and a proposed listing of those in their community partnership. The deadline for receipt of applications is July 15, 2002. Applications will be considered on time if they are either received on or before the deadline date in the HRSA Grants Application Center or postmarked on or before the deadline date. Any changes to the aforementioned dates will be posted on the Office of Rural Health Policy homepage at <http://www.ruralhealth.hrsa.gov>.

**ADDRESSES:** To receive an application kit, applicants may telephone the HRSA Grants Application Center at (877) 477-2123 (877-HRSA-123) or the application forms can be downloaded via the Web at <http://www.ruralhealth.hrsa.gov/funding.htm>. The instructions for preparing the applications will be included with the grant guidance as part of the grant application kit. The Rural Access to Emergency Devices Grant Program uses PHS Forms 424 and 5161 for applications. Applicants must use the formal title "Rural Access to Emergency Devices Grant Program" and CFDA number 93.259 when requesting applications. The CFDA is a Government-wide compendium of enumerated Federal programs, projects services, and activities that provide assistance. All applications must be mailed or delivered to the Grants Management Officer, Office of Rural Health: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879; telephone (877) 477-2123. This notice will appear in the **Federal Register** at [http://www.gpo.gov/su\\_docs/aces/aces140.html](http://www.gpo.gov/su_docs/aces/aces140.html) and the Office of Rural Health Policy homepage at <http://www.ruralhealth.hrsa.gov/>.

**FOR FURTHER INFORMATION CONTACT:** Evan Mayfield, Office of Rural Health Policy, HRSA, Room 9A-55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, or email address [ruralaed@hrsa.gov](mailto:ruralaed@hrsa.gov), telephone number