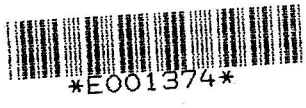
E001374

APPENDIX 2

Regulations
Regional Medical Programs

Subpart E-Grants and Contracts
for Regional Medical Programs

(Added 1/18/67, 32 FR 571.)
Authority: The provisions of the Subpart E issued under sec, 215, 58 Stat. 690, sec. 906, 79 Stat. 930; 42 U.S.C. 216, 299f, Interpret or apply secs. 900, 901, 902, 903, 904, 905, 909, 910, 79 Stat. 926, 927, 928, 929, 930, 42 U.S.C. 299, 299a. 299b. 299c. 299d. 299e. 299i.

54.401 APPLICABILITY.

The provisions of this subpart apply to grants and contracts for planning, establishment, and operation of regional medical programs as authorized by Title IX of the Public Health Service Act, as amended by Public Law 89-239, and amended and extended by PL 90-574 and PL 91-515.

54.402 DEFINITIONS.

(a) All terms not defined herein shall have the meaning given them in the Act.
(b) "Act" means the Public Health Service Act, as amended.
(c) "Title IX" means Title IX of the Public Health Service Act as amended.
(d) "Related diseases" means those diseases which can reasonably be considered to bear a direct relationship to heart disease, cancer, stroke, or Kidney Disease.
(e) "Title IX diseases" means heart disease, cancer, stroke, kidney disease and related diseases.
(f) "Program" means the regional medical program as defined in section 902 (a) of the Act.
(g) "Practicing physician" means any physician licensed to practice medicine in accordance with applicable State laws and currently engaged in the diagnosis or treatment of patients.
(h) "Construction" means new construction of facilities for demonstrations, research, and training when necessary to carry out regional medical programs.
(i) "Major repair" includes restoration of an existing building to a sound state.
(j) "Built-in Equipment" is equipment affixed to the facility and customarily included in the construction contract.
(k) "Advisory group" means the group designated pursuant to section 903(b) (4) of the Act.

(l) "Geographic area" means any area that the Secretary determines forms an economic and socially related region, taking into consideration such factors as present and future population trends and patterns of growth; location and extent of transportation and communication facilities and systems; presence and distribution of educational, medical and health facilities and programs, and other activities which in the opinion of the Secretary are appropriate for carrying out the purposes of Title IX.

54.403 ELIGIBILITY.

In order to be eligible for a grant, the applicant shall:
(a) Meet the requirements of section 903, 904, or 910 of the Act;
(b) Be located in a State;
(c) Be situated within a geographic area appropriate under the provisions of this subpart for carrying out the purposes of the Act.

54.404 APPLICATION.

(a) Forms. An application for a grant shall be submitted on such forms and in such manner as the Secretary may prescribe.
(b) Execution. The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant all of the obligations specified in the terms and conditions of the grant including those contained in these regulations.
(c) Description of program. In addition to any other pertinent information that the Secretary may require, the applicant shall submit a description of the program in sufficient detail to clearly identify the nature, need, purpose, plan, and methods of the program, the nature and functions of the participating institutions, the geographic area to be served, the cooperative arrangements in effect, or intended to be made effective, within the group, the justification supported by a budget or other data, for the amount of the funds requested, and financial or other data demonstrating that grant funds will not supplant funds otherwise available for establishment or operation of the regional medical program.
(d) Advisory group; establishment; evidence. An application for a grant under section 903 of the Act shall contain or be supported by documentary evidence of the establishment of an advisory group to provide advice in formulating and carrying out the establishment and operation of a program.
(e) Advisory group; membership; description. The application or supporting material shall describe the selection and membership of the designated advisory group, showing the extent of inclusion in such group of practicing physicians, members of other health professions, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary agencies, representatives of other organizations, institutions and agencies concerned with activities of the kind to be carried on under the program (including as an es officio member, if there is located in such region one or more hospitals or other health facilities of the Veterans' Administration, the individual whom the Administrator of Veterans' Affairs shall have designated to serve on such advisory facilities of such Administration which are located in such region) and members of the public familiar with the need for and financing of the services provided under the program.

(f) Construction; purpose, plans, and specifications; narrative description. With respect to an application for funds to be used in whole or part for construction as defined in Title IX, the applicant shall furnish in sufficient detail plans and specifications as well as a narrative description, to indicate the need, nature, and purpose of the proposed construction.

(g) Advisory group; recommendation. An application for a grant under section 904 of the Act shall contain or be supported by a copy of the written recommendation of the Advisory group.

(h) Advisory groups; recommendation. An application for a grant under section 910 of the Act shall contain or be supported by a copy of a joint recommendation of all advisory groups within the geographic area of the application.

54.405 TERMS, CONDITIONS, AND ASSURANCES.

In addition to any other terms, conditions, and assurances required by law or imposed by the Secretary, each grant shall be subject to the following terms, conditions, and assurances to be furnished by the grantee. The Secretary may at any time approve exceptions where he finds that such exceptions are not inconsistent with the Act and the purposes of the program.

(a) Use of funds. The grantee will use grant funds solely for the purposes for which the grant was made, as set forth in the approved application and award statement. In the event any part of the amount paid a grantee is found by the Secretary to have been expended for purposes or by any methods contrary to the Act, the regulations of this subpart, or contrary to any condition to the award, then such grantee, upon being notified of such finding, and in addition to any other requirement, shall pay an equal amount to the United States. Changes in grant purposes may be made only in accordance with procedures established by the Secretary.

(b) Obligation of funds. No funds may be charged against the grant for services performed or material or equipment delivered, pursuant to a contract or agreement entered into by the applicant prior to the effective date of the grant.

(c) Inventions or discoveries. Any grant award hereunder in whole or in part for research is subject to the regulations of the Department of Health, Education, and Welfare as set forth in Parts 6 and 8 of Title 45, as amended. Such regulations shall apply to any program activity for which grant funds are in fact used whether within the scope of the program as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligation. Laboratory notes, related technical data, and information pertaining to inventions or discoveries made through activities supported by grant funds shall be maintained for such periods, and filed with or otherwise made available to the Secretary or those he may designate at such times and in such manner as he may determine necessary to carry out such Department regulations.

(d) Reports. The grantee shall maintain and file with the Secretary such progress, fiscal, and other reports, including reports of meetings of the advisory group or groups convened before and after award of a grant under section 904 of the Act, as the Secretary may prescribe.

(e) Records retention. All construction, financial, and other records relating to the use of grant funds shall be retained until the grantee has received written notice that the records have been audited unless a different period is permitted or required in writing by the Secretary.

(f) Responsible official. The official designated in the application as responsible for the coordination of the program shall continue to be responsible for the duration of the period for which grant funds are made available. The grantee shall notify the Secretary immediately if such official becomes unavailable to discharge this responsibility. The Secretary may terminate the grant whenever such official shall become thus unavailable unless the grantee replaces such official with another official found by the Secretary to be qualified.

54.406 AWARD.

Upon recommendation of the National Advisory Council on Regional Medical Programs, and within the limits of available funds, the Secretary shall award a grant to those applicants whose approved programs will in his judgment best promote the purposes of Title IX. In awarding grants, the Secretary shall take into consideration, among other relevant factors the following:

(a) Generally, the extent to which the proposed program will carry out, through regional cooperation, the purposes of Title IX, within a geographic area.

(b) The capacity of the institutions or agencies within the program, individually and collectively, for research, training, and demonstration activities with respect to Title IX.

(c) The extent to which the applicant or the participants in the program plan to coordinate or have coordinated the regional medical program with other activities supported pursuant to the authority contained in the Public Health Service Act and other Acts of Congress including those relating to planning and use of facilities, personnel, and equipment, and training of manpower.

(d) The population to be served by the regional medical program and relationships to adjacent or other regional medical programs.

(e) The extent to which all the health resources of the region have been taken into consideration in the planning and/or establishment of the program.

(f) The extent to which the participating institutions will utilize existing resources and will continue to seek additional nonfederal resources for carrying out the objectives of the regional medical program.

(g) The geographic distribution of grants throughout the Nation.

54.407 TERMINATION.

(a) Termination by the Secretary. Any grant award may be revoked or terminated by the Secretary in whole or in part at any time whenever he finds that in his judgment the grantee has failed in a material respect to comply with requirements of Title IX and the regulations of this subpart. The grantee shall be promptly notified of such finding in writing and given the reasons therefor.

(b) Termination by the grantee. A grantee may at any time terminate or cancel its conduct of an approved project by notifying the Secretary in writing setting forth the reasons for such termination.

(c) Accounting. Upon any termination, the grantee shall account for all expenditures and obligations charged to grant funds: Provided, That to the extent the termination is due in the judgment of the Secretary to no fault of the grantee, credit shall be allowed for the amount required to settle at costs demonstrated by evidence satisfactory to the Secretary to be minimum settlement costs, any noncancellable obligations incurred prior to receipt of notice of termination.

54.408 NONDISCRIMINATION.

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Regulations implementing the statute have been issued as Part 80 of the Title 45, Code of Federal Regulations. The regional medical programs provide Federal financial assistance subject to the Civil Rights Act and the regulations. Each grant is subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, 30 F.R. 12319, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

54.409 EXPENDITURES BY GRANTEE.

(a) Allocation of costs. The grantee shall allocate expenditures as between direct and indirect costs in accordance with generally accepted and established accounting practices or as otherwise prescribed by the Secretary.

(b) Direct costs in general. Funds granted for direct costs may be expended by the grantee for personal services, rental of space, materials, and supplies, and other items of necessary cost as are required to carry out the purposes of the grant. The Secretary may issue rules, instructions interpretations, or limitations supplementing the regulations of this subpart and prescribing the extent to which particular types of expenditures may be charged to grant funds.

(c) Direct costs; personal services. The costs of personal services are payable from grant funds substantially in proportion to the time or effort the individual devotes to carrying out the purposes of the grant. In such proportion, such costs may include all direct costs incident to such services, such as salary during vacation and retirement and workmen's compensation charges, in accordance with the policies and accounting practices consistently applied by the grantee to all its activities.

(d) Direct costs; care of patients. The cost of hospital, medical or other care of patients is payable from grant funds only to the extent that such care is incident to the research, training, or demonstration activities supported by a grant hereunder. Such care shall be incident to such activities only if reasonably associated with and required for the effective conduct of such activities, and no such care shall be charged to such funds unless the referral of the patient is documented with respect to the name of the practicing physician making the referral, the name of the patient, the date of referral, and any other relevant information which may be prescribed by the Secretary. Grant funds shall not be charged with the cost of-

(1) Care for intercurrent conditions (except of an emergency nature where the intercurrent conditions result from the care for which the patient was admitted for treatment) that unduly interrupt, postpone, or terminate the conduct of such activities.

(2) Inpatient care if other care which would equally effectively further the purposes of the grant could be provided at a smaller cost.

(3) Bed and board for inpatients in excess of the cost of semiprivate accommodations unless required for the effective conduct of such activities. For the purpose of this paragraph, "semiprivate accommodations" means two-bed; three-bed, and four-bed accommodations.

54.410 PAYMENTS.

The Secretary shall, from time to time, make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses to be incurred or incurred to the extent he determines such payments necessary to carry out the purposes of the grant.

54.411 DIFFERENT USE OR TRANSFER: GOOD CAUSE FOR OTHER USE.

(a) Compliance by grantees. If, at any time, the Secretary determines that the eligibility requirements for a program are no longer met, or that any facility or equipment the construction or procurement of which was charged to grant funds is, during its useful life, no longer being used for the purposes for which it was constructed or procured either by the grantee or any transferee, the Government shall have the right to recover its proportionate share of the value of the facility or equipment from either the grantee or the transferee or any institution that is using the facility or equipment. The Government's proportionate share shall be the amount bearing the same ratio to the then value of the facility or equipment, as determined by the Secretary as the amount the Federal participation bore to the cost of construction or procurement.

(b) Different use or transfer; notification. The grantee shall promptly notify the Secretary in writing if at any time during its useful life the facility or equipment for construction or procurement of which grant funds were charged is no longer to be used for the purposes for which it was constructed or procured or is sold or otherwise transferred.

(c) Forgiveness. The Secretary may for good cause release the grantee or other owner from the requirement of continued eligibility or from the obligation of continued use of the facility or equipment for the grant purposes. In determining whether good cause exists, the Secretary shall take into consideration, among other factors, the extent to which-

(1) The facility or equipment will be devoted to research, training, demonstrations, or other activities related to Title IX diseases.

(2) The circumstances calling for a change in the use of the facility were not known, or with reasonable diligence could not have been known to the applicant, at the time of the application, and are circumstances reasonably beyond the control of the applicant or other owner.

(3) There are reasonable assurances that other facilities not previously utilized for Title IX purposes will be so utilized and are substantially the equivalent in nature and extent for such purposes.

54.412 PUBLICATIONS.

Grantees may publish materials relating to their regional medical program without prior review provided that such publications carry a footnote acknowledging assistance from the Public Health Service, and indicating that findings and conclusions do not represent the views of the Service.

54.413 COPYRIGHTS.

Where the grant-supported activity results in copyrightable material, the author is free to copyright, but the Health Services and Mental Health Administration reserves a royalty-free, nonexclusive, irrevocable license for use of such material.

54.414 INTEREST.

Interest or other income earned on payments under this subpart shall be paid to the United States as such interest is received by the grantee.

APPENDIX 3

SUGGESTED AFFILIATION AGREEMENT
FOR COOPERATION IN A REGIONAL
MEDICAL PROGRAM

For the purpose of accepting Regional Medical Program funds and for the further purpose of voluntarily acknowledging the required fiscal responsibility,_____
the Regional Medical Program grantee, and _____
the affiliating institution (or agency), in full recognition of the necessity for the affiliate to expend Federal monies received by the grantee under Title IX of the Public Health Act, as amended, and to assist the grantee in meeting its responsibilities under the terms of the grant, do enter into this agreement in support of the provisions of Sections 903(b), 904(b), or 910 of the Act (copy of Title IX should be attached to this agreement).

Further, as a basis of assuring appropriate fiscal accountability in the expenditure of Regional Medical Program grant funds, the above institutions (or agencies) do hereby execute this Agreement of Affiliation. And the affiliating institution does hereby give its assurances that it will administer, expend and be accountable for Regional Medical Program grant funds in accordance with the Act and in accordance with the current and future regulations and policies as may be outlined in the Guidelines of the grantor.

Accordingly, the above is mutually agreed by the parties to this affiliation agreement as witnessed by the signatures of their responsible officials.

_____	_____
Regional Medical Program Grantee	Affiliate
_____	_____
Responsible Official	Responsible Official
_____	_____
Title	Title

Date _____ 19 _____