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12/20/65

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE
Public Health Service

[42 CFR Part 66]

Grants--Regional Medical Programs

Part 66--Regional Medical Programs

Preface Sec. 900. The purposes of this title are--

(a) Through grants, to encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutions, and hospitals for research and training (including continuing education) and for related demonstrations of patient care in the fields of heart disease, cancer, stroke, and related diseases;

(b) To afford to the medical profession and the medical institutions of the Nation, through such cooperative arrangements, the opportunity of making available to their patients the latest advances in the diagnosis and treatment of these diseases; and

(c) By these means, to improve generally the health manpower and facilities available to the Nation, and to accomplish these ends without interfering with the patterns, or the methods of financing, of patient care or professional practice, or with the administration of hospitals, and in cooperation with practicing physicians, medical center officials, hospital administrators, and representatives from appropriate voluntary health agencies.

Sec. 66.1 Applicability

The provisions of the Part apply to grants 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.

Sec. 66.2 Definition

(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, and stroke.

(e) "Title IX diseases" means heart disease, cancer, stroke, and related diseases.

(f) "Program" means the regional medical program as defined in Sec. 902(a) of the Act.

(g) "Practicing physician" means any physician licensed to practice medicine in accordance with applicable State laws, ~~who is primarily engaged in the diagnosis and treatment of patients.~~

(h) "Major repair" includes restoration of an existing building to a sound state.

(i) "Built-in equipment" is equipment affixed to the facility and usually included in the construction contract.

Sec. 66.3 Eligibility

(a) In order to be eligible for a grant, the applicant shall meet the criteria specified in Secs. 903 and 904 of the Act and such other criteria not inconsistent therewith as the Surgeon General may establish in order to carry out the purposes of Title IX.

Sec. 66.4 Application

(a) An application for a grant shall be submitted on such forms and in such manner as the Surgeon General may prescribe.

(b) 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) In addition to any other pertinent information that the Surgeon General may require, the applicant shall submit a description of the program in sufficient detail to clearly identify the nature, need, purpose, and plan of the program, the nature and functions of the participating institutions, the area to be served, the cooperative arrangements in effect, or intended to be made effective, within the group, and the justification for the amount of the funds requested.

Sec. 66.5 Terms, conditions, and assurances

In addition to any other terms, conditions, and assurances required by law or imposed by the Surgeon General, each grant shall be subject to the following terms, conditions, and assurances to be furnished by the grantee. The Surgeon General 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 application and award statement. Changes may be made only in accordance with procedures established by the Surgeon General.

(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.

Sec. 66.6 Award

(a) General. Upon recommendation of the National Advisory Council on Regional Medical Programs, and within the limits of available funds, the Surgeon General 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 Surgeon General shall take into consideration, among other relevant factors, the following:

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

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

(3) The extent to which the applicant or the participants in the program plan to coordinate or have coordinated the regional medical program with research projects and other activities supported pursuant to the authority contained in the Public Health Service Act and other

Acts of Congress including those relating to use of facilities, personnel, and equipment, and training of manpower.

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

(5) The degree to which the proposed geographic area substantially overlaps other areas served or to be served by a similar regional medical program.

(6) 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.

(7) The extent to which the distance between participating facilities, in the light of available modes of transportation and communication, are not detrimental to the effective implementation of the program.

Sec. 66.7 Establishment and operation of regional medical programs
documentary evidence

An application for a grant to establish and operate a program must be accompanied by documentary evidence of (a) the cooperative arrangements necessary in the opinion of the Surgeon General to effectively carry out the purposes of Title IX and (b) budgets or other financial data establishing that grant funds will not supplant funds otherwise available for activities under the regional medical programs.

Sec. 66.8 Termination

(a) Termination by the Surgeon General. Any grant award may be revoked or terminated by the Surgeon General 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 part. 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 Surgeon General in writing setting forth the reasons for such termination.

Sec. 66.9 Civil Rights

Section 601 of Title VI of the Civil Rights Act of 1964 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 (42 USC 2000(d)). Therefore, the regional medical programs, like every program or activity receiving financial assistance from the Department of Health, Education, and Welfare, must be operated in compliance with this law. To the extent that a grant under this part involves a construction contract in excess of \$10,000, it is subject to 28 FR 9812 (September 7, 1963) (Exhibit 7 of the PHS Grant Regulations regarding equal employment opportunities).

Sec. 66.10 Expenditures by grantee

(a) Allocation of costs. Except as may otherwise be provided by or pursuant to the regulations of this part, the allocation of expenditures by a grantee as between direct and indirect costs shall be in accordance with generally accepted and established accounting practices and in accordance with the same policies and methods that the grantee applies to all its research and related activities.

(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 Surgeon General may issue rules, instructions, interpretations, or limitations supplementing the regulations of this Part 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 vacations 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 provided in the course of carrying out a program supported by a grant hereunder and only if the referral of the patient is documented

by 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 Surgeon General.

Sec. 66.11 Payments.

The Surgeon General 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 Act.

Sec. 66.12 Disposition of facility and equipment; good cause for other use

(a) The grantee shall promptly notify the Surgeon General in writing if at any time within ten years 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.

(b) The Surgeon General shall determine the disposition of any facility or equipment, for construction or procurement of which grant funds were charged, in the event such facility or equipment is, within ten years after completion of construction or procurement, no longer used for the purposes for which grant funds were awarded, or if the applicant or other owner of the facility or equipment shall cease to be or is not a public or nonprofit institution, and may for good cause release the applicant or other owner from the obligation to so use such facility or equipment. In determining whether such good cause exists, the Surgeon General 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 purposes.

(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 for the remainder of the period other facilities not previously utilized for such research will be so utilized and are substantially the equivalent in nature and extent for such purposes.

(c) In lieu of disposing of such facility or equipment pursuant to the determination of the Surgeon General, the grantee or other owner may pay, and where transfer to the United States or other transferee pursuant to the determination of the Surgeon General is impractical or impossible (e.g., a floor of a building or attachment to realty) shall pay, to the United States the amount bearing the same ratio to the then value of the facility or equipment, as determined by the Surgeon General, as the amount the Federal participation bore to the cost of construction or procurement.

(d) For the purposes of this section, "facility" means that part of a building, such as a floor or other part of a building directly and substantially affected, as determined by the Surgeon General, by the construction for which grant funds were charged.

Sec. 66.13 Inventions or discoveries

Any grant award hereunder is subject to the regulations of the Department of Health, Education, and Welfare as set forth in Title 45, CFR Parts 6 and 8, as amended. Such regulations shall apply to any 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 Surgeon General 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 shall be maintained for such periods, and filed with or otherwise made available to the Surgeon General or those he may designate at such times and in such manner as he may determine necessary to carry out such Department regulations.

Sec. 66.14 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.

Sec. 66.15 Copyrights

Where the grant-supported activity results in copyrightable material, the author is free to copyright, but the Public Health Service reserves a royalty-free, non-exclusive, irrevocable license for use of such material.

Sec. 66.16 Interest

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

W. H. ...

AMERICAN ACADEMY OF GENERAL PRACTICE

VOLKER BOULEVARD AT BROOKSIDE · KANSAS CITY 12, MISSOURI

OFFICE OF THE PRESIDENT
AMOS N. JOHNSON, M. D.
GARLAND, NORTH CAROLINA

December 14, 1965

Stuart M. Sessoms, M.D.
Deputy Director
National Institutes of Health
Bethesda, Maryland 20014

Dear Stuart:

You indicated, in your remarks last Thursday, that you would like some comments from those of us who attended the Conference on Regional Medical Programs. I hope to keep my comments brief and related to the area of my experience; that of patient care and the practicing physician who will, of necessity, screen these patients and make patient referral to the proposed Medical Centers.

The majority of concern, as relates to the implementation of this bill, appears to focus on problems of selecting specific areas, financing, and implementing these regional centers. Perhaps, at this stage of planning these areas are most urgent.

Conversely, little of comment and discussion was directed towards the methodology of obtaining patient acceptance and utilization. If all potential patients are to obtain benefits equally, much consideration must be given to this area of implementation.

Aside from the directive that "two members of the National Advisory Council be practicing physicians" and the rather vague implication that the local advisory group should include practicing physicians in its membership, little consideration was given to acquiring physician approval and participation of those practicing physicians supplying patient services outside the centers. Perhaps this will come later and at a local level.

Can the identity of a "practicing physician" be specifically defined? Is there the implication, in this instance, that this "practicing physician" may well be a member of the staff of a given center? (Dr. DeBakey, who has as a patient one referred person from every several hundred screened by local physicians, classifies himself as a "practicing physician".

It seems possible, under present regulations, that a "local advisory group", carefully selected, could well become a tool for total control by a local power group with vested interest.

In discussions, little or no consideration was given to the requirement that patients must be referred to the centers.

Stuart M. Sessoms, M.D.

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order to have any patient care cost paid out of grant funds. Actually, I thought that Mr. Yordy, rather astutely, passed over this requirement in his preliminary discussion. Here, again, is our "practicing physician". Does this requirement, as written, leave the strong implication that anyone able to pay for services in full may walk into a center and be seen for a general physical evaluation (screening) before there is indication that this patient needs the special services of this center? Is the corporate practice of medicine intended in these regional medical programs?

To what extent does a paying patient pay? Does this payment include a reasonable sum for remuneration for professional services rendered, in addition to reimbursal for comprehensive hospitalization costs?

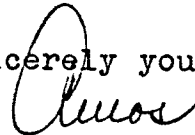
Stuart, these are a few of the many thoughts which occurred to me concerning the implementation of these regional medical programs. Educators and others present having especial areas of interests will pose to you questions and comments peculiar to their individual approach. All told, there should be some interesting questions and comments coming to you.

It was both a challenge and a pleasure to participate in this discussion. As President of the American Academy of General Practice, representing some 29,000 "practicing physicians", I invite you to contact me at any time that I, or the organization over which I preside, can be of any service to you or the NIH.

I am missing no opportunity to tell your friends in and about Roseboro of your great competence and success.

With very kind personal regards and best wishes for a Happy Holiday Season, I am

Sincerely yours,



Amos N. Johnson, M.D.

ANJ/maj