

LEO 4 EO

FIRST DRAFT REGULATIONS

Grants for Regional Medical Programs

D 51b. 101 Applicability.

The provision of this Part are applicable to the award of grants under section 903 and 904 of the Public Health Service Act (42 USC 299 c and d) for planning, establishment and operation of Regional Medical Programs.

51b. 102 Definition. *See fine Care (Primary, Secondary)*

All terms not defined herein shall have the meanings given them in the Act. As used in this Part:

(a) "Act" means Title IX of the Public Health Service Act, as amended (42 USC 299 et req.).

(b) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.

(c) "Related Diseases" means those diseases which can reasonably be considered to bear a direct relationship to heart disease, cancer, stroke, or kidney disease.

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

(e) "National Advisory Council" means the National Advisory Council on Regional Medical Programs, established by section 905 of the Act.

(f) "Regional Advisory Group" means the advisory group designated pursuant to section 903(b)(4) of the Act, and meeting the requirements of 51b. 109, to advise a particular Regional Medical Program.

51b. 103 Eligibility.

To be eligible for a grant under this subpart, the applicant must:

(a) Be a public or nonprofit private university, medical school, research institution, or other public or non-profit private agency or institution, or a combination thereof; and

(b) Be authorized to represent each of the agencies and institutions which propose to cooperate in planning for and the development and operation of a Regional Medical Program.

51b. 104 Application.

- D** (a) An application for grant under this subpart shall be submitted to the Secretary in such form and manner and at such time as the Secretary may prescribe.
- (b) Such application shall be executed by an individual authorized to act for the applicant, and to assume on behalf of the applicant, the obligation imposed by the terms and conditions of any award, including the Regulation of this subpart.
- (c) In addition to any other pertinent information which 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 agencies and institutions participating in the program, the geographic area to be served by the program, the cooperative arrangements in effect, or intended to be made effective, among the participating agencies and institutions, and the justification, supported by a budget or other data, for the amount of funds requested.

51b. 105 Approval of Applications.

(a) General. An application for a grant under this subpart may be approved by the Secretary only upon recommendation of the National Advisory Council, and only if he makes each of the following determinations:

- (1) That the application contains or is supported by reasonable assurances that Federal funds paid pursuant to such grant will be used only for the purpose for which paid and in accordance with the applicable provision of the Act and the Regulation of this support.
- (2) That the application contains or is supported by reasonable assurances that the applicant will provide for fiscal control and fund accounting procedures in accordance with 51b. _____
- (3) That the application contains or is supported by reasonable assurances that the applicant will make reports and keep records in accordance with 51b. _____
- (4) That the applicant is situated within geographical area that 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 facilities and systems; presence and distribution of educational, medical and health facilities and programs, and other activities which in the judgment of the Secretary are appropriate for carrying out the purposes of the Act.

D (b) Planning. In addition to the determination required by paragraph (a) of this section, an application for a grant which includes planning activities under section 903 of the Act may be approved by the Secretary only if he finds that the applicant has designated a Regional Advisory Group which meets the requirements of 51b. 108.

(c) Establishment and Operation. In addition to the determination required by paragraph (a) of this section, application for a grant which includes establishment and operational activities under section 904 of the Act may be approved by the Secretary only if he makes each of the following determinations:

(1) That the application contains or is supported by reasonable assurances that Federal funds paid pursuant to such grant will not be used to support funds that are otherwise available for establishment and operation of the Regional Medical Program with respect to which the grant is made.

(2) That the application has been recommended by the Regional Advisory Group.

(3) That opportunity has been provided, prior to the recommendation of the Regional Advisory Groups, for consideration of the application by each public or nonprofit private agency or organization which has developed a comprehensive regional, metropolitan area, or other local area plan referred to in section 314(b) of the Public Health Service Act covering any area in which the Regional Medical Program for which the application is made will be located.

Mission
51b. 106 Priority of Regional Medical Programs. *(Revise)*

In determining priority among approved applications for grants for Regional Medical Programs, the Secretary will take into account the following:

(a) The relative extent to which the proposed Regional Medical Program will

- ✓ (1) Link and strengthen the ability of multiple health institutions and professions to provide care in the Title IX diseases;
- ✓ (2) Provide early increases in the quality and accessibility, and moderation of the cost, of care in the Title IX diseases;
- ✓ (3) More broadly disperse new or improved knowledge and treatment of Title IX diseases so that larger numbers of persons will receive better care;

D

(4) Lead to increased utilization and effectiveness of community health facilities and manpower, especially new or existing kinds of allied health personnel, so as to alleviate maldistribution of health services in the Title IX diseases;

(5) Include health maintenance, disease prevention, and early detection activities as integral components;

✓ (6) Provide for expanded ambulatory care and outpatient diagnosis and treatment;

✓ (7) Strengthen and improve the relationship between primary and secondary care so as to produce greater continuity and accessibility of care; and

(8) Be supported by local, State and other non-Federal funds.

(b) The relative effectiveness of the organizational structure of the Regional Medical Program, including the extent to which

(1) All health related interests, institutions, and professions in the geographic area to be served are actively participating in the program;

(2) Organizational planning and activity are carried out at the local level; and

(3) There is systematic and ongoing identification and assessment of needs, problems, and resources.

(c) In the case of an application for continuation support (in addition to the criteria listed in paragraphs (a) and (b) of this section)

(1) Whether the Regional Medical Program has established its own goals, objectives, and priorities.

(2) The extent to which activities previously undertaken with the aid of funds under the Act have been productive in terms of the specific ends sought to be achieved; and

(3) The extent to which activities stimulated and previously supported by funds under the Act have been or will be supported under other health care financing systems.

51b. 107 Grant Award.

(a) Within the limits of funds available for such purpose, the Secretary may award grants with respect to those applications

T

D for the planning, establishment and operation of Regional Medical Programs which will in his judgment, after the application of the priority consideration set forth in 51b. 106, best promote the purposes of the Act.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary to carry out the approved activities.

(c) All grant awards shall be in writing, and shall set forth the amount of funds granted and the period for which support is recommended.

(d) Neither the approval of any application nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation or other award with respect to any approved application or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

51b. 108 Approval and award of funds for specific operational projects.

(a) Except as provided in subparagraph (b) of this section, funds for specific operational projects within a grant for establishment and operation of a Regional Medical Program must be specifically approved by the Secretary upon the recommendation of the National Advisory Council, in accordance with the priorities set forth in 51b. 106 of this subpart.

(b) The Secretary may authorize any recipient of a grant for establishment and operation of a Regional Medical Program to approve, within the limits of available funds awarded to such grantee for such purpose, specific operational projects where he determines, upon the recommendation of the National Advisory Council, that such grantee and such Regional Medical Program have satisfied the following requirements:

(1) Application. There must be established within the Regional Medical Program a standardized application form and procedures, approved by the Secretary, for the submission of applications for funds for operational projects.

(2) Review criteria and priorities. Technical review criteria and program priorities, approved by the Secretary, must be established and made available to all prospective applicants within the geographic area to be served by the Regional Medical Program.

(i) Technical review criteria shall include, but need not be limited to the following:

- (A) The feasibility of the proposed project;
- (B) The quality of the personnel and facilities to be devoted to the project;
- (C) Financial and other resources available to support the project; and
- (D) The adequacy of the proposed method of evaluation of the project.

(ii) Program priorities must reflect the needs of the geographic area served and be consistent with the priorities set forth in 51b. 106 of this subpart.

(3) Technical Review. There must be established within the Regional Medical Program, in addition to the Regional Advisory Group, a system for obtaining review of application by technical review committees or groups acceptable to the Secretary.

(i) The composition of such committee or group must be such that their technical, scientific, and professional expertise adequately covers the scope of their respective review functions.

(ii) The manner in which the members of such committees are chosen and the procedures governing the frequency and conduct of meetings must be in writing and be approved by the Regional Advisory Group.

(iii) Written summaries of the findings and recommendations of the technical review committees must be made available to the Regional Advisory Group prior to the meeting at which the applications involved will be considered by the Regional Advisory Group.

(4) Review by areawide health planning agencies. Opportunities must be provided, prior to action by the Regional Advisory Group, for consideration of each application by each public or non-profit private agency or organization which has developed a comprehensive regional metropolitan area, or other local area plan referred to in section 314(b) of the Public Health Service Act covering any area which will be served by the proposed project. Copies of any comments made by such agencies shall be furnished to the Secretary on request.

D

(5) Approval of applications. Applications shall be approved only upon the recommendation of the Regional Advisory Group.

(6) Project ranking and funding determination. There must be established a priority ranking system, based upon the program priorities established pursuant to subparagraph (2) of this paragraph and approved by the Secretary, to be applied by the Regional Advisory Group in determining the order in which approved projects will be funded.

(7) Appeal procedure. In the case of any review procedure in which an application may be disapproved by a group other than the Regional Advisory Group, a written procedure, approved by the Secretary, must be established under which an applicant whose application is so disapproved may request appeal of such disapproval by the Regional Advisory Group. The levels of review under such procedure must be clearly described, and copies of such procedure should be made available to all applicants.

51b. 109 Regional Advisory Group.

Each grant award under this subpart is subject to the condition that there has been established in or for the geographic area to be served by the Regional Medical Program a Regional Advisory Group which meets the requirements of this section.

(a) The membership of the Regional Advisory Group shall be sufficient in number to insure adequate community orientation, and shall include practicing physicians and members of other health professions; medical center officials; hospital administrators; representatives from appropriate medical societies and voluntary health agencies; representatives of each agency administering or supervising the administration of a State plan approved under section 314(a) of the Public Health Service Act for a State in which the geographic area served by the Regional Medical Program is located, and of each public or nonprofit private agency or organization which has developed a comprehensive areawide health plan referred to in section 314(b) of the Public Health Service Act for an area in which such geographic area is located; representatives of other organizations, institutions, and agencies concerned with activities of the kind to be carried on under the program (including as an ex officio member, if there is located in such geographic area 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 Regional Advisory Group as the representative of such hospitals or other health care facilities); and members of the public familiar with the need for and financing of the services to be provided under the program.

(b) Members of the Regional Advisory Group shall meet as often as necessary, but not less often than four times per year, for the purpose of

(1) Advising the grantee in formulating and carrying out the plan for the establishment and operation of the Regional Medical Program; and

(2) Reviewing, and making recommendations with respect to, applications for funds for specific operational projects within the Regional Medical Program.

51b. 110 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 incurred or to be incurred, to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved program.

51b. 111 Use of grant funds.

(a) Any funds granted pursuant to their subpart, and any non-Federal funds required as a condition of the grant to be expended in the project, shall be expended by the grantee solely for carrying out the approved program in accordance with the Act, the Regulations of this subpart, the terms and conditions of the award, and the cost principles set forth in the Department of Health, Education, and Welfare Grants Administration Manual (available for purchase at the Government Printing Office (GPO 894-523)).

(b) Prior approval by the Secretary of revision of the budget and program plan is required whenever there is to be a significant change in the scope or nature of program activities.

51b. 112 Nondiscrimination

Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (42 USC 2000d; 78 Stat. 252) which 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. A regulation implementing such Title VI, which is applicable to grants made under this subpart, has been issued by the Secretary of Health, Education, and Welfare with the approval of the President (45 CFR Part 80).

51b. 113 Inventions or discoveries.

A grant award is subject to the regulations of the Department of Health, Education, and Welfare as set forth in 42 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 project 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 obligations are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries 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.

51b. 114 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this subpart, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

51b. 115 Records, reports, and inspection.

(a) Records and reports. Each grant awarded pursuant to this subpart shall be subject to the condition that the grantee shall maintain such operational and accounting records, identifiable by grant number, and file with the Secretary such operational and fiscal reports relating to the use of grant funds, as the Secretary may find necessary to carry out the purposes of the Act and the Regulations. All records shall be retained for 3 years after the close of the budget period. Such records may be destroyed at the end of such 3-year period if the applicant has been notified of the completion of the Federal audit by such time. If the applicant has not been so notified such records shall be retained (1) for 5 years after the close of the budget period or (2) until the grantee is notified of the completion of the Federal audit, whichever comes first. In all cases where audit questions have arisen before the expiration of such 5-year period, records shall be retained until resolution of all such questions.

(b) Inspection and audit. Any application for a grant under this subpart shall constitute the consent of the applicant to inspections of the facilities, equipment and other resources of the applicant at reasonable times by persons designated by the Secretary and to interview with principal staff members to the extent that such resources and personnel are, or will be, part of the project. In addition, the acceptance of any grant under this subpart shall constitute the consent of the grantee to inspections and fiscal audits by such persons of the supported activity and of progress and fiscal records relating to the use of grant funds.

D 51b. 116 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

51b. 117 Suspension and early termination.

Whenever the Secretary finds that a grantee has failed in a material respect to comply with the Act or with the terms of the grant, including the Regulations of this subpart, he may, on reasonable notice to the grantee, withhold further payments, and take such other action, including the termination of the grant, as he finds appropriate to carry out the purposes of the Act and the Regulations. Noncancellable obligations of the grantee properly incurred prior to the receipt of the notice of termination will be honored. The grantee shall be promptly notified of such termination in writing and given the reasons therefore.

A

F

T

RMP SUGGESTED ADDITIONS TO PROPOSED REGULATIONS

D A. Grantee-RAG-Coordinator Relationships

The respective responsibilities of the Regional Advisory Group, RMP grantee organization, and the Chief Executive Officer (program coordinator) and their relationships to one another shall be in accord with such requirements as the Director of Regional Medical Programs Service may prescribe. In general, the RAG will be responsible for formulating the program policies, objectives, and priorities of an RMP; the grantee organization will be responsible for managing the RMP grant in a manner that will implement the program established by the RAG; and the Chief Executive Officer will be responsible for the day-to-day direction and management of the RMP in a manner that accords with the program policy established by the RAG and the administrative and other procedures of grantee organizations.

B. Section 910

1. Funds awarded under Title IX may be used to carry out the purposes of Section 910.
2. A Regional Medical Program may support activities authorized by Section 910 subject to the policies promulgated by the Secretary. No special application is required unless otherwise specified by RMPS.
3. Public or nonprofit private agencies, institutions, or combinations thereof other than Regional Medical Programs may request special project grants to support activities authorized by Section 910.
4. Contracts may be awarded by RMPS to Regional Medical Programs and other organizations pursuant to Section 910 to support any activity authorized under Title IX. At the option of the Secretary, contracts may be negotiated in lieu of grants.

C. Construction

No funds shall be authorized to be expended for construction unless specifically approved in advance by the Secretary.

Construction projects shall be subject to the Regulations of the Department which are applicable to the type of facility for the construction of which a grant is made, specifically the Regulations relating to Hospitals and Medical Facilities____, Health Research Facilities____, and Medical Teaching Facilities____, and the General Standards of Construction and Equipment thereunder.