

efficacy of somatic cell and gene therapy products. This limited access may, in the long term, unduly restrict progress in the field of somatic cell and gene therapy in the United States.

To obtain more information, FDA would like to discuss several issues related to the limited access to ancillary components on the development of somatic cell and gene therapies, including: (1) What are the ancillary components that are most critical to somatic cell and gene therapy trials? (2) What are the main reasons for the lack of availability of ancillary components? (3) Are there alternate suppliers of ancillary components? and (4) What is the impact of the limited supply of ancillary components on somatic cell and gene therapy development?

FDA is soliciting public testimony from biomedical researchers, university faculty and administrators, biotechnology associations, other Federal and government agencies, and other individuals and organizations with relevant information concerning limited access to critical ancillary components for gene therapy and somatic cell therapy manufacturing. FDA also solicits testimony, in particular, from affected individuals and consumer organizations. All interested parties are invited to participate in the meeting.

Every effort will be made to accommodate each person who wants to participate in the public meeting. However, because presentations will be limited to the first 30 minutes of the meeting, the time allotted for each presentation will be restricted to 5 minutes. Due to the time limitations of the meeting, all requests may not be granted. Therefore, each person who wants to participate in the meeting is encouraged, by close of business on February 27, 1995, to do the following: (1) File a written request of participation containing the name, address, phone number, facsimile number, affiliation, if any, of the participant, and topic of the presentation, and (2) submit a copy or summary of their presentation. The requested information, including the written notice of participation, may be submitted to the Dockets Management Branch (address above). After the presentations, the remainder of the meeting will be used to allow for discussion.

Before the meeting, CBER will determine the schedule for the presenters. A schedule of the presenters will be filed with the Dockets Management Branch (address above) and mailed or FAX'ed to each participant before the meeting. Interested persons attending the meeting

who did not request an opportunity to make a presentation or those who did request an opportunity to make a presentation but due to the time limitations were not granted the request will be given the opportunity to make an oral presentation at the conclusion of the meeting, as time permits.

FDA will consider information presented and discussed at the meeting in the developing of future points to consider and regulatory and guidance documents, and in identifying topics for future discussion.

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript of the public meeting and copies of information and comments submitted to the meeting record will be available for examination at the Dockets Management Branch (address above) approximately 15 working days after the meeting, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-3800 Filed 2-10-95; 3:00 pm]

BILLING CODE 4160-01-F

Indian Health Service

Health Professions Preparatory, Pregraduate and Indian Health Scholarship (Professions) Programs

AGENCY: Indian Health Service, HHS.

ACTION: Standing Notice of Availability of Funds for Health Professions Preparatory, Pregraduate and Indian Health Scholarship (Professions) Programs for Fiscal Years (FYs) 1995 and 1996.

SUMMARY: The Indian Health Service (IHS) announces the availability of approximately \$3,578,200 to fund scholarships for the Health Professions Preparatory and Pregraduate Scholarship Programs for FY 1995 awards. Pending the availability of funds, a similar amount is anticipated in FY 1996. These programs are authorized by section 103 of the Indian Health Care Improvement Act (IHCA), Pub. L. 94-437, as amended by Pub. L. 100-713 and by Pub. L. 102-573.

The Indian Health Scholarship (Professions) Program, authorized by section 104 of the IHCA, Pub. L. 94-437, as amended by Pub. L. 100-713

and by Pub. L. 102-573, has approximately \$8,160,751 available for FY 1995 awards. Pending the availability of funds, a similar amount is anticipated in FY 1996.

Scholarships under the three programs will be awarded utilizing the Notice of Grant Award, form PHS-5152-1 (Rev. 7/92). For academic years 1995-1996 and 1996-1997, full-time and part-time scholarships will be funded for each of the three scholarship programs.

The Health Professions Preparatory Scholarship Program is listed as No. 93-123 in the Office of Management and Budget Catalog of Federal Domestic Assistance (CFDA). The Health Professions Pregraduate Scholarship Program is listed as No. 93.971, and the Indian Health Scholarship (Professions) Program is listed as No. 93.972 in the CFDA.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2000*, a PHS-led activity for setting priority areas. This program announcement is related to the priority area of Education and Community-Based programs. Potential applicants may obtain a copy of *Healthy People 2000*, (Full Report; Stock No. 017-001-00474-0) or *Healthy People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone 202-783-3238).

DATES: The application deadline is April 1, 1995 and 1996. If April 1 falls on the week-end, the application will be due on the following Monday. Applications shall be considered as meeting the deadline if they are received by the appropriate Scholarship Coordinator on the deadline date or postmarked on or before the deadline date. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.) Applications received after the announced closing date will be returned to the applicant and will not be considered for funding.

ADDRESSES: Application packets may be obtained by calling or writing to the addresses listed below. The IHS Scholarship Program application forms include: IHS-856, 856-2 through 856-8, 815, 816, 818 and, F-01 through L-04 (approved under OMB No. 0917-0006, expires 12/31/97).

IHS area office and States/locality served	Scholarship coordinator/address
Aberdeen Area IHS: Iowa, Nebraska, North Dakota, South Dakota	Ms. Alice LaFontaine, Scholarship Coordinator, IHS Aberdeen Area, Federal Building, 115 4th Avenue, SE, Aberdeen, SD 57401, Tele: 605-226-7553.
Alaska Area Native Health Service: Alaska	Ms. Rose Jerue, Scholarship Coordinator, IHS Alaska Area, 250 Gambell Street, Anchorage, Alaska 99501, Tele: 907-257-1307.
Albuquerque Area IHS: Colorado, New Mexico	Ms. Alvina Waseta, Scholarship Coordinator, IHS Albuquerque Area, 505 Marquette, NW., Suite 1502, Albuquerque, NM 87102, Tele: 505-766-2143.
Bemidji Area IHS: Illinois, Indiana, Michigan, Minnesota, Wisconsin	Mr. Dennis O'Keefe, Scholarship Coordinator, IHS Bemidji Area, 203 Federal Building, Bemidji, MN 56601, Tele: 218-759-3377.
Billings Area IHS: Montana, Wyoming	Mr. Sandy Macdonald, Scholarship Coordinator, IHS Billings Area, P.O. Box 2143, Billings, MT 59103-6601, Tele: 406-657-6909.
California Area IHS: California, Hawaii	Ms. Michelle Hadsell/Luana Hill, Scholarship Coordinator, IHS California Area, 1825 Bell Street—Suite 200, Sacramento, CA 95825-4202, Tele: 916-566-7001.
Nashville Area IHS: Alabama, Arkansas, Connecticut, Delaware, Florida, Georgia, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, District of Columbia, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, West Virginia.	Mr. Steven Holder, Scholarship Coordinator, IHS Nashville Area, 3310 Perimeter Hill Drive, Nashville, TN 37211, Tele: 615-736-2431.
Navajo Area IHS: Arizona, New Mexico, Utah	Ms. Rosalinda Allison, Scholarship Coordinator, IHS Navajo Area, P.O. Box 9020, Window Rock, AZ 86515-9020, Tele: 602-871-1367.
Oklahoma City Area IHS: Kansas, Missouri, Oklahoma	Mr. Jim Ingram/Ms. Barbara Roy, Scholarship Coordinator, IHS Oklahoma City Area, 3625 N.W. 56th Street, Five Corporate Plaza, Oklahoma City, OK 73211, Tele: 405-945-6939.
Phoenix Area IHS: Arizona, Nevada, Utah	Mr. Eric LaRose, Scholarship Coordinator, IHS Phoenix Area, 3738 N. 16th Street—Suite A, Phoenix, AZ 85016-5981. Tele: 602-261-2066.
Portland Area IHS: Idaho, Oregon, Washington	Ms. Darlene Marcellay, Scholarship Coordinator, IHS Portland Area, 1220 SW 3rd Street, Rm 315, Portland, OR 97204-2892, Tele: 503-326-2019.
Tucson Area IHS: Arizona, Texas	Ms. Adeline Horst, Scholarship Coordinator, IHS Tucson Area, 7900 S.J. Stock Road, Tucson, AZ 85746, Tele: 602-295-2484.

FOR FURTHER INFORMATION CONTACT:

Please address application inquiries to the appropriate Indian Health Service Area Scholarship Coordinator. Other programmatic inquiries may be addressed to Ms. Rosh Foley, Acting Chief, Scholarship Branch, Indian Health Service, Twinbrook Metro Plaza Building, Suite 100A, 12300 Twinbrook Parkway, Rockville, Maryland, 20852; Telephone 301-443-6197. (This is not a toll free number.) For grants information, contact Ms. Patricia Lee-McCoy, Grants Scholarship Coordinator, Grants Management Branch, Division of Acquisition and Grants Operations, Indian Health Service, Suite 100, 12300 Twinbrook Parkway, Rockville, Maryland, 20852; Telephone 301-443-0243. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Health Professions Preparatory and Pregraduate Scholarship Programs are authorized by section 103 of the IHCA, Pub. L. 94-437, as amended by Pub. L. 96-537, Indian Health Care Amendments of 1980; Pub. L. 100-713, Indian Health Care Amendments of 1988; and Pub. L. 102-573, Indian Health Care Amendments of 1992.

The Indian Health Scholarship (Professions) Program, formerly authorized by section 338I of the Public Health Service Act (42 U.S.C. 254r), is

now authorized by section 104 of the IHCA, as amended by the Indian Health Care Amendments of 1988, Pub. L. 100-713 and Pub. L. 102-573, Indian Health Care Amendments of 1992.

A. General Program Purpose

These scholarship programs are intended to encourage American Indians and Alaska Natives to enter the health professions and to assure the availability of Indian health professions to serve Indians.

B. Eligibility Requirements

1. The Health Professions Preparatory Scholarship awards are made to American Indians or Alaska Natives who meet the criteria in section 4(c) of the IHCA, as amended, who have successfully completed high school education or high school equivalency and who have been accepted for enrollment in a compensatory, pre-professional general education course or curriculum. Support is limited to 2 years for full-time students and the part-time equivalent of 2 years not to exceed 4 years for part-time students.

2. The Health Professions Pregraduate Scholarship awards are made to American Indians or Alaska Natives who meet the criteria in section 4(c) of the IHCA, as amended, who have

successfully completed high school education or high school equivalency and who have been accepted for enrollment or are enrolled in an accredited pregraduate program leading to a baccalaureate degree in pre-medicine or pre-dentistry. Support is limited to 4 years for full-time students and the part-time equivalent of 4 years not to exceed 8 years for part-time students.

3. The Indian Health Scholarship (Professions) may be awarded only to an individual who is a member of a federally recognized tribe as provided by section 104, 4(c), and 4(d) of the IHCA. Membership in a tribe recognized only by a state does not meet this statutory requirement. To receive an Indian Health Scholarship (Professions) an otherwise eligible individual must be enrolled in an appropriately accredited school and pursuing a course of study in a health profession as defined by section 4(n) of the IHCA. Support is limited to 4 years for full-time students and the part-time equivalent of 4 years not to exceed 8 years for part-time students.

Awards of Indian Health Scholarships (Professions) will be made in accordance with 42 CFR 36.330. Recipients shall incur a service obligation prescribed under section 338C of the Public Health Service Act

(43 U.S.C. 244m) which shall be met by service:

- (1) In Indian Health Service;
- (2) In a program conducted under a contract entered into under the Indian Self-Determination Act;
- (3) In a program assisted under title V of the Indian Health Care Improvement Act (Pub. L. 94-437) and its amendments; and
- (4) In private practice of his or her profession, if the practice (a) is situated in a health professional shortage area, designated in regulations promulgated by the Secretary and (b) addresses the health care needs of a substantial number of Indians as determined by the Secretary in accordance with guidelines of the Service.

Pursuant to the Indian Health Amendment of 1992 (Pub. L. 102-573), a recipient of an Indian Health Scholarship (Professions) may, at the election of the recipient, meet his/her active duty service obligation prescribed under section 338c of the Public Health Service Act (42 U.S.C. 254m) by a program specified in options (1)-(4) above that:

- (i) Is located on the reservation of the tribe in which the recipient is enrolled; or
- (ii) Serves the tribe in which the recipient is enrolled.

In summary, all recipients of Indian Health Scholarship (Professions) are reminded that recipients of this scholarship incur a service obligation. Moreover, this obligation shall be served at a facility determined by the Director, IHS, consistent with IHCA, Pub. L. 94-437, as amended by Pub. L. 100-713 and Pub. L. 102-573.

C. Fund Availability

Both part-time and full-time scholarship awards will be made in accordance with regulations and 42 CFR 36.320, incorporated in the application materials, for Health Professions Preparatory Scholarship Program for Indians and 42 CFR 36.370, incorporated in the application materials, for Health Professions Pregraduate Scholarship Program for Indians. Approximately 238 awards, 92 of which are continuing, will be made under the Health Professions Preparatory and Pregraduate Scholarship Programs for Indians in each fiscal year covered by this standing announcement. The awards are for 10 months in duration and the average award to a full-time student is approximately \$15,000. In FY 1995, approximately \$1,380,000 is available for continuation awards and approximately \$2,190,000 is available for new awards. Pending the availability

of funds, a similar amount is anticipated to be available in FY 1996.

Approximately 453 awards, 350 of which are continuing, will be made under the Indian Health Scholarship (Professions) program in each fiscal year covered by this announcement. Awards will be made to both full-time and part-time students. The awards are for 12 months in duration and the average award to a full-time student is for approximately \$18,000. In FY 1995, approximately \$6,300,000 is available for continuation awards, and \$1,860,751 is available for new awards. Pending availability of funds, a similar amount is anticipated for FY 1996.

No more than 20% of available funds will be used for part-time scholarships this fiscal year. Students are considered part-time if they are enrolled for a minimum of 6 hours of instruction and are not considered in full-time status by their college/university. Documentation must be received from part-time applicants that their school and course curriculum allows less than full-time status.

D. Criteria for Evaluation

Applicants will be evaluated against the following criteria:

1. *Needs of the IHS.* Applicants are considered for scholarship awards based on their desired career goals and how these goals relate to current Indian health manpower needs. Applications for each health career category are reviewed and ranked separately.

2. *Academic performance.* Applicants are rated according to their academic performance as evidenced by transcripts and faculty evaluations. In cases where a particular applicant's school has a policy not to rank students academically, faculty members are asked to provide a personal judgment of the applicant's achievement. Health Professions applicants with a cumulative GPA below 2.0 are not eligible to apply.

3. *Faculty/employer recommendations.* Applicants are rated according to evaluations by faculty members and current and/or former employers regarding the applicant's potential in the chosen health related professions.

4. *Stated reasons for asking for the scholarship and stated career goals.* Applicants must provide a brief written explanation of reasons for asking for the scholarship and of career goals. The applicant's narrative will be judged on content and how well it is written.

5. *Applicants who are closest to graduation or completion are awarded first.* For example, senior and junior applicants under the Health Professions

Pregraduate Scholarship receive funding before freshmen and sophomores.

E. Priority Categories

Regulations at 42 CFR 36.304 provide that the IHS shall, from time to time, publish a list of health professions eligible for consideration for the award of Indian Health Professions Preparatory and Pregraduate Scholarships and Indian Health Scholarships (Professions). Section 104(b)(1) of the IHCA, as amended by the Indian Health Care Amendment of 1988, Pub. L. 100-713, authorizes the IHS to determine specific health professions for which Indian Health Scholarships will be awarded. The lists of priority health professions that follow, by scholarship program, and based upon the needs of the IHS as well as upon the needs of the American Indians and Alaska Natives for additional service by specific health profession.

1. *Health Professions Preparatory Scholarships.* (Below is the list of disciplines to be supported and priority is based on academic level).
 - A. Pre-Medical Technology.
 - B. Pre-Dietetics.
 - C. Pre-Nursing.
 - D. Pre-Pharmacy.
 - E. Pre-Physical Therapy.
 - F. Pre-Social Work (JR and SR undergraduate years).
2. *Health Professions Pregraduate Scholarships.* (Below is the list of disciplines to be supported and priority is based on academic level: Senior, Junior, Sophomore, Freshman)
 - A. Pre-Dentistry.
 - B. Pre-Medicine.
3. *Indian Health Scholarships (Professions).* (Below is a list of disciplines to be supported and priority is based on academic level, unless specified: Graduate, Senior, Junior Sophomore, Freshman)
 - A. Associate Degree Nurse.
 - B. Chemical Dependency Counseling.
 - C. Clinical Psychology: PH.D. only.
 - D. Computer Science: B.S.
 - E. Dentistry.
 - F. Dietician: B.S.
 - G. Engineering: B.S. Civil.
 - H. Health Education: Masters level only.
 - I. Health Records: A.R.T. and R.R.T.
 - J. Medical Technology: B.S.
 - K. Medical Social Work: Masters level only.
 - L. Medicine: Allopathic and Osteopathic.
 - M. Nurse Practitioner: R.N.A. and F.N.P.
 - N. Nurse Midwife: C.N.M.
 - O. B.S. Nurse.*
 - P. M.S. Nurse.*

*(Priority consideration will be given to Registered Nurses employed by the Indian Health Service; in a program assisted under a contract entered into under the Indian Self-Determination Act; or in a program assisted under title V of the Indian Health Care Improvement Act.)

Q. Optometry.

R. Para-Optometric.

S. Pharmacy: B.S.

T. Physician Assistant: B.S.

U. Physical Therapy.

V. Podiatry: D.P.M.

W. Public Health: M.P.H. only.

(Applicants must be enrolled or accepted in a school of public health in specialty areas such as Dietetics and Community Development in health).

X. Public Health Nutrition: Masters level only.

Y. Radiologic Technology: Associate and B.S.

Z. Respiratory Therapy: Associate.

AA. Sonography.

Interested individuals are reminded that the list of eligible health and allied health professions is effective for the applicants for the 2 academic years covered by this standing announcement. These priorities will remain in effect until superseded.

Dated: February 7, 1995.

Michael H. Trujillo,

Assistant Surgeon General, Director.

[FR Doc. 95-3740 Filed 2-14-95; 8:45 am]

BILLING CODE 4160-16-M

Health Resources and Services Administration

Federal Financial Assistance for Rural Regional Trauma and Emergency Medical Services System Demonstration Project in South Central Florida

AGENCY: Health Resources and Services Administration, PHS.

ACTION: Notice of availability of funds.

SUMMARY: The Office of Rural Health Policy, Health Resources and Services Administration (HRSA), Public Health Service, Department of Health and Human Services, announces the availability of funds in Fiscal Year (FY) 1995 for a grant to support the development of a rural regional Trauma and Emergency Medical Services (EMS) System in South Central Florida for a one year project period. The successful applicant will develop a plan to integrate existing rural emergency services (EMS), local community hospitals, a metropolitan tertiary care

center/level I trauma center and its medical helicopter to develop a regionalized system of care. This project is intended to serve as a model for other rural, underserved areas of the United States.

Authority

The award will be made from funds appropriated under Pub. L. 103-333 (HHS Appropriation Act for FY 1995). The Senate Committee on Appropriations Report 103-318, included a set-aside to support the Rural Regional Trauma and EMS System Demonstration Project under the FY 1995 appropriations to support Outreach grants. Grants for these projects are authorized under Section 301 of the Public Health Service Act.

Eligible Applicants

Justification for Other Than Full and Open Competition

In the Senate Committee on Appropriations Report 103-318, the Senate directed this demonstration project grant award to be made only to an entity located in South Central Florida. Specifically, the eligible applicant must be located either in an urban-based, level I trauma hospital in Florida, or in one of the Florida counties comprising the demonstration grant service area (Okeechobee, Highlands, Hendry, DeSoto, Glades, or Hardee County). The applicant can be a public or private, not-for profit entity. The Department agrees that this set-aside will further program objectives.

Funds Available

An estimated total award of up to \$600,000 will be available to support a single grant project for a one-year grant period.

Cost Participation

Cost participation serves as an indicator of community and institutional support for the project and the likelihood that the project will continue after Federal grant support has ended. The successful applicant must share in the project costs by providing equipment, personnel, building space, indirect costs, other in-kind contributions, or cash.

DATES: Applications for the program must be received by the close of business on April 25, 1995. Completed applications must be sent to the Bureau of Primary Health Care at the address shown below. Applications shall be considered as meeting the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date and received

in time for orderly processing. Applicants must obtain a legible dated receipt from a commercial carrier or the U.S. Postal Service in lieu of a postmark. Private metered postmarks will not be acceptable as proof of timely mailing. Late applications will be returned to the sender.

ADDRESSES: Requests for grant application kits should be directed to Lt. Colleen Hennessy, Program Management, Office of Rural Health Policy, 5600 Fishers Lane, Room 9-05, Rockville, Maryland, 20857, telephone: 301/443-0835. Completed applications and requests for additional information regarding business or fiscal issues should be directed to Ms. Opal McCarthy, Grants Management, at the Bureau of Primary Health Care, East West Building, 11th Floor, 4350 East West Highway, Bethesda, Maryland 20857, telephone: (301) 594-4260. The standard application form and general instructions for completing applications (Form PHS 5161-1, OMB 0937-0189) have been approved by the Office of Management and Budget (OMB).

FOR FURTHER INFORMATION CONTACT:

Requests of a programmatic nature should be directed to Lt. Colleen Hennessy, at the Office of Rural Health Policy, 5600 Fishers Lane, Room 9-05, Rockville, Maryland, 20857, telephone: 301/443-0835.

SUPPLEMENTARY INFORMATION:

Program Objectives

The purpose of the Rural Regional Trauma and EMS System Demonstration Project is to support the development of a regional trauma and EMS system to serve rural communities. The successful applicant will integrate existing rural prehospital providers (EMS), local community hospitals, and rural community providers, with a metropolitan tertiary care center/level I trauma center and its aeromedical transport services, into a services network that is capable of improving emergency services to rural populations. Specifically, these rural populations are located in the Florida counties of Okeechobee, Highlands, Hendry, DeSoto, Glades, and Hardee; and are comprised of medically underserved populations, such as migrant laborers and Native Americans. Currently these populations do not receive timely, comprehensive trauma care.

Consistent with the requirements of the Rural Health Outreach Program, under which this demonstration project is funded, all qualified applicants must develop consortia of three or more participatory entities, each of which must play an active contributory role in