



DRAFT

RMPS  
GRANT ADMINISTRATION  
MANUAL

Health Services and Mental Health Administration  
Regional Medical Programs Service  
Bethesda, Maryland 20814

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CHAPTER I  
USE AND REVISION OF MANUAL

I-1 INTRODUCTION

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CHAPTER I  
USE AND REVISION OF MANUAL

I-1 INTRODUCTION

## I-1 INTRODUCTION

### 1-1 SUMMARY OF CONTENTS

This Manual is intended to be used as a resource and reference work. It has been developed for use by the staff of the Regional Medical Programs Service, Regional Medical Programs themselves, and grantees. The Manual includes all currently applicable policies of the Regional Medical Programs Service and either includes, cites, or summarizes policies of the Department of Health, Education and Welfare and the Health Services and Mental Health Administration when applicable to grants under Title IX of the Public Health Service Act, Public Law 89-239, as amended. In addition to these items, the Manual also contains (1) copies of necessary forms and instructions, (2) references to other documents where appropriate, and (3) the text of applicable regulations.

### 1-2 AUDIENCE

The Chief Executive Officer of every Regional Medical Program, the Chairmen of Regional Advisory Groups and the financial management officials of RMPs should be thoroughly familiar with the contents of this document. In addition, they should keep current with changes as these occur. It is also advisable for the entire professional staffs of Regional Medical Programs and affiliated institutions to be acquainted with the Manual and to have access to a copy as needed for reference.

Each member of the professional staff of the Regional Medical Programs Service will be furnished with a copy of the Manual. RMPs staff will use the Manual in answering inquiries and will follow procedures prescribed therein.

### 1-3 STYLE

Because the Manual is a compilation, it contains a variety of material developed over a period of time by different offices and individuals. The literary style may therefore vary from chapter to chapter or within chapters. In some places, legislative or regulatory language or Department policy is quoted verbatim in the text. As of the date of issuance, however, the entire text of the Manual is correct and currently applicable. Revisions will be furnished to RMPs, grantees and RMPs staff as they are issued together with instructions for deletion of obsolete sections or pages.

The types of material included in the Manual also vary. Most of the Manual is concerned with requirements for applicants and

## I-1 INTRODUCTION

grantees. Some sections, however, are primarily concerned with RMPS internal processes. For example, Subchapter IV-3 describes the operation of RMPS review groups. Subchapter IV-4 illustrates the RMPS Review Criteria and Rating System. Subchapter IV-6 contains site visit guidelines. While these documents relate primarily to action by RMPS staff and reviewers, they are included in this Manual, rather than a separate document for staff, so that applicants and grantees are fully informed about governmental processes which affect them.

Users will note that policies contained in the Manual do not represent a monolithic position. Some policies clearly delegate authority to RMPs or Regional Advisory Groups. Other policies specify Federal requirements that must be followed, and still others call for negotiation. These differences are intentional. The Federal Government cannot and should not monitor or approve every transaction or decision of a grantee nor can it delegate all responsibility or foresee every contingency. Variations in policy such as those noted above, therefore, are designed to identify the locus of decision-making or the method of arriving at a decision on particular matters.

### 1-4 ARRANGEMENT OF MATERIAL

The Manual is divided into chapters and subchapters as indicated in the Table of Contents. The Contents also lists exhibits located throughout the text. These principally illustrate regulations, forms and related instructions. Exhibits are printed on blue paper.

Each chapter begins with a face page showing the name of the chapter and listing any subchapters by title and number. The subchapter title appears at the top of each page, and pages are numbered within each subchapter. The latter procedure permits revision of subchapters without renumbering the entire Manual. The numbering system and arrangement of the text is illustrated on the following page.

FIGURE 1  
Format and Numbering of Manual

XXX NAME OF CHAPTER (appears on Chapter  
title page only)

XXX-1 SUBCHAPTER TITLE

1-1 MAJOR HEADING

Text begins here. Items listed within the text are shown as follows: (1) first item, (2) second item, etc.

1-2 MAJOR HEADING

A. Minor Heading

Text for minor headings begins as shown.

B. Minor Heading

1. Subheading

Minor headings and subheadings are sometimes omitted when items are listed down a page.

a. Individual item under a subheading

1-5 CROSS REFERENCES

It is not always possible to present a complete discussion of a single topic in one place under one heading. Therefore, various aspects of a given subject are sometimes discussed in different chapters within the Manual. For example certain requirements relating to civil rights are discussed under the topic of "Assurances" in Chapter VI. Other civil rights requirements are covered in Chapter IX, "Civil Rights," and elsewhere in the text in relation to contracts and construction. Wherever the discussion of a given topic appears under several headings, cross references have been included. (Citations are made in accordance with the heading and numbering system illustrated on this page. This paragraph, for example, would be cited as Subchapter I-1, 1-5.) In a few places, where it could be done concisely, previously mentioned material is repeated rather than being cross referenced.

## I-1 INTRODUCTION

### 1-6 RELATED MANUALS AND PUBLICATIONS

In addition to this Manual, other applicable policies are contained in the "HEW Grants Administration Manual," which may be obtained from the Government Printing Office, Washington, D.C. Every RMP and grantee should maintain both manuals. The present publication makes reference to HEW Grants Administration Manual in a number of places, rather than repeat detailed financial management policies spelled out in that document. Other references are made, at appropriate points in the text, to publications of the Office of Grants Administration Policy (part of the Office of the Secretary, DHEW) relating to indirect costs and to the quality of grantee management.

### 1-7 POLICY REQUIREMENTS ADMINISTERED BY HEW UNITS OTHER THAN RMPS

Some of the policies applicable to RMPS grantees and contained in this Manual are administered by units of the Department of Health, Education, and Welfare other than the Regional Medical Programs Service and HSMHA. For example, payments are made through the National Institutes of Health, which is also responsible for giving certain approvals relating to research and experimentation involving human subjects or laboratory animals. The Office of Grants Administration Policy is responsible for negotiating and approving indirect cost rates. Another part of the Office of the Secretary is responsible for handling inventions developed with grant support, etc. Wherever it is necessary for RMPS or grantees to deal with these or other units of the Department besides RMPS, the name and address of the appropriate office is given in the text of the Manual. Affiliates should direct communications to RMPS, or any other HEW Agency, only through the RMP or the grantee for the RMP.

### 1-8 TERMINOLOGY

Terms used in the Manual are defined in Subchapter III-1, "Definitions." Some of the defined terms appear frequently throughout the Manual. Others may appear once or only occasionally. The definitions in Subchapter III-1 are identical with the Act and Regulations for the terms defined therein. Definitions for various cost and budget items are those prescribed by the HSMHA Office of Grants Management. A few definitions are taken from other standard Government sources, and certain terms such as "program staff," and "affiliate" are defined specifically in relation to the RMP program.

### 1-9 WAIVER

The Director, RMPS, may waive any policy contained in this Manual provided that the effect of such waiver is not contrary to law, regulations, instructions, or HSMHA policy. Waivers will be granted only in exceptional circumstances.

CHAPTER I  
USE AND REVISION OF MANUAL

I-2 PROCEDURES FOR REVISION

## I-2 PROCEDURES FOR REVISION

### 2-1 POLICY ISSUANCE

The Manual is issued in loose leaf form so that policy changes can be incorporated easily. Policy will be reviewed periodically by RMPS staff and amended as necessary. Any interested member of the public may submit suggested revisions at any time to the Director, RMPS.

All policy changes will state the entire correct policy, as revised, and (1) be accompanied by a covering statement that includes any needed background explanation; (2) explains where to insert the material in the Manual; (3) states the effective date of the new policy; and (4) indicate what obsolete material needs to be deleted from the Manual, if any. At least one set of any deleted obsolete materials should be retained by the grantees or RMP, since audit questions can frequently be avoided by referring to the policies in effect during the life of the grant, as opposed to those in effect at the time of audit.

Grantees and RMPs are responsible for keeping their Manuals up to date. In order to insure delivery of new or revised material, all policy issuances will be mailed with a return receipt requested. Policy issuances will also be consecutively numbered as a check against missing material.

Policy will be issued only when approved in writing by the Director, RMPS, and in the form approved by the Director.

### 2-2 PROCEDURE FOR REVISING POLICY

#### A. Submission

Suggestions and recommendations relating to policy matters may be submitted at any time by RMPs' grantees, affiliates, and RMPS staff.

The Director, RMPS, will periodically solicit suggestions for policy changes and for new policy from staff.

#### B. Required Material

Policy suggestions submitted to the Director, RMPS, by staff, RMPs, grantees, or affiliates should include:

1. The proposed wording of the policy, and where applicable, how such wording differs from existing policy (i.e., strike

## I-2 PROCEDURES FOR REVISION

out deleted wording by using slashes, ////, and underline the proposed new wording to be inserted.)

2. A copy of any other related existing policies or communications.
3. A brief statement of what the proposed changes are intended to accomplish.
4. If new, a statement of why the additional policy is needed.
5. The names, titles and institutional affiliations of individuals with whom the proposed new modified policy has been discussed.
6. An estimate of how many RMPs will be affected, and how.
7. A proposed effective date or implementation schedule, plus, where appropriate, a resume of any special problems of transition from the old policy to the new.

### C. Clearances

All proposed changes in grant policy will be sent to the HSMMA Office of Grants Management prior to final approval, pursuant to Chapter 1-20 of the HEW Grants Administration Manual.

All proposed policy issuances approved by the Director, RMPS, will be sent to the Office of the General Counsel, DHEW, for legal review and determination of the need for publication in the Federal Register.

CHAPTER II  
MISSION STATEMENT

II-1 MISSION STATEMENT, REGIONAL MEDICAL PROGRAMS

## II-1 MISSION STATEMENT, REGIONAL MEDICAL PROGRAMS

### 1-1 INTRODUCTION AND PURPOSE

The initial concept of Regional Medical Programs was to provide a vehicle by which scientific knowledge could be more readily transferred to the providers of health services and, by so doing, improve the quality of care provided with a strong emphasis on heart disease, cancer, stroke, and related diseases.

The implementation and experience of RMP in the past, coupled with the broadening of the initial concept especially as reflected in the most recent legislation extension, has clarified the operational premise on which it is based--namely, that the providers of care in the private sector, given the opportunities, have both the innate capacity and the will to provide quality care to all Americans.

Given this premise, the purpose of this statement is to specify (1) what Regional Medical Programs are, (2) what their evolving mission has become, and (3) the basis on which they will be judged.

### 1-2 RMP--THE MECHANISM

RMP is a functioning and action-oriented consortium of providers responsive to health needs and problems. It is aimed at doing things which must be done to resolve those problems.

RMP is a framework or organization within which all providers can come together to meet health needs that cannot be met by individual practitioners, health professionals, hospitals and other institutions acting alone. It also is a structure deliberately designed to take into account local resources, patterns of practice and referrals, and needs. As such it is a potentially important force for bringing about and assisting with changes in the provision of personal health services and care.

RMP also is a way or process in which providers work together in a structure which offers them considerable flexibility and autonomy in determining what it is they will do to improve health care for their communities and patients, and how it is to be done. As such, it gives the health providers of this country an opportunity to exert leadership in addressing health problems and needs and provides them with a means for doing so. RMP places a great corollary responsibility upon providers for identifying the health problems and needs which they must help to meet and which concern and affect all the people.

## II-1 MISSION STATEMENT

### 1-3 RMP--THE MISSION

#### A. Goals

RMP shares with all health groups, institutions, and programs, private and public, the broad, overall goals of (1) increasing availability of care, (2) enhancing its quality, and (3) moderating its costs--making the organization of services and delivery of care more efficient.

Among government programs RMP is unique in certain of its salient characteristics and particular approaches. Specifically:

1. RMP is primarily linked to and works through providers, especially practicing health professionals; this means the private sector largely.
2. RMP essentially is a voluntary approach drawing heavily upon existing health resources.
3. Though RMP continues to have a categorical emphasis, to be effective that emphasis frequently must be subsumed within or made subservient to broader and more comprehensive approaches.

#### B. Principal Objectives

It is these broad, shared goals on the one hand and the characteristics and approaches unique to RMP on the other, that shape its more specific mission and objectives. The principal of these are to:

1. Promote and demonstrate among providers at the local level both new techniques and innovative delivery patterns for improving the accessibility, efficiency, and effectiveness of health care. At this time the latter would include, for example, encouraging provider acceptance of and extending resources supportive of Health Maintenance Organizations.
2. Stimulate and support those activities that will both help existing health manpower to provide more and better care and will result in the more effective utilization of new kinds (or combinations) of health manpower. Further, to do this in a way that will insure that professional, scientific, and technical activities of all kinds (e.g., informational, training) do indeed lead to professional growth and development and are appropriately placed within the context of medical practice and the community. At this time emphasis will be on activities which most effectively and immediately lead to provision of care in urban and rural areas presently underserved.

## II-1 MISSION STATEMENT

3. Encourage providers to accept and enable them to initiate regionalization of health facilities, manpower, and other resources so that more appropriate and better care will be accessible and available at the local and regional levels. In fields where there are marked scarcities of resources, such as kidney disease, particular stress will be placed on regionalization so that the costs of such care may be moderated.
4. Identify or assist to develop and facilitate the implementation of new and specific mechanisms that provide quality control and improved standards of care. Such quality guidelines and performance review mechanisms will be required especially in relation to new and more effective comprehensive systems of health services.

### C. Interagency Cooperation

Even in its more specific mission and objectives, RMP cannot function in isolation, but only by working with and contributing to related Federal and other efforts at the local, state, and regional levels, particularly state and areawide Comprehensive Health Planning activities.

### D. Spin-Off and Continued Support

Moreover, to be maximally effective requires that most RMP-supported endeavors make adequate provision for continuation support once initial Regional Medical Program grant support is terminated; that is, there generally must be assurance that future operating costs can be absorbed within the regular health care financing system within a reasonable and agreed upon period. Only in this way can RMP funds be regularly re-invested.

## 1-4 RMP--THE MEASURE

### A. Criteria For Assessment

It follows that the measure of a Regional Medical Program, reflecting as it does both mission and mechanism, must take into account a variety of factors and utilize a number of criteria. The criteria by which RMPs will be assessed relate to (1) intended results of its program, (2) past accomplishments and performance, and (3) the structure and process developed by the RMP to date.

#### 1. Program Criteria

- a. Criteria relating to a Regional Medical Program's proposed program, and the intended or anticipated results of its future activities, will include:

## II-1 MISSION STATEMENT

- (1) The extent to which they reflect a provider action-plan of high priority needs and are congruent with the overall mission and objectives of RMP.
  - (2) The degree to which new or improved techniques and knowledge are to be more broadly dispersed so that larger numbers of people will receive better care.
  - (3) The extent to which the activities will lead to increased utilization and effectiveness of community health facilities and manpower, especially new or existing kinds of allied health personnel, in ways that will alleviate the present maldistribution of health services.
  - (4) Whether health maintenance, disease prevention, and early detection activities are integral components of the action-plan.
  - (5) The degree to which expanded ambulatory care and out-patient diagnosis and treatment can be expected to result.
  - (6) Whether they will strengthen and improve the relationship between primary and secondary care, thus resulting in greater continuity and accessibility of care.
- b. There are, moreover, other program criteria of a more general character that also will be used. Specifically:
- (1) The extent to which more immediate pay-off in terms of accessibility, quality, and cost moderation, will be achieved by the activities proposed.
  - (2) The degree to which they link and strengthen the ability of multiple health institutions and/or professions (as opposed to single institutions or groups) to provide care.
  - (3) The extent to which they will tap local, state and other funds or, conversely, are designed to be supportive of other Federal efforts.

### 2. Performance Criteria

Performance criteria will include:

- a. Whether a region has succeeded in establishing its objectives and priorities.

## II-1 MISSION STATEMENT

- b. The extent to which activities previously undertaken have been productive in terms of the specific ends sought.
- c. Whether and the degree to which activities stimulated and initially supported by RMP have been absorbed within the regular health care financing system.

### 3. Process Criteria

- a. The viability and effectiveness of an RMP as a functioning organization, staff, and advisory structure.
- b. The extent to which all the health related interests, institutions and profession of a region are committed to and actively participating in the program.
- c. The degree to which there is an adequate functioning planning organization and endeavor, developed separately or in conjunction with CHP, at the local (or subregional) level.
- d. The degree to which there is a systematic and ongoing identification and assessment of needs, problems, and resources; and how these are being translated into the region's continuously evolving plans and priorities.
- e. The adequacy of the region's own management and evaluation processes and efforts to date in terms of feedback designed to validate, modify, or eliminate activities.

CHAPTER III  
TERMINOLOGY

III-1 DEFINITIONS

CHAPTER III  
TERMINOLOGY

III-1 DEFINITIONS  
III-2 ABBREVIATIONS

CHAPTER III  
TERMINOLOGY

III-2 ABBREVIATIONS

## III-2 ABBREVIATIONS

### 2-1 ABBREVIATIONS

Some of the more commonly used abbreviations associated with RMPS are listed below:

- DOD - Division of Operations and Development, RMPS
- DPTD - Division of Professional and Technical Development, RMPS
- DRG - Division of Research Grants, NIH
- HEW - Department of Health, Education, and Welfare
- HSMHA-- Health, Services and Mental Health Administration
- ICR - Indirect Cost Rate
- LAG - Local Advisory Group ( of an RMP)
- MIS - Management Information System (of RMPS)
- NAC - National Advisory Council
- NIH - National Institutes of Health
- OA - Office of the Administrator, HSMHA
- OD - Office of the Director, RMPS
- OGAP - Office of Grant Administration Policy, OS
- OPPE - Office of Program Planning and Evaluation, RMPS
- OS - Office of the Secretary
- OSM - Office of Systems Management, RMPS
- RAG - Regional Advisory Group
- RMP - A Regional Medical Program
- RMPs - Two or more Regional Medical Programs
- RMPS - Regional Medical Programs Service
- RO - An HEW Regional Office
- SARP - Staff Anniversery Review Panel

CHAPTER IV  
APPLICATION AND REVIEW

- IV-1 RMPS REVIEW PROCESS REQUIREMENTS AND STANDARDS
- IV-2 REVIEW RESPONSIBILITIES UNDER THE TRIENNIAL REVIEW SYSTEM
- IV-3 REVIEW GROUPS-STRUCTURE, FUNCTIONS, AND AUTHORITY
- IV-4 REVIEW CRITERIA AND RATING SYSTEM
- IV-5 RMPS PROGRAM ANALYSIS GUIDE
- IV-6 SITE VISIT GUIDELINES
- IV-7 PROCEDURES FOR REQUESTING SUPPLEMENTS TO RMPS GRANTS
- IV-8 GUIDES FOR REVIEW OF COMMUNITY BASED MANPOWER PROGRAM PROPOSALS

CHAPTER IV  
APPLICATION AND REVIEW

IV-1 RMPS REVIEW PROCESS REQUIREMENTS AND STANDARDS

## IV-1 RMP REVIEW PROCESS REQUIREMENTS AND STANDARDS\*

### 1-1 PURPOSE

This document sets forth those minimum standards which must be met by a Region for it to make the final decisions regarding (1) the technical adequacy of proposed operational activities and (2) which proposed activities are to be funded within the total amount available to it. The document also outlines the general manner and schedule for implementation to be followed.

### 1-2 REQUIREMENTS

The minimum requirements or standards that a Region's review process must meet if project review and funding authority is to be decentralized to it are grouped as follows:

1. Review Criteria and Program Priorities
2. Application
3. Staff Assistance, Review, and Surveillance
4. CHP Review and Comment
5. Technical Review
6. Project Ranking and Funding Determinations
7. Feedback
8. Appeal Procedures

#### A. Review Criteria and Program Priorities

There must be explicit (1) technical review criteria and (2) program priorities which are applied to all operational proposals. These criteria and program priorities must be made available to all prospective applicants and appropriate areawide CHP agencies within the Region as well as RMPS.

The review criteria must, as a minimum, reflect those factors considered in assessing the technical and intrinsic adequacy of operational proposals (e.g., the feasibility of the project, quality of the personnel and facilities, resources to be involved, and adequacy of the proposed evaluation). These criteria must, in fact, be used in the technical review process--for example, those committees and other groups with substantive responsibilities for reviewing and making recommendations to the Regional Advisory Group as to the technical adequacy of operational proposals.

Program priorities should reflect regional needs and problems and appropriately complement RMPS and other national priorities. Put another way, those things which the Regional Medical Program and its Regional Advisory Group have identified, and perhaps are actively promoting, that warrant particular and more immediate attention and thus have a special claim on their limited dollar

## IV-1 REVIEW REQUIREMENTS AND STANDARDS

and other resources. As such, the program priorities constitute a major factor taken into account in determining which regionally approved proposals (i.e., technically adequate) are to be funded. The final responsibility for funding determinations, and thus the application of these program priorities, must reside with the Regional Advisory Group.

### B. Application

The Region must have a standardized application form or format (e.g., instructions and outline to be followed) that is employed by community hospitals, local medical societies, medical centers, and other applicants in requesting grant funds of it. It would be desirable if the review criteria and program priorities of the Region were an integral part of the application package sent to all prospective applicants.

### C. Staff Assistance Review and Surveillance

Program staffs must respond to preliminary applications and stand prepared to advise and assist all prospective applicants in a similar or equitable fashion.

It is suggested that program staffs prepare summaries of proposed projects for the technical review committees and Regional Advisory Group. Furthermore, where proposals have been substantively reviewed by program staff, these critiques should be provided to the technical review committees. Similarly, any suggested substantive changes in the proposal should be transmitted to applicants.

Periodic surveillance or monitoring of funded operational projects by program staff is required so as to insure that the original intent and purpose of such projects are being fulfilled and progress is satisfactory. One way in which this requirement might be satisfied would be to assign a program staff member this responsibility at the outset of a project and have him follow that project through to its completion. It also would be desirable if periodic progress reports on projects were made to the Regional Advisory Group.

### D. CHP Review and Comment

P.L. 91-515 provides that an RMP application may be approved at the Federal level only if recommended by the Regional Advisory Group and only "if opportunity has been provided, prior to such recommendation, for consideration of the application by each public or nonprofit private agency or organization which has

## III-1 DEFINITIONS

### 1-1 PURPOSE AND INTRODUCTION

To facilitate understanding the policies set forth in the Manual, definitions of key terms are listed alphabetically below. Where applicable, the definitions are identical with those in the Act and/or Regulations. Definitions of cost and budget categories are those prescribed by Departmental or HSMHA policy. Some of the terms defined below, however, are not defined elsewhere. These are generally those terms specifically associated with the RMP program.

### 1-2 DEFINITIONS

#### 1. Act (Title IX)

Public Law 89-239, as amended.

#### 2. Administrator

the Administrator of the Health Services and Mental Health Administration (HSMHA).

#### 3. Affiliate; Affiliated Agency; Affiliated Institution

a public or nonprofit private agency or institution, other than the grantee, which receives RMP grant funds for specific operational activities.

#### 4. Alteration and Renovation

the work required to change the interior arrangements of other physical characteristics of an existing facility or installed equipment so that it may be more effectively utilized for its currently designated purpose, or adapted to a changed use as a result of a programmatic requirement. Alterations and Renovations may include work referred to as improvements, conversion, rehabilitation, remodeling or modernization.

#### 5. AntiLymphocyte Globulin; AntiLymphocyte Serum

products of animal serum used to prevent rejection of transplanted organs, especially kidneys.

#### 6. Applicant

a public or nonprofit corporate organization, institution or agency which submits a request for funds under the Act and which proposes to accept the grants for the RMP for which funds are requested.

## III-1 DEFINITIONS

7. Application

a request for Federal funds submitted on the prescribed application form (RMP-34-1 for RMPs).

8. Artificial Kidney

total system used for hemodialysis consisting of dialyzer and dialysate delivery system.

9. Basic Education

educational activities designed principally to qualify the students for a degree, diploma, or certification. Internships and residency programs are part of basic education.

10. Budget Period

the period of time indicated in Item 7 of the Notice of Grant Award, HSM-457, for which grant funds are obligated by the Federal Government (usually twelve months). (Also, see "Obligation of Federal Funds.")

11. Built-in Equipment

permanently attached equipment--such as, plumbing and lighting fixtures, built-in cabinets, etc.

12. Chief Executive Officer (of an RMP)

the person who begins the principal administrative responsibility for the overall coordination of a Regional Medical Program. The Chief Executive Officer is frequently called "Coordinator," or "Director."

13. Clinical Research Center

an institution (or part of an institution), the primary function of which is research, training of specialists, and demonstrations which, in connection therewith, provides specialized, high-quality diagnostic and treatment services for inpatient and outpatients.

14. Communication Costs

those costs incurred for mailing, telephone, telegrams, radio and television (used for education, diagnostic, or other purposes), etc.

## III-1 DEFINITIONS

15. Construction

the erection, installation or assembly of a facility, including the expansion, addition, extension of an existing facility which provides new floor space, cubeage, or applicable units of measurements, total replacement of a facility and/or the physical relocation of a facility from one location to another. For buildings and structures, it may include site preparation, including demolition, excavation, landfill, utility system connections and extensions, site improvements such as roads, walks, parking areas, landscaping, and exterior or interior real property and installed (built-in) equipment.

16. Consultant Costs

Those costs incurred for consultant fees and supporting costs such as travel and per diem in payment of services related to any program element of a Regional Medical Program.

17. Continuation

a request or grant for funding of an additional budget period for which support has been recommended previously by the National Advisory Council.

18. Continuing Education

those educational endeavors which are above and beyond those normally considered appropriate for qualification or entrance into practice in a health profession or an occupation in a health related field.

19. Contractual Services

specialized services which cannot be provided by the applicant, such as statistical services, special studies, etc.

20. Coordinator

See Chief Executive Officer.

21. Core

See "Program Staff."

22. Decremental Funding

system of phased reduction of the Federal share of the costs of an activity, usually by increased assumption of costs through earned income and local third-party payments.

23. Department

the Department of Health, Education, and Welfare.

## III-1 DEFINITIONS

### 24. Descriptors

a standard classification scheme prescribed by RMPS which is used by grantees to provide RMPS with selected salient characteristics of individual operational and program staff activities. Special forms, RMP Descriptor Activity Reports (RMP 47-1 and 47-2), are used for classifying activities in accordance with the descriptors.

### 25. Dialysis

process by which waste products are removed from the blood by diffusion from one fluid compartment to another across a semipermeable membrane. In the case of kidney dialysis, blood is one of the fluids and the bath solution or dialysate is the other. (Also, see "Self Dialysis.")

### 26. Direct Assistance

is Federal assistance "in kind," in lieu of grant funds.

### 27. Director

See "Chief Executive Officer."

### 28. Director, RMPS

the Director of the Regional Medical Programs Service, who is responsible, through formal delegations, for the administration of RMPS, and Title IX of the Public Health Service Act, PL 89-239, as amended.

### 29. Employee Benefits

are allowances and services provided by the institution to its employees as compensation in addition to regular wages and salaries.

### 30. End-Stage (Renal) Disease

that stage of renal impairment which cannot be favorably influenced by conservative management and which requires dialysis and/or kidney transplantation to maintain life and health.

### 31. End-Stage (Renal) Treatment

refers to either dialysis or kidney transplantation or both forms of therapy.

## III-1 DEFINITIONS

### 32. Equipment Accountability

the obligation of a grantee to return to the Regional Medical Programs Service the residue or residual value of equipment purchased with grant funds in accordance with the law and applicable Federal Regulations. Such residue includes as much of the equipment, or a fair market value thereof, as represented by the proportion of the initial cost of the equipment charged to the grant account (i.e., the amount originally charged to RMPS multiplied by the product of the current value divided by the original cost.)

### 33. FECA

Facilities Engineering and Construction Agency

### 34. Feasibility Studies

is the testing of an activity for a specific trial period to determine if larger scale long-term or permanent operation is desirable (e.g., a pilot program for development of an operational activity).

### 35. Final Indirect Cost Rate

the indirect cost rate established after an institution's actual costs for a given accounting period (normally its fiscal year) are known. Once established, the final indirect cost rate is used as the institution's current provisional rate. (also, see "Indirect Cost Rate," "Provisional Indirect Cost Rate," and Chapter VII-3.)

### 36. Financial Data Record

form RMP-34-1

### 37. Fringe Benefits

see "Employee Benefits"

### 38. Grantee

the agency designated as the grantee in Item 9 of a Notice of Grant Award, HSM-457. The grantee's responsibilities include the management of and accounting for funds awarded in accordance with applicable Federal policy.

### 39. Grant Related Income

the Federal share of the net income derived by a grantee or affiliate from fees or charges made in connection with activities supported in whole or in part by an RMPS grant, or, where applicable, derived from the sale of items developed with RMPS grant support (i.e., publications, films, medical or other devices).

## III-1 DEFINITIONS

### 40. HEW

Department of Health, Education, and Welfare (also abbreviated DHEW). Major agencies of the Department include: (1) the Health Services and Mental Health Administration, HSMHA; (2) the National Institutes of Health, NIH; (3) the Food and Drug Administration, FDA; (4) the Social and Rehabilitation Service, SRS; (5) the Social Security Administration; and (6) the Office of Education.

### 41. HEW Region

the States served by an HEW Regional Office (also, see "Regional Office.")

### 42. HEW Regional Office

see "Regional Office"

### 43. Hospital

a facility including general, or other types of hospitals and related facilities, such as laboratories, outpatient departments, nursing home facilities, extended care facilities, facilities related to programs for home health services, self-care units, central service facilities operated in connection with hospitals. The term "hospital" also includes education or training facilities for health professions personnel operating as an integral part of a hospital but does not include any hospital furnishing primarily domiciliary care. In addition, with respect to Title IX, the term hospital also includes other health facilities in which local capability for diagnosis and treatment is supported and augmented by the program established under the Act.

### 45. Indirect Costs

those costs of an institution which are not readily identifiable with a particular project or activity, but nevertheless are necessary to the general operation of the institution and the conduct of the activities it performs. (Also, see "Provisional Indirect Cost Rate," "Final Indirect Cost Rate," and Chapter VII-3)

### 46. Indirect Cost Rate

#### 1. Provisional Indirect Cost Rate

a temporary rate established to allow the obligation and payment of funds by an awarding agency until actual indirect costs can be determined and a final rate established. provisional rates are subject to adjustment at a future date.

## III-1 DEFINITIONS

### 2. Final Indirect Cost Rate

a rate established after an institution's actual costs are known and the amount of indirect costs applicable to federally-sponsored activities has been determined. This rate is not subject to adjustment.

### 47. Long Term Training

see "Training."

### 48. Maintenance of Effort

the principle which applies to all Federal funds paid pursuant to a grant, and which requires that Federal grant funds will not be supplant funds that are otherwise available for establishing or operating a Regional Medical Program.

### 49. Management Information System (MIS)

the system devised for handling, within RMPS, program information from applications and other sources and used for review, planning, legislative and budget justifications, and program management. Operation of the MIS is the responsibility of the Office of Systems Management (OSM), which is part of the Office of the Director, RMPS.

### 50. Management Survey

an assessment performed by RMPS staff and Regional Office Personnel to evaluate the internal management of an RMP with the intent of recommending constructive action for a more effective and efficient operation.

### 51. Medical Center

a medical school or other medical institution involved in postgraduate medical training that is affiliated with one or more hospitals for teaching, research, and demonstration purposes.

### 52. Movable Equipment

a complete, identifiable, durable item which is not built-in (see "Built-in Equipment") and which has an expected service life of one year or more. (Expendable items and spare parts are classed as supplies. See "Supplies.")

### 53. National Advisory Council on Regional Medical Programs

the body appointed pursuant to Section 905 of the Act to advise on the administration of the RMP program.

### III-1 DEFINITIONS

54. NIH

National Institutes of Health. NIH is one of the major constituent agencies within the Department of Health, Education, and Welfare and is located at 9000 Rockville Pike, Bethesda, Maryland 20014.

55. Nonprofit Institution (Agency)

an institution or agency which is owned and operated by one or more nonprofit corporations and associations, no part of the net earnings of which inure, or may lawfully inure to the benefit of any private shareholder or individual.

56. Notice of Grant Award

form HSM-457

57. Obligation of funds (by the Federal Government for a grant)

the amount shown in item 12, f of a Notice of Grant Award (HSM-457).

58. Obligation of funds (by a grantee)

a commitment or promise to pay for goods, facilities or services whether or not the goods or services have been received or a bill rendered. (Purchase orders, contracts, etc., are evidence of obligation of funds.

59. OCAP

Office of Grants Administration Policy. OCAP is part of the Office of the Secretary, HEW, and is under the Assistant Secretary Comptroller. The Office of Grant Administration Policy's address is: Department of HEW, 330 Independence Avenue SW, Washington, D.C.

60. Operational Activity (Project)

is an activity managed and carried out by other than program staff. (See "Program Staff.")

61. Organ Preservation

maintenance of an organ after it has been removed from the donor and until it has been transplanted into a recipient. Organ preservation is an integral part of a kidney transplantation program.

62. Organ Procurement

the identification of a prospective donor; the surgical removal and transportation of a donor organ.

### III-1 DEFINITIONS

70. Regional Medical Program (RMP)

a nonprofit organization or group which meets all the requirements of Section 902(a) of the Act.

71. Regional Medical Programs Service (RMPS)

the unit of the Health Services and Mental Health Administration which is responsible for the administration of the Act.

72. Regional Office

an HEW Regional Office. (There are 10 HEW Regional Offices located, respectively, in Boston, New York, Philadelphia, Kansas City, Atlanta, Chicago, Dallas, Denver, San Francisco, and Seattle.) (Also, see "HEW Region.")

73. Regional Office Program Director

a member of the HEW Regional Office staff, assigned to advise, monitor and assist the RMPs in the HEW Region.

74. Regulation

a rule or series of rules, having the force of law, formally promulgated by a Department of the Federal Government. Regulations are published in the "Federal Register" and codified in the "Code of Federal Regulations." All regulations of the Department of Health, Education, and Welfare are promulgated by the Secretary.

75. Review Process Verification

special site visits and reports by RMPS staff to insure that RMPs comply with the RMPS "Review Process Requirements and Standards." (Also, see Subchapter IV-1.)

76. RMPS Review Committee

a 20 member advisory committee of non-Federal individuals appointed by the Director, RMPS, to perform initial review of grant applications, under Title IX, prior to consideration by the National Advisory Council. The Committee provides the major analytic review of each application. (Also, see Subchapter IV-3, 3-2.)

77. Secretary

the Secretary of Health, Education, and Welfare (HEW).

III-1 DEFINITIONS

84. Triennial Application

an application for three years of grant support to an RMP.

85. Unexpended Balance

unobligated funds remaining in the grant account at the end of a budget period.

86. Unliquidated Obligation

a bill received or obligation incurred, but not paid.

87. Verification Visit

see "Review Process Verification."

#### IV-1 REVIEW REQUIREMENTS AND STANDARDS

developed a comprehensive regional, metropolitan area or other local area plan referred to in Section 314(b) covering any area in which the regional medical Program for which the application is made will be located."

Agencies from which comments must be solicited include:

1. Areawide Comprehensive Health Planning agencies receiving Federal assistance under Section 314(b) of the Public Health Service Act as amended ("B" agencies).
2. Other organizations meeting the requirements of Section 314(b) and designated as areawide comprehensive health planning agencies by the appropriate State Comprehensive Health Planning Agency ("A" agency).

Furthermore, each application to RMPS requesting grant Federal support must be accompanied by copies of any "B" agency comments received by the Region or in lieu of such comments, by a letter signed by the Chairman of the Regional Advisory Group certifying that the application or materials adequately describing the activities proposed application or materials adequately describing the activities proposed in the application have been furnished to the appropriate "B" agency or agencies and that, after a period of 30 days, no comments have been received. While the signature of the Chairman of the Regional Advisory Group on the application, among other things, signifies that any comments received have been taken into consideration by that group, it would be highly desirable if the application submitted to RMPS explicitly took cognizance of and spoke to any especially critical and/or negative "B" agency comments.

Material sent to "B" agencies for comment should describe RMP activities in sufficient detail to enable the "B" agency to make appropriate comments. It is suggested that such material

1. List or call attention to all health care facilities or institutions involved in the RMP activities described in the application.
2. Indicate the amount of RMPS funds to be requested for each.
3. Summarize any proposed steps to strengthen primary care through cooperative arrangements and regional linkages among health care institutions and providers.
4. Identify any major therapeutic equipment to be acquired or constructed or major alteration or renovation of health care facilities to be undertaken in connection with proposed RMP activities.

#### IV-1 REVIEW REQUIREMENTS AND STANDARDS

Materials sent to "B" agencies for review and comment should encompass and include proposed program staff and developmental component activities as well as operational proposals. Information relating to program staff activities or a developmental component must be sent for comment to all "B" agencies serving the Region, in whole or in part. Information relating to projects whose impact is confined to a specific area within the region, need to be sent for comment only to those "B" agencies directly concerned.

#### D. Technical Review

Each Region must have, in addition to the legislatively required Regional Advisory Group, technical review committees or groups. These may be either standing committees or ad hoc groups; they may be subcommittees of the Regional Advisory Group itself, linked to it, or quite separate from it; and they may be single or multi-purpose groups (e.g., ad hoc review group, categorical planning and review committee). In short, Regions have considerable latitude as to how their technical review is structured.

The composition of these technical review committees, individually and collectively, must be such that the technical, scientific, and professional expertise represented adequately embraces the scope of its review function (e.g., cancer, manpower, research and evaluation). This may necessitate bringing in additional expertise, possibly from outside the Region, to provide adequate technical review of specific proposals from time to time.

It would be desirable if the selection process for technical review committees include nominations or suggestions from a variety of sources, including the Regional Advisory Group. It also is desirable that the composition of these committees reflect a broad spectrum of health interests and institutions, including private practitioners, community hospitals, and allied health personnel.

The manner in which members are chosen or appointed, procedures or practices governing the frequency and conduct of meetings, and the like must be in writing and have the concurrence of the Regional Advisory Group. In addition to employing explicit review criteria, these committees should always have available to them and be guided by any RMPS requirements currently applicable.

Summaries of technical review committee findings and recommendations must be available to the Regional Advisory Group prior to their meeting at which the projects in question will be considered.

With respect to technical review committees, the Regional Advisory Group and any other groups taking actions on applications, situations involving a potential conflict of interest must be avoided in the regional review process as well as in

## IV-1 REVIEW REQUIREMENTS AND STANDARDS

the Federal review system. Thus, it is required that persons affiliated with an institution or project being considered, not be a part of the review process considering that application.

### F. Project Ranking and Funding Determinations

Inherent in Anniversary Review is the requirement or need for Regions to establish a priority ordering or ranking system (in general) for all project applications for which support is requested. Since such ordering or ranking would by definition reflect the relative position of projects in relation to stated goals and priorities of the program, the system itself should incorporate regional needs and program objectives, priorities, and policies.

The specifics of such a project ordering or ranking system, however, are left to each Region to determine. Thus, it might provide for either an interval (e.g., 1-2-3-4-5) or ordinal (e.g., high-medium-low priority) ranking of projects, or some other suitable means for reflecting priorities.

The application of the system must be the responsibility of the Regional Advisory Group. Final determination must be made by it as to the relative or comparative priority ordering or ranking of approved projects and their eventual funding. It is anticipated that regional funding decisions (e.g., whether to fund level of funding) generally would be guided by each Region's own project priorities.

### G. Feedback

Each Region must have a formal feedback mechanism. Applicants and prospective project directors, whose proposals have been disapproved, should be given specific reasons why they have been disallowed in terms of technical adequacy and/or regional priorities.

Applicants generally should not have to wait more than four months between the time the application is entered into the RMP review process and RAG notification of its action. If a project is approved with conditions, or has been modified as a result of the regional review, there should be evidence of acceptance of such conditions and/or modifications by the applicant organization and/or project director.

### H. Appeal Procedure

A formal appeal mechanism must exist in any Region where a proposal may be disapproved by a body other than the Regional Advisory Group (e.g., an executive or steering committee, the board of trustees of a new corporation) without reference to the RAG in order to provide applicants with the option of appealing such adverse action to the Regional Advisory Group itself.

## IV-1 REVIEW REQUIREMENTS AND STANDARDS

The levels of review, prior to RAG action, should be clearly outlined, including the method of appointing the membership of these groups and be made available at the time of site visit or management assessment visit. Copies of this procedure should also be made known to all applicants.

### 1-3 SCOPE

The regional review process must not only meet the minimum requirements or standards set for above, it also must encompass or embrace all operational proposals or projects, for project review and funding authority to be decentralized to the regional level. In addition, it should provide for general Regional Advisory Group consideration of and concurrence in the overall program staff that share many characteristics of operational projects (e.g., disease registries, library services, pilot or experimental training programs for new kinds of health personnel) it would be desirable if these were subject to the same kind of review process, including review for technical adequacy, as those clearly identified as operational proposals.

An exception to the decentralization of project review and funding authority to Regions are major kidney or renal disease projects-- for example, proposals for integrated dialysis-transplantation centers or programs or major constituent elements thereof, such as tissue typing or organ procurement. All such proposed projects must continue to be submitted to RMPS for approval at the national level in accordance with procedures specified in Subchapter X-2.

### 1-4 DOCUMENTATION

The following documentation reflective of a Region's review process and structure must either be routinely submitted to RMPS as specified elsewhere (e.g., application) and/or be available for its review and examination:

1. The review criteria and program priorities currently employed in determining the technical adequacy of proposals and their priority rankings respectively.
2. The standard application form or format, and instructions being used.
3. The comments submitted by area wide CHP (or "B") agencies.
4. The current membership of technical review committees.
5. The procedures or practices governing appointment to and the operations of these committees.
6. The minutes, reports, or summaries of technical review committee and RAG meetings covering their deliberations and actions on proposals, including final funding determinations.

#### IV-1 REVIEW REQUIREMENTS AND STANDARDS

7. Where appropriate, the established appeal procedure; and RAG minutes reflecting any appeal actions.
  8. Any other written materials, including general application review procedures, pertaining to the review of proposals, either generally or specifically, at the regional or local level.
- D. Implementation

In the transition from national to regional review of operational activities the assumption is being made that the review processes of all Regional Medical Programs meet the requirements set forth herein, or can be made to do so with certain minimum adaptations.

Actual compliance with the requirements will be verified for each RMP prior to December 31, 1972. In many cases this will be carried out through special staff visits to assess the regional review process subsequent to submission and examination of the documentation enumerated above in 1-4. In some instances, however, assessment of the regional review process will be undertaken in conjunction with regularly scheduled management assessment visits. Where the verification process indicates that any Region does not meet the requirements, RMPS staff is prepared to provide necessary consultation and assistance to secure compliance.

Any Regional Medical Program which is not in substantial compliance with the minimum standards set forth in this Subchapter by December 31, 1972, may forfeit its project review and funding authority. In addition, regions that are not in substantial compliance will not be eligible for a developmental component. Furthermore, noncompliance with these standards after December 31, 1972 will be brought to the attention of the National Advisory Council. (This deadline may be waived where verification visits take place in late 1972.)

CHAPTER IV  
APPLICATION AND REVIEW

IV-2 REVIEW RESPONSIBILITIES UNDER THE TRIENNIAL REVIEW SYSTEM

## IV-2 REVIEW RESPONSIBILITIES UNDER THE TRIENNIAL REVIEW SYSTEM\*

### 2-1 NATURE OF COUNCIL ACTION

Under the triennial review system, each Regional Medical Program normally will be reviewed by the National Advisory Council only once each three years. The triennial review serves to recognize the Region as an "accredited" organization and to set a general level of annual support for the three-year period. Thus, the Council's favorable recommendation constitutes a time-limited approval for an RMP as an organization having recognized capabilities, rather than being approval for a specific set of activities. In addition to recommending the general level of support, Council actions on individual applications may include advice to the applicant Regional Medical Program, or specific conditions for the grant.

### 2-2 PRELIMINARY REVIEW

Prior to review by the Council, each triennial application will be reviewed by assigned RMPS staff, a site visit team and the RMPS Review Committee.

### 2-3 CONTINUATION SUPPORT (Also, see Subchapter IV-3, 3-1.)

#### A. Role of the Director, RMPS

Except as specified below, the Director, RMPS, will make continuation awards, including support for new activities, for second and third (02 and 03) year support without further Council action insofar as the proposed activities are consistent with relevant policies. Specifically, the Council's advice will be sought when:

1. The Director, RMPS, has determined, or the Review Committee has recommended to the Director, that a change in the Council-approved level is indicated.
2. A new Developmental Component is requested.
3. The Director, the Review Committee, the Region, or a member(s) of the Council itself requests Council review.
4. The applicant has failed in a material respect to meet the requirements of the Program or applicable laws, regulations or formally promulgated policies of the Department, HSMHA, or RMPS.

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\*Initially approved by the National Advisory Council, August 1971.  
Amended and approved by Council, February 1972.

## IV-2 REVIEW RESPONSIBILITIES UNDER THE TRIENNIAL REVIEW SYSTEM

### B. Staff Summaries (Also, see Subchapter IV-3, 3-1, G.)

A summary will be provided to the Council on each Region reviewed by staff for continuation support. This summary will include:

1. The findings as determined by the review of the Director, together with a statement of the amount previously recommended by the Council for funding and amount awarded.
2. A list of activities supported during the most recent grant year, identifying those which have been completed and those which have been supported through a developmental component.
3. A statement of the Region's response to any advice specified by the Council or limitations upon or conditions of the award.
4. Identification of any outstanding accomplishments.
5. Identification of any outstanding problems.
6. Annual reports from the Regional Advisory Group and from RMPS staff. (These will be made available on request by the Council.)

CHAPTER IV  
APPLICATION AND REVIEW

IV-3 REVIEW GROUPS--STRUCTURE, FUNCTIONS AND AUTHORITY

## IV-3 REVIEW GROUPS--STRUCTURE, FUNCTIONS AND AUTHORITY

### 3-1 Staff Anniversary Review Panel

#### A. Establishing Authority

The RMPS Staff Anniversary Review Panel (SARP) was established by the Director, RMPS, in September, 1971, to enable him to discharge responsibilities delegated to him by the National Advisory Council for determining second and third year continued funding levels for RMPs within the amounts previously recommended by Council. The delegation is contained in the Council's policy statement entitled "Review Responsibilities Under the Triennial Review System." The statement was initially approved by the Council on August 3, 1971, and was modified on February 8, 1972, to insure greater clarity. (See IV-2.)

#### B. Duration

The Staff Anniversary Review Panel operates at the pleasure of the Director, Regional Medical Programs Service. The SARP is an internal staff group. It is not a public advisory committee, and is not subject to the rules governing establishment and operation of public advisory bodies.

#### C. Structure

The Staff Anniversary Review Panel is composed of members of the senior professional staff of RMPS, including the four Operations Branch Chiefs, Chief of the Grants Management Branch, Director, Division of Operations and Development, Director and Deputy Director, Division of Professional and Technical Development, Director, Office of Program Planning and Evaluation and The Chief, Office of Systems Management. The Director, Division of Operations and Development, serves as Chairman.

#### D. Appointments

Members of the Staff Anniversary Review Panel are appointed by the Director, RMPS. The Executive Secretary for the SARP is assigned by the Director of the Division of Operations and Development.

#### E. Meetings

The Staff Anniversary Review Panel meets prior to each RMPS Review Committee meeting (usually a month prior to the Review Committee).

## IV-3 REVIEW GROUPS--STRUCTURE, FUNCTIONS AND AUTHORITY

### F. Functions

The principal function of the Staff Anniversary Review Panel is to relieve the RMPS Review Committee and the National Advisory Council of the need to review annually requests for previously recommended continuation support. This enables the Committee and the Council to more thoroughly evaluate triennial applications and requests from Regional Medical Programs which have not yet been approved for three year support.

### G. Scope of Review

In reviewing requests for Council-recommended second and third year funding of Regional Medical Programs, the Staff Anniversary Review Panel makes recommendations to the Director, RMPS, on (1) the level of funding, noting the Council-recommended level for the year in question, (2) whether further review by the RMPS Review Committee may be advisable, and (3) whether Council action is required for any specific request in the application or on any matter deemed important by the Panel. In making these determinations, the SARP is required to take into consideration the applicant Region's response to any advice specified by the Council or the Director, RMPS, and the Region's response to any conditions of the previous award.

In addition, the SARP evaluates the relative merit of each Regional Medical Program which it reviews through numerical ratings in accordance with criteria in IV-4. The SARP's rating is subject to subsequent review and modification by the Review Committee and Council at the option of those bodies.

The Director, RMPS, is free, of course, to accept or reject any recommendation of the SARP. A summary, including proposed action by the Director and the SARP's rating, is provided to the Review Committee and the Council on each Region reviewed by SARP for continuation support.

Further Committee and Council action is required whenever (1) the Director, RMPS, or the applicant Regional Medical Program requests such review, (2) a change is needed in the Council-approved level of support, (3) a new developmental component is requested, (4) the Region in question has materially failed to meet requirements. In all other instances, the summary of the SARP's findings and the proposed action of the Director will be transmitted to the Committee and Council for their information.

The Committee and Council may, if they wish, make alternative recommendations on any application. In order to permit full consideration by these groups, second and third year continuation applications are referred to the Council. The Council and Council have had an opportunity to study the SARP's recommendations and the Director's proposed action.

## IV-3 REVIEW GROUPS--STRUCTURE, FUNCTIONS AND AUTHORITY

### 3-2 RMPS Review Committee

#### A. Establishing Authority

The Regional Medical Programs Review Committee was established in June 1966, by the Director, NIH, and later transferred to the Health Services and Mental Health Administration when the RMP Program became part of that agency.

#### B. Duration

Since the RMPS Review Committee is an administratively established group, its continued operation is subject to renewed Departmental approval at two year intervals.

#### C. Structure

The Review Committee consists of 20 members, including the Chairman, appointed by the Director, Regional Medical Programs Service, for overlapping terms of four years. Members are leaders in the practice of medicine, other health professions, public health, medical center administration, hospital administration, and other areas related to the activities of the Regional Medical Programs Service.

#### D. Appointments

Members of the Review Committee are appointed by the Director, RMPS, subject to prior clearance by the Office of the Administrator, HSMHA. In making appointments the composition of the Committee with regard to professional fields is designed to cover the major areas of endeavor of the program as well as representation of the public, women and minorities.

No individual may serve on the Committee for more than four years, and no individual may be appointed who serves on any other public advisory committee of the Department of Health, Education and Welfare.

#### E. Meetings

The Review Committee meets on a regularly scheduled basis at least three times per year, usually in January, May and September. Meeting dates are established a year in advance, and meetings are scheduled for two full days.

#### F. Functions

The Review Committee reviews applications for grants under Title IX and makes recommendations to the National Advisory Council on Regional Medical Programs with respect to their approval and funding. While the Committee's recommendations

#### IV-3 REVIEW GROUPS--STRUCTURE, FUNCTIONS AND AUTHORITY

to the Council are advisory, the Committee provides the major analytic review of applications. The Committee's criticisms and recommendations together with those of the Council are regularly transmitted to applicants by the Director, RMPS, subsequent to Council action. In addition, Committee members participate in site visits to evaluate grantee performance and provide continuing professional consultation to strengthen RMPS's technical assistance.

Specifically, the Review Committee regularly reviews (1) triennial applications from Regional Medical Programs, and (2) applications from Regional Medical Programs not yet approved for a triennial period.

The Review Committee regularly receives summaries of (1) kidney proposals, and (2) proposed action recommended by the Staff Anniversary Review Panel on continued funding of grants within an approved triennium or other approved period of support. In addition, the Committee is regularly informed of final Council action as well as RMPS's advice in connection with applications.

At the discretion of the Director, the Review Committee reviews and makes recommendations to the Council on special project grants or applications for special program priorities if and when funds become available for such purposes. The Committee shall be kept fully informed of any special review procedures or requirements established by the Director in such cases. Where ad hoc review procedures are established for special categories of funds they shall include, to the extent possible, participation by Review Committee members.

In discharging their responsibilities, Committee members participate with RMPS staff and Council in both formal site visits and other site visits as deemed necessary in connection with applications. Committee members also participate in other special review activities as the Director may request in order to further the progress of the overall program.

#### G. Scope of Review

In the case of any application considered by the RMPS Review Committee, the Committee recommends to the Council (1) the level of funding, (2) the period of support, (3) any conditions to be attached to the grant, and (4) any appropriate advice.

In reviewing applications for Regional Medical Programs, the Review Committee considers the appropriateness of proposed activities, and consistency with RMPS policies. In addition, the Committee establishes the relative merit of each Regional Medical Program through numerical ratings in accordance with criteria specified in Subchapter IV-4.

#### IV-3 REVIEW GROUPS--STRUCTURE, FUNCTIONS AND AUTHORITY

The Review Committee is free, at its discretion, to review any application for continued support and to accept or modify any action or recommendation of the Staff Anniversary Review Panel with respect to such application including the priority rating assigned by the SARP. (See 3-1.) In such instances, the recommendations of the Review Committee shall be specifically brought to the attention of the Council for action.

In the case of kidney applications, the Review Committee will make recommendations to the Council only in those cases in which the IAC, CHP Agency, the Director, RMFS, or the Review Committee itself indicate a concern apart from the technical merits of the project. The Committee specifically will not review on a technical basis the merits of any kidney proposal or establish formal numerical ratings for kidney activities.

Activities for which special priorities have been established shall be incorporated into the standard RMFS review cycle at the earliest possible time consistent with sound program management.

3-3 National Advisory Council On Regional Medical Programs

A. Establishing Authority

The National Advisory Council on Regional Medical Programs was initially established on November 24, 1965, by P.L. 89-239, section 905 of the Public Health Service Act, as amended, and further amended by P.L. 91-515, 42 USC 299e(a).

P.L. 91-515 expanded the Council from 16 to 20 members and provided that the Chief Medical Director of the Veterans' Administration shall be an ex officio member in addition to these. In addition, it required that the Council include 4 members of the public, 1 member who is outstanding in the kidney disease field, and 2 who are outstanding in the prevention of heart disease, cancer or stroke. It also added language encouraging representation in the field of health care administration, and made the Assistant Secretary of Health Education and Welfare for Health and Scientific affairs (rather than the Surgeon General of the Public Health Service) the Council's Chairman.

B. Duration

The Council exists during the life of the authorizing legislation, or until applicable provisions are amended or repealed.

C. Structure

The Council consists of the Administrator, Health Services and Mental Health Administration, as Chairman (through a delegation from the ASHSA), the Chief Medical Director of the Veterans' Administration, ex officio, and 20 members who are leaders in the fields of the fundamental sciences, the medical sciences, health care administration or public affairs. At least two of the appointed members must be practicing physicians; one must be outstanding in the study or health care of persons suffering heart diseases; one shall be outstanding in the study or health care of persons suffering from cancer; one shall be outstanding in the study or health care of persons suffering from stroke; one must be outstanding in the study or health care of persons suffering from kidney disease; two must be outstanding in the field of prevention of heart disease, cancer, stroke, or kidney disease, and four must be members of the public.

D. Appointments

Council members are appointed by the Secretary of Health, Education, and Welfare for overlapping terms of four years and are not eligible to serve continuously for more than two terms. A full term may be less than four years where a Council member is appointed to fill a new place, or to fill an unexpired term.

#### IV-3 REVIEW GROUPS--STRUCTURE, FUNCTIONS AND AUTHORITY

No individual may be appointed who serves on any other public advisory committee of the Department of Health, Education, and Welfare.

##### E. Meetings

The Council meets on a regularly scheduled basis at least three times per year, usually in February, June and October. Meeting dates are established a year in advance, and meetings are scheduled for two full days.

##### F. Functions

The Council advises and assists in the preparation of regulations for, and as to policy matters arising with respect to, the administration of the RMP Program, Title IX, and makes recommendations to the Director, RMPS, with respect to approval of applications for and the amounts of grants under Title IX.

Specifically, the Council regularly reviews (1) triennial applications from Regional Medical Programs, (2) applications from Regional Medical Programs not yet approved for a triennial period, (3) kidney disease projects, and (4) grants for special projects or program priorities under Title IX whenever funds are available for such purposes.

The Council has delegated to the Director, RMPS, authority to make grants for the second and third years of programs recommended for triennial support. Applications for second and third year continuation support are reviewed and rated by the Staff Anniversary Review Panel. The recommendations of the Director based on such review and rating and the comments of the Review Committee, if any, are regularly presented to the Council for information. The Council, however, may make alternative recommendations if it wishes to do so and/or change the rating. (See Subchapter IV-4.)

As requested, the Council considers advice from the Review Committee with respect to policies relating to the review of grants.

The Council's recommendations are binding on the Director with respect to the maximum amount and maximum period of support and conditions for any grant. The Director, however, may make an award for a lesser amount or a shorter period than that recommended by Council. No grant may be awarded under Title IX without the affirmative recommendation of the Council.

##### G. Scope of Review

In the case of any application, the Council takes into account the recommendations of the Review Committee for other initial

#### IV-3 REVIEW GROUPS--STRUCTURE, FUNCTIONS AND AUTHORITY

review group and makes recommendations to the Director, RMPS, on approval, disapproval, or other action. For recommended applications, the Council also advises on (1) the level of funding, (2) the period of support, (3) any conditions to be attached to the grant, and (4) any appropriate advice.

In reviewing applications for Regional Medical Programs, the Council considers the appropriateness of proposed activities and consistency with RMPS policies. In addition, the Council considers and may at its discretion change the ratings assigned by the Review Committee or the SARP.

CHAPTER IV  
APPLICATION AND REVIEW

IV-4 REVIEW CRITERIA AND RATING SYSTEM

## IV-4 REVIEW CRITERIA AND RATING SYSTEM

### 4-1 USES OF THE CRITERIA

This Subchapter illustrates the RMPS Review Criteria and Rating System used in evaluating grant applications for Regional Medical Programs. A copy of the Criteria themselves, and the Scoring Sheet used by reviewers is attached.

Each Region is rated annually. Regions requesting triennial approval are rated by the RMPS Review Committee. (See Subchapter IV-3, 3-2.) Applicants for recommended second or third year support of a triennial grant are rated by the Staff Anniversary Review Panel. (See Subchapter IV-3, 3-1.)

The Criteria are used to provide a relative ranking of RMPs on the basis of numerical scores. About a third of the Regions are reviewed at each review cycle. Therefore, the relative standing of an individual Region may change on completion of any cycle, based on the ratings for the Regions then under consideration.

The scores represent the subjective opinions of reviewers at a given time and are only one of a number of factors considered by the staff and Director of RMPS in an approved level of determining support.

### 4-2 THE CRITERIA

The Criteria are divided into three groups: (1) "Performance," (2) "Process," and (3) "Program Proposal." Each criterion is assigned a relative weight. Weights were originally developed on a subjective basis, modified after a trial period and approved by the Review Committee and Council. In addition, a series of questions appear under each criterion. The questions are not criteria themselves, but are used to illustrate and amplify the kinds of things covered by the individual criteria. Copies of the Criteria are furnished to the reviewers at each SARP and Review Committee meeting.

### 4-3 THE SCORING SHEET

The Scoring Sheet (Figure I) is used by individual reviewers to provide their ratings. Each column is used to record the reviewer's ratings for an individual Region. The Criteria and the weights for each are shown in the left hand column. Space is also provided on the Scoring Sheet for an overall assessment of the Region (line D), a recommendation for a Developmental Component, if requested (line E),

#### IV-4 REVIEW CRITERIA AND RATING SYSTEM

and finally for recording the basis for the reviewer's evaluation (lines F, 1-7). The latter is used by RMPS for monitoring and evaluating the rating system itself. The "Basis for Evaluation" lines are for RMPS use only and do not effect the numerical scores.

Each reviewer rates each region on a 1-5 scale for each criterion. The reviewers do not sign the sheets. At the end of the meeting, the Scoring Sheets are collected and a computerized composite score for each Region is generated almost immediately through the RMPS Management Information System. The overall numerical ratings for each Region are made available to the Council which may, at its discretion, modify any rating.

# IV-4 REVIEW CRITERIA AND RATING SYSTEM

## Scoring Sheet

ADMINISTRATIVE COUNCIL

SCORING SHEET AND INSTRUCTIONS: \_\_\_\_\_ (WRITE AND SIGN UP)

Using a five-point rating scale (5-outstanding, 4-good, 3-satisfactory, 2-fair, 1-poor) rate the Region in accordance with the criteria set forth below.

Reviewers are reminded to consult the 117 Review Criteria which is located in sheet 23, 1973 which includes specific criteria or elements in the form of questions designed to pose "check points" several criteria may be specific and unambiguous. These are intended to be of help to the reviewer in determining a rating. To ease the task of the reviewer, the assignment of scores by the assigned reviewers and the necessary notation will be done by staff, reviewers need not make these assignments.

Reviewers should provide their overall evaluation of the Region and its evaluation by rating on a one to five basis in Item D, Overall Assessment. Feel free to make any special assignments to the overall scores (Items 3, 5).

Use a check  in Item E, Developmental Potential, if in your best judgment this Region has achieved sufficient program maturity and status to warrant award of a developmental potential.

In Item F, Basis for Evaluation, indicate for each Region the basis for your evaluation. When appropriate, more than one item in Item F may be checked for each Region.

REGION

| CRITERIA   | WEIGHT | REGION |  |  |  |  |  |  |  |  |  |
|--|--------|--------|--|--|--|--|--|--|--|--|--|
| DATE OF MOST RECENT SITE VISIT                           |        |        |  |  |  |  |  |  |  |  |  |
| <b>A. PERFORMANCE - 40</b>                               |        |        |  |  |  |  |  |  |  |  |  |
| 1. GOALS, OBJECTIVES & PRIORITIES                        | 8      |        |  |  |  |  |  |  |  |  |  |
| 2. ACCOMPLISHMENTS & IMPLEMENTATION                      | 15     |        |  |  |  |  |  |  |  |  |  |
| 3. CONTINUED SUPPORT                                     | 10     |        |  |  |  |  |  |  |  |  |  |
| 4. MUNICIPAL INTERESTS                                   | 7      |        |  |  |  |  |  |  |  |  |  |
| <b>B. PROCESS - 35</b>                                   |        |        |  |  |  |  |  |  |  |  |  |
| 1. COORDINATOR   | 10     |        |  |  |  |  |  |  |  |  |  |
| 2. CORE STAFF  | 3      |        |  |  |  |  |  |  |  |  |  |
| 3. REGIONAL ADVISORY GROUP                               | 5      |        |  |  |  |  |  |  |  |  |  |
| 4. GROUPS ORGANIZATION                                   | 2      |        |  |  |  |  |  |  |  |  |  |
| 5. PARTICIPATION   | 3      |        |  |  |  |  |  |  |  |  |  |
| 6. LOCAL PLANNING  | 3      |        |  |  |  |  |  |  |  |  |  |
| 7. ASSESSMENT OF NEEDS & RESOURCES                       | 3      |        |  |  |  |  |  |  |  |  |  |
| 8. MANAGEMENT  | 3      |        |  |  |  |  |  |  |  |  |  |
| 9. EVALUATION  | 3      |        |  |  |  |  |  |  |  |  |  |
| <b>C. PROGRAM PROCESS - 25</b>                           |        |        |  |  |  |  |  |  |  |  |  |
| 1. ACTION PLAN   | 5      |        |  |  |  |  |  |  |  |  |  |
| 2. DISSEMINATION OF KNOWLEDGE                            | 2      |        |  |  |  |  |  |  |  |  |  |
| 3. SKILL, SUPPORT & FACILITIES                           | 4      |        |  |  |  |  |  |  |  |  |  |
| 4. INVOLVEMENT OF COPS                                   | 4      |        |  |  |  |  |  |  |  |  |  |
| 5. SHORT-TERM PLANNING                                   | 3      |        |  |  |  |  |  |  |  |  |  |
| 6. REORGANIZATION  | 4      |        |  |  |  |  |  |  |  |  |  |
| 7. OTHER PLANNING  | 3      |        |  |  |  |  |  |  |  |  |  |
| <b>D. DETAIL ASSIGNMENT</b>                              |        |        |  |  |  |  |  |  |  |  |  |
| <b>E. DEVELOPMENTAL POTENTIAL (CHECK ALL APPLICABLE)</b> |        |        |  |  |  |  |  |  |  |  |  |
| <b>F. BASIS FOR EVALUATION (CHECK ALL APPLICABLE)</b>    |        |        |  |  |  |  |  |  |  |  |  |
| 1. CURRENT SITE VISIT                                    |        |        |  |  |  |  |  |  |  |  |  |
| 2. PREVIOUS SITE VISIT                                   |        |        |  |  |  |  |  |  |  |  |  |
| 3. EVALUATION  |        |        |  |  |  |  |  |  |  |  |  |
| 4. COMMITTEE DISCUSSION                                  |        |        |  |  |  |  |  |  |  |  |  |
| 5. OTHER   |        |        |  |  |  |  |  |  |  |  |  |
| 6. PRIMARY REVIEWER                                      |        |        |  |  |  |  |  |  |  |  |  |
| 7. SECONDARY REVIEWER                                    |        |        |  |  |  |  |  |  |  |  |  |

## IV-4 REVIEW CRITERIA AND RATING SYSTEM

### RMPS REVIEW CRITERIA\*

#### A. PERFORMANCE (40)

##### 1. GOALS, OBJECTIVES, AND PRIORITIES (8)

- a. Have these been developed and explicitly stated?
- b. Are they understood and accepted by the health providers and institutions of the Region?
- c. Where appropriate, were community and consumer groups also consulted in their formulation?
- d. Have they generally been followed in the funding of operational activities?
- e. Do they reflect short-term, specific objectives and priorities as well as long-range goals?
- f. Do they reflect regional needs and problems and realistically take into account available resources?

##### 2. ACCOMPLISHMENTS AND IMPLEMENTATION (15)

- a. Have core activities resulted in substantive program accomplishments and stimulated worthwhile activities?
- b. Have successful activities been replicated and extended throughout the Region?
- c. Have any original and unique ideas, programs or techniques been generated?
- d. Have activities led to a wider application of new knowledge and techniques?
- e. Have they had any demonstrable effect on moderating costs?
- f. Have they resulted in any material increase in the availability and accessibility of care through better utilization of manpower and the like?
- g. Have they significantly improved the quality of care?
- h. Are other health groups aware of and using the data, expertise, etc., available through RMP?
- i. Do physicians and other provider groups and institutions look to RMP for technical and professional assistance, consultation and information?
- j. If so, does or will such assistance be concerned with quality of care standards, peer review mechanisms, and the like?

##### 3. CONTINUED SUPPORT (10)

- a. Is there a policy, actively pursued, aimed at developing other sources of funding for successful RMP activities?
- b. Have successful activities in fact been continued within the regular health care financing system after the withdrawal of RMP support?

#### IV-4 REVIEW CRITERIA AND RATING SYSTEM

##### 4. MINORITY INTERESTS (7)

- a. Do the goals, objectives, and priorities specifically deal with improving health care delivery for underserved minorities?
- b. How have the RMP activities contributed to significantly increasing the accessibility of primary health care services to underserved minorities in urban and rural areas?
- c. How have the RMP activities significantly improved the quality of primary and specialized health services delivered to minority populations; and, have these services been developed with appropriate linkages and referrals among in-patient, out-patient, extended care, and home health services?
- d. Have any RMP-supported activities resulted in attracting and training members of minority groups in health occupations? Is this area included in next year's activities?
- e. What steps have been taken by the RMP to assure that minority patients and professionals have equal access to RMP-supported activities?
- f. Are minority providers and consumers adequately represented on the Regional Advisory Group and corollary committee structure; and do they actively participate in the deliberations?
- g. Does the core staff include minority professional and supportive employees and does it reflect an adequate consideration of Equal Employment Opportunity?
- h. Do organizations, community groups, and institutions which deal primarily with improving health services for minority populations work closely with the RMP core staff? Do they actively participate in RMP activities?
- i. What surveys and studies have been done to assess the health needs, problems, and utilization of services of minority groups?

##### B. PROCESS (35)

###### 1. COORDINATOR (10)

- a. Has the coordinator provided strong leadership?
- b. Has he developed program direction and cohesion and established an effectively functioning core staff?
- c. Does he relate and work well with the RAG?
- d. Does he have an effective deputy in name or fact?

###### 2. CORE STAFF (3)

- a. Does core staff reflect a broad range of professional and discipline competence and possess adequate administrative and management capability?

#### IV-4 REVIEW CRITERIA AND RATING SYSTEM

##### 2. CORE STAFF (3) (continued)

- b. Are most core staff essentially full-time?
- c. Is there an adequate central core staff (as opposed to institutional components)?

##### 3. REGIONAL ADVISORY GROUP (5)

- a. Are all key health interests, institutions, and groups within the region adequately represented on the RAG (and corollary planning committee structure)?
- b. Does the RAG meet as a whole at least 3 or 4 times annually?
- c. Are meetings well attended?
- d. Are consumers adequately represented on the RAG and corollary committee structure? Do they actively participate in the deliberations?
- e. Is the RAG playing an active role in setting program policies, establishing objectives and priorities, and providing overall guidance and direction of core staff activities?
- f. Does the RAG have an executive committee to provide more frequent administrative program guidance to the coordinator and core staff?
- g. Is that committee also fairly representative?

##### 4. GRANTEE ORGANIZATION (2)

- a. Does the grantee organization provide adequate administrative and other support to the RMP?
- b. Does it permit sufficient freedom and flexibility, especially insofar as the RAG's policy-making role is concerned?

##### 5. PARTICIPATION (3)

- a. Are the key health interests, institutions, and groups actively participating in the program?
- b. Does it appear to have been captured or co-opted by a major interest?
- c. Is the Region's political and economic power complex involved?

##### 6. LOCAL PLANNING (3)

- a. Has RMP in conjunction with CHP helped develop effective local planning groups?
- b. Is there early involvement of these local planning groups in the development of program proposals?
- c. Are there adequate mechanisms for obtaining substantive CHP review and comment?

#### IV-4 REVIEW CRITERIA AND RATING SYSTEM

##### 7. ASSESSMENT OF NEEDS AND RESOURCES (3)

- a. Is there a systematic, continuing identification of needs, problems, and resources?
- b. Does this involve an assessment and analysis based on data?
- c. Are identified needs and problems being translated into the Region's evolving plans and priorities?
- d. Are they also reflected in the scope and nature of its emerging core and operational activities?

##### 8. MANAGEMENT (3)

- a. Are core activities well coordinated?
- b. Is there regular, systematic and adequate monitoring of projects, contracts, and other activities by specifically assigned core staff?
- c. Are periodic progress and financial reports required?

##### 9. EVALUATION (3)

- a. Is there a full-time evaluation director and staff?
- b. Does evaluation consist of more than mere progress reporting?
- c. Is there feedback on progress and evaluation results to program management, RAG, and other appropriate groups?
- d. Have negative or unsatisfactory results been converted into program decisions and modifications; specifically have unsuccessful or ineffective activities been promptly phased out?

#### C. PROGRAM PROPOSAL (25)

##### 1. ACTION PLAN (5)

- a. Have priorities been established?
- b. Are they congruent with national goals and objectives, including strengthening of services to underserved areas?
- c. Do the activities proposed by the Region relate to its stated priorities, objectives and needs?
- d. Are the plan and the proposed activities realistic in view of resources available and Region's past performance?
- e. Can the intended results be quantified to any significant degree?
- f. Have methods for reporting accomplishments and assessing results been proposed?
- g. Are priorities periodically reviewed and updated?

##### 2. DISSEMINATION OF KNOWLEDGE (2)

- a. Have provider groups or institutions that will benefit been targeted?

#### IV-4 REVIEW CRITERIA AND RATING SYSTEM

##### 2. DISSEMINATION OF KNOWLEDGE (2) (continued)

- b. Have the knowledge, skills, and techniques to be disseminated been identified; are they ready for widespread implementation?
- c. Are the health education and research institutions of the Region actively involved?
- d. Is better care to more people likely to result?
- e. Are they likely to moderate the costs of care?
- f. Are they directed to widely applicable and currently practical techniques rather than care or rare conditions of highly specialized, low volume services?

##### 3. UTILIZATION MANPOWER AND FACILITIES (4)

- a. Will existing community health facilities be more fully or effectively utilized?
- b. It is likely productivity of physicians and other health manpower will be increased?
- c. Is utilization of allied health personnel, either new kinds or combinations of existing kinds, anticipated?
- d. Is this an identified priority area; if so, is it proportionately reflected in this aspect of their overall program?
- e. Will presently underserved areas or populations benefit significantly as a result?

##### 4. IMPROVEMENT OF CARE (4)

- a. Have RMP or other studies (1) indicated the extent to which ambulatory care might be expanded or (2) identified problem areas (e.g., geographic, institutional) in this regard?
- b. Will current or proposed activities expand it?
- c. Are communications, transportation services and the like being exploited so that diagnosis and treatment on an out-patient basis is possible?
- d. Have problems of access to care and continuity of care been identified by RMP or others?
- e. Will current or proposed activities strengthen primary care and relationships between specialized and primary care?
- f. Will they lead to improved access to primary care and health services for persons residing in areas presently underserved?
- g. Are health maintenance and disease prevention components included in current or proposed activities?
- h. If so, are they realistic in view of present knowledge, state-of-the-art, and other factors?

##### 5. SHORT-TERM PAYOFF (3)

- a. Is it reasonable to expect that the operational activities proposed will increase the availability of and access to services, enhance the quality of care and/or moderate its costs, within the next 2-3 years?

#### IV-4 REVIEW CRITERIA AND RATING SYSTEM

5. SHORT-TERM PAYOFF (3) (continued)

- b. Is the feedback needed to document actual or prospective pay-offs provided?
- c. Is it reasonable to expect that RMP support can be withdrawn successfully within 3 years?

6. REGIONALIZATION (4)

- a. Are the plan and activities proposed aimed at assisting multiple provider groups and institutions (as opposed to groups or institutions singly)?
- b. Is greater sharing of facilities, manpower and other resources envisaged?
- c. Will existing resources and services that are especially scarce and/or expensive, be extended and made available to a larger area and population than presently?
- d. Will new linkages be established (or existing ones strengthened) among health providers and institutions?
- e. Is the concept of progressive patient care (e.g., OP clinics, hospitals, ECF's, home health services) reflected?

7. OTHER FUNDING (3)

- a. Is there evidence the Region has or will attract funds other than RMP?
- b. If not, has it attempted to do so?
- c. Will other funds, (private, local, state, or Federal) be available for the activities proposed?
- d. Conversely, will the activities contribute financially or otherwise to other significant Federally-funded or locally-supported health programs?

CHAPTER IV  
APPLICATION AND REVIEW

IV-5 RMPS PROGRAM ANALYSIS GUIDE

## IV-5 RMPS PROGRAM ANALYSIS GUIDE

### 5-1 USE OF THE GUIDE

The attached RMPS Program Analysis Guide was developed primarily to assist RMPS staff to develop information on individual RMPs in relation to the RMPS Review Criteria. (See Subchapter IV-4.)

Regional Medical Programs may also find the document helpful in insuring that the most appropriate information is conveyed in applications, reports, RMPS staff contacts, and site visit presentations.

The Program Analysis Guide consists of two columns. The left hand column lists the Criteria and summarizes the illustrative questions under each. (The questions are fully spelled out in Subchapter IV-4.) The right hand column shows where information relating to each question may possibly be found in the application form RMP-34-1, or other sources such as site visit and staff reports or computer outputs from the RMPS Management Information System.

RMPS PROGRAM ANALYSIS GUIDE  
(for use in connection with "RMP Review Criteria")

CRITERIA

SOURCE OF INFORMATION

A. PERFORMANCE

1. Goals, Objectives and Priorities (8)

- a. explicitly stated?
- b. understood and accepted?
- c. community and consumers consulted?
- d. followed in funding operation activities
- e. short as well as long term goals
- f. realistically reflect needs problems and resources

RAG Report, Site Visit, Staff Visits

Site Visits, Staff Visits

Page 4 (Consumers on RAG)  
Page 5 (Consumers on appropriate Committees)  
Page 9 (Relationships with any consumer groups)  
Page 10 (Consultation and Community Relations)  
Page 11 (Consumer related feasibility and planning studies)

Page 13a (Items 5,6 and 7)  
Page 13b (Items 8 & 9)  
Page 15 (esp. item 9, Target Groups)  
Page 16 (Printouts of descriptors)

RAG Report, Site Visit, Staff Visits

Site Visit

2. Accomplishments and Implementation (15)

- a. worthwhile activities and substantive accomplishments?

Page 8 (Core activities)  
Page 10 (Community Relations & Consultation)  
Page 11 (Feasibility and Planning Studies -- esp. Have any resulted in Operational Activities)

CRITERIA

SOURCE OF INFORMATION

|   |  |
|---|--|
|   | Page 12 (Central Services)   |
|   | Page 15 (Progress on operational activities)<br>In all cases above compare reported progress with proposal in previous applications.   |
| b. successful activities replicated         | Page 15 (Check "Progress" on all terminations).  |
| c. generation of unique ideas and programs  | Page 8, 10, 11, 15<br>Page 14b (evaluation activities, Items 5 and 3)  |
| d. wider application of new knowledge       | Descriptor print-outs (to determine relevant activities)<br>RAG report (esp. goals and objectives)<br>Page 11 (Results of applicable studies)<br>Page 3 (Distribution of performance sites for applicable operational activities)                                |
| e. demonstrable effect on costs?            | Same as "2d" above   |
| f. material increase in accessibility etc.? | Same as "2d" above   |
| g. improved quality of care?                | Same as "2d" above   |
| h. other health groups using RMP            | Page 9 (Cooperative Relationships)<br>Page 11 (Results of applicable studies and participating organizations)<br>Page 12 (Central Services and participating organizations)<br>Page 15 (Operational activities, Items 4, 9 and 11)<br>Page 3 (Performance sites) |
| i. providers use RMP as resource?           | Page 9 (Cooperative Relationships)<br>Page 15 (Provider targets, Item 9b)  |
| j. assistance on quality of care, etc.?     | Same as "2d" above   |

CRITERIA

SOURCE OF INFORMATION

3. Continued Support (10)

- a. policy to develop other support?
- b. activities continued after RMP phase-out?

RAG Report, Site Visit, Staff Visits

Page 15 (Progress, Item 11e)

Page 16 (Budget print out -- other funding)

4. Minority Interests (7)

- a. goals and objectives relate to minorities?

RAG Report, Site Visit, Staff Visits

- b. accessibility of 1<sup>o</sup> care to minorities?

Descriptor print-out (to determine relevant activities)

Page 8 (Applicable Core activities)

Page 11 (Applicable studies)

Page 15 (Applicable operational activities, Item 9)

- c. improved 1<sup>o</sup> care quality and linkages?

Same as "4b" above //

- d. attracting minorities to health field?

Same as "4b" above

- e. minority access to RMP activities?

RAG Report, Site Visit, Staff Visits

Page 4 (Minority representatives on RAG)

Page 5 (Minorities on advisory groups)

Page 7 (Equal employment)

Page 9 (Cooperative relationships with applicable organizations)

Page 13b (Item 11 Civil Rights assurance by sponsor)

- f. minority representation on RAG etc.?

Page 4 (Minority representatives on RAG)

Page 5 (Minorities on advisory groups)

CRITERIA

SOURCE OF INFORMATION

- g. minorities on core staff? Page 7 (Equal employment)
- h. cooperation with community groups serving minorities? Page 9 (Cooperative relationships)  
Page 10 (Community consultation and liaison)
- i. studies of health needs of minorities? Page 10 (Community consultation and liaison)  
Page 11 (Feasibility studies)  
Page 15 (Applicable operational activities, Item 9a, consumer targets)  
Descriptor print-out to determine relevant activities.

D. PROCESS

1. Coordinator

- a. strong leadership? Site Visit, Staff Visits
- b. program direction and effective staff? Same as "1a" above "
- c. works well with RAG Same as "1a" above
- d. has effective Deputy? Page 6 (Core personnel list)  
Site Visit, Staff Visits

2. Core Staff

- a. range of disciplines and management capabilities? Page 6 (Core personnel list)  
Site Visit, Staff Visits
- b. most core staff essentially full time? Page 6 (Core personnel list)
- c. adequate central vs. institutional staff? Page 6 (Core personnel list)  
Page 8 ("Central Office" and "Field Office" items)

CRITERIA

SOURCE OF INFORMATION

3. Regional Advisory Group

a. key health interests on RAG and committees?

Page 4 (RAG list)  
Page 5 (Advisory groups)

b. RAG meets 3 or 4 times a year?

RAG Report  
Page 5 (Advisory groups - "Number of Meetings" column)

c. meetings well attended

Site Visit, Staff Visits, inspection of RAG minutes, RAG report

d. adequate consumer participation?

Page 4 (RAG list)  
Page 5 (Advisory groups)  
Page 7 (EEO - "Planning and Advisory Groups" item)  
Site Visit, Staff Visits

e. RAG active re policies objectives and program guidance?

RAG Report, Site Visit, Staff Visits  
Page 13a & b (Items 2,7,9,10,12,13,16 re law  
Page 14a (3,4,5) (actions)  
Page 14b (Items 4,5,6,7, and 2 at bottom page

f. Executive Committee exists and meets frequently?

Page 4 (RAG list - "Steering/Executive Committee" check blocks)  
Page 5 (Advisory groups - "Number of Meetings" column)  
Site Visit, Staff Visits, meeting minutes

g. Executive Committee is Representative?

Page 4 (RAG list)

4. Grantee Organization

a. provides adequate administrative support to RMP?

Site Visit, Staff Visits.  
Page 16 (Print-out of indirect cost data)

CRITERIA

SOURCE OF INFORMATION

b. permits RAG flexibility re policy?

RAG Report, Site Visit, Staff Visits  
Review process verification visit reports  
RMP charter or By-Laws

5. Participation

a. key health interests participating in program?

Page 3 (Type sponsorship and performance sites)  
Page 4 (RAG list)  
Page 9 (Cooperative Relationships)  
Page 11 (Core studies - "Participating Organization" item)  
Page 12 (Central Services - "Organizations Providing Service" item)  
Page 15 (Item 4, Sponsor; Item 9 "Target Groups"; Item 10 "Other Programs")

b. RMP co-opted by any major interest?

Site Visit, Staff Visits  
Page 4 (RAG list)  
Page 5 (Advisory groups)  
Verification visit reports  
Charter and Bylaws

1 c. Region's political and economic power complex involved?

Site Visit, Staff Visits  
Page 4 (RAG list)

6. Local Planning

a. effective local planning groups developed?

Page 3 (Performance Sites - Check distribution of operational activities)  
Page 5 (Advisory groups - Check for local committees and frequency of meetings)  
Page 8 (Core summary - "Field Office" item)  
Page 9 (Cooperative relationships)  
Page 10 (Community relations and liaison)  
Verification visit reports

CRITERIA

SOURCE OF INFORMATION

- |   |   |
|---|---|
| <p>b. early local involvement in proposal development?</p>          | <p>Site Visit, Staff Visits<br/>Verification visit report</p>   |
| <p>c. adequate mechanisms for CHP review and comment?</p>           | <p>Page 13 (Item 16)<br/>CHP comments (Check for substance and value to RMP)</p>  |
| <p>7. <u>Assessment of Needs and Resources</u></p>                  |   |
| <p>a. systematic identification of needs?</p>                       | <p>Page 8 (Core activities)<br/>Page 9 (Cooperative relationships - "Data Collecti<br/>item)<br/>Page 11 (Core studies)</p>   |
| <p>b. involves data analysis?</p>                                   | <p>Same as "7a" above<br/>RAG Report, Site Visit, Staff Visits<br/>Reports of actual studies</p>  |
| <p>c. identified problems translated into plans and priorities?</p> | <p>RAG Report, Site Visit, Staff Visits<br/>Page 11 (Core Studies "Results" item)<br/>Also check previous application to see if current<br/>goals have been derived from prior studies.</p>   |
| <p>d. reflected in scope and nature of operational activities?</p>  | <p>Page 15 (Operational activities)<br/>Page 16 (Descriptor print-out)</p>  |
| <p>8. <u>Management</u></p>   |   |
| <p>a. Core activities well coordinated</p>                          | <p>Site Visit, Staff Visits<br/>Page 6 (Core personnel list - check for adequacy o<br/>staffing for established functions, adequa<br/>number of supervisors in relation to organ<br/>zational units, number of vacancies).<br/>Page 8 (Core summary - "Program Functions" item)</p> |

CRITERIA

SOURCE OF INFORMATION

b. regular and systematic monitoring?

Page 13a & b (Item 2,9,12,15 - core review functions)  
 Page 14a (Items 1,3,4,5 under "Monitoring")  
 Page 14b (Item 3 & 7 under "Operational and Core Monitoring")  
 Page 14 b (Items 1 & 2 under "Program Evaluation")

c. periodic progress and financial reports?

Page 14a (Items 2,3,4,5 under "Monitoring")  
 Inspection of actual reports to the RMP  
 Verification visit reports

9. Evaluation

a. full time Evaluation Director?

Page 6 (Core staff list)

b. evaluation consists of more than process reporting?

Pages 14a & b  
 Inspection of actual reports

c. adequate feedback of evaluations?

Site Visit, Staff Visits  
 Verification visit reports

d. unsuccessful activities are phased out?

Page 11 (Core studies - "Results" item for "Completed" studies)  
 Page 15 ("Progress" item for terminated activities)

C. PROGRAM PROPOSAL

1. Action Plan

a. priorities have been established?

RAC Report  
 Page 13a (Item 5,6 and 7)

b. congruent with National goals?

Site Visit, Staff Visits  
 Applicable NEW, HSMHA & RMPS internal documents  
 (ie statements by Secretary, Administrator, Director  
 Council minutes and highlights, etc:)

c. RMP activities relate to stated goals?

Page 8 (Core summary)  
 Page 10 (Cooperative relationships)  
 Page 11 (Core studies)  
 Page 12 (Central Service Activities)  
 Page 15 (Operational Activities)

|  |   |
|--|---|
| d. activities realistic in relation to resources and past performance? | Site Visit  |
| e. results are quantifiable  | Page 11 ("Results" item)<br>Page 15 (Operational Activities - Items 11 & 12)  |
| f. reporting mechanisms established?                                   | Pages 13a & b<br>Page 15 (Operational Activities - Item 12)   |
| g. priorities periodically reviewed and updated?                       | Page 13a (Items 5, 6 and 7)   |
| 2. <u>Dissemination of Knowledge</u>                                   |   |
| a. provider groups have been targeted?                                 | RAC Report, Site Visit, Staff Visits<br>Page 15 (Item 9b, "Provider targets")<br>Descriptor print-out   |
| b. specific knowledge or skills identified for dissemination?          | RAC Report, Site Visit, Staff Visits<br>Page 11 (Core studies - "Results" item)<br>Page 15 (Operational Activities - Items 11 & 12)   |
| c. health education and research institutions of region involved?      | Page 3 (Item 1, 8b and "Performance sites")<br>Page 9 (Cooperative Relationships - "Other" item)<br>Page 11 (Core studies - "Participating Organization" item)<br>Page 15 (Operational Activities - Item 4) |
| d. better care to more people will result?                             | Site Visit<br>Page 15 (Operational Activities - especially items 10b, 10c and 10i)<br>Descriptor print-out  |

## CRITERIA

## SOURCE OF INFORMATION

- |   |  |
|---|--|
| e. likely to moderate cost of care?                                 | Same as "2d" above   |
| f. widely applicable - not directed to rare conditions?             | Page 15 (Operational Activities - Item 8)<br>Descriptor print-out  |
| <b>3. <u>Utilization of Manpower and Facilities</u></b>             |  |
| a. community facilities more effectively utilized                   | Site Visit<br>Page 15 (Operational Activities, especially items 10d, 10g and 10i)<br>Descriptor print-out  |
| b. increase productivity of physicians and manpower?                | Site Visit<br>Page 15 (Operational Activities - Item 9b, "Provider" targets)<br>Descriptor print-outs  |
| c. improved utilization of allied health?                           | Same as "3b" above   |
| d. manpower and facilities utilization identified as priority area? | RAC Report, Site Visit, Staff Visits<br>Page 13a. (Items 5, 6 and 7)   |
| e. underserved population will benefit?                             | Page 3 ("Performance sites")<br>Page 15 (Operational Activities - Items 9a, 10 -- especially a, b, h and I, -- 11 and 12)<br>Descriptor print-outs |
| <b>4. <u>Improvement of Care</u></b>                                |  |
| a. need for improved ambulatory care?                               | Site Visit, Staff Visits<br>Page 11 (Core studies)<br>Page 13a (Items 5 and 6)<br>Page 14b (Item 5 "Evaluations last year")                        |

CRITERIA

SOURCE OF INFORMATION

|   |  |
|---|--|
| b. activities will expand ambulatory care?  | Site Visit   |
| c. improving communication and transportation services to facilitate outpatient care?                 | Site Visit<br>Page 11 (Core studies)<br>Page 15 (Operational Activities - Items 11 and 12)<br>Descriptor print-outs ("Non emergency transportation   |
| d. access and continuing care problems have been identified?  | RAG Report, Site Visit, Staff Visits<br>Page 11 (Core studies)<br>Page 15 (Operational Activities - Items 11 and 12)<br>Descriptor print-out   |
| e. activities strengthen primary care?  | Same as "4d" above   |
| f. improved access to primary for residents of underserved areas?                                     | Same as "4d" above   |
| g. Health maintenance and prevention included?  | Same as "4d" above //  |
| h. activities are realistic?  | Site Visit   |
| 5. <u>Short-term Payoff</u>   |  |
| a. operational activities will have visible payoff re access availability and quality within 3 years? | Site Visit<br>Page 14b (Item 3, "Evaluation criteria" under "Program Evaluation")<br>Page 15 (Operational Activities - Items 3,6, 11 and<br>Descriptor print-out   |
| b. necessary feedback is available?   | Page 14a (Item 2, "Periodic reports")<br>Page 14b (Item 5 under "Operational and Core Monitoring")<br>Review of actual progress reports submitted to RMP on applicable operational activities, on feasibility studies. |

## CRITERIA

## SOURCE OF INFORMATION

- c. RMP support can be phased out within e years?  
 Page 11 (Core studies - "Completion date" item)  
 Page 15 (Operational Activities - Items 3, 6 and 11)  
 Page 16 (Print-out of "RMP support year,"  
 "Component Support year," "Estimated" and  
 "Actual Termination" dates)
6. Regionalization (4)
- a. activities aimed at multiple provider groups?  
 Page 15 (Operational Activities - Item 9b)  
 Descriptor print-outs -- "Provider target groups"
- b. sharing of facilities, manpower resources?  
 Site Visit  
 Page 15 (Operational Activities - Items 11 and 12)
- c. expanding existing resources  
 Same as "6b" above
- d. linkages among providers and institutions?  
 Same as "6b" above
- e. progressive patient care?  
 Same as "6b" above
7. Other Funding (3)
- a. evidence of other funding?  
 Page 16 (print-out - "State funds, Local funds,  
 other Federal funds, other non-Federal fun  
 Expenditure report print-outs for past activities
- b. if not RMP has attempted to raise other  
 funds?  
 Site Visit, Staff Visits
- c. other funds available for proposed activities?  
 Page 16 (print-out as in "7a")
- d. activities contribute to other Federally or  
 locally funded programs?  
 Site Visit, Staff Visits  
 Page 9 (Cooperative relationships - check for  
 possible mention of joint funding)
- Page 15 (Operational Activities - Item 10)

CHAPTER IV  
SITE VISIT GUIDELINES

IV-6 SITE VISIT GUIDELINES

## IV-6 SITE VISIT GUIDELINES

### 6-1 INTRODUCTION

These Guidelines outline standard RMPS site visit procedures used in reviewing grant applications. A copy of the Site Visit Guidelines will be furnished regularly to all site visitors.

### 6-2 RESPONSIBILITIES OF SITE VISITORS

It is important that each site visitor come to the meeting with advance knowledge of the site visit process and through familiarity with the content of materials provided for review. Site visit team members should contact the coordinating RMPS Operations Officer\* immediately if they have any questions about procedures, review materials, the site visit agenda or substantive issues for exploration during the visit.

All members of the site visit team are expected to be present during the entire site visit including the Executive Session described in 6-5, C, below. Attendance through the entire site visit is necessary to insure fair treatment of applicants and essential to the development of team consensus and a meaningful report for consideration by the RMPS Review Committee and National Advisory Council.

### 6-3 COMPOSITION OF THE SITE VISIT TEAM

#### A. Non Federal Members

Site visit teams should include at least the following:

1. Review Committee member who serves as Chairman;
2. National Advisory Council member;
3. A Regional Medical Program representative with program experience, e.g., a Coordinator, RAG Chairman or a member of the RMP evaluation staff;
4. Practicing physician who has had working experience with a Regional Medical Program; and

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\*An "Operations Officer" in the RMPS Division of Operations and Development is assigned to each RMP. The Operations Officer for a particular RMP is responsible for coordinating the site visit for that RMP's application. The name and telephone number of the responsible Operations Officer appears on the first page of the "Staff Briefing Document" which is furnished to all RMP site visitors. In those cases where a site visit is conducted with respect to special program priorities or particular technical issues, staff of other RMPS units may be assigned to coordinate the visit.

## IV-6 SITE VISIT GUIDELINES

5. Consultants or members of past site visit teams
6. As necessary, appropriate technical experts are included. These might include allied health professionals, medical or nursing educators, persons with backgrounds in community organization, and consumer problems, etc.

### B. RMPS Staff

RMPS staff members involved at site visits are as follows:

1. Operations Officer responsible for the RMP who coordinates the visit arrangements with all parties concerned.
2. Operations Branch Chief when possible.
3. RMP Regional Office Program Director responsible for the RMP.
4. Wherever possible and as necessary, a staff representative from (1) the Office of Planning and Evaluation, and (2) a staff representative from the Division of Professional and Technical Development.
5. Depending on special issues which must be explored by the team, other HSMIA and Regional Office personnel may be included.
6. RMPS staff who are in training capacity or in orientation may be included as appropriate.

### 6-4 ADVANCE PREPARATION FOR THE SITE VISIT

#### A. Advance Materials to Team

Several weeks in advance of the site visit, the team members are to be provided with copies of:

1. the site visit guidelines
2. the application
3. previous site visit report
4. appropriate trip reports from staff\*\*
5. a staff briefing document (or other special purpose summary in the case of special projects).

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\*\* RMPS Operations Officers and Regional Office staff visit RMPs regularly throughout the year.

## IV-6 SITE VISIT GUIDELINES

6. selected Management Information System printouts
7. the letter to the Coordinator outlining the purpose of the site visit
8. the suggested agenda-format (submitted by the Coordinator)
9. copies of RMPS review criteria for RMPs (or other special criteria in the case of applications relating to special program priorities or special projects) along with blank criteria forms for use by visitors in noting their observations prior to the visit
10. current, applicable Management Survey Report and/or Review Process Verification Report, if any
11. other documents considered by staff to be pertinent

### B. Pre-Site Visit Briefing

The site visit team will meet the evening before the designated day of the site visit to discuss issues, assignment of visitors for special sections of the report, adjustment of agenda as needed because of shifts in schedules, etc.

## 6-5 CONDUCTING THE SITE VISIT

### A. The Site Visit Agenda

The site visit itself may take several forms. All site visits include a review of the effectiveness of the Regional Advisory Group, of program accomplishments, of involvement of Regional provider and consumer constituencies and plans for new program developments. The agenda should provide an opportunity for the team to obtain information by which to evaluate the 20 review criteria (See Subchapter IV-4) and specific elements as they relate to the RMP which is being assessed.

### B. Mid-Meeting Team Evaluation

The site visit team usually meets the evening after the first day to discuss their findings and their reactions to the review criteria. This provides an opportunity for discussion of those areas that need further exploration and those that have been sufficiently covered.

### C. Team Executive Session

It is imperative that all the site team members remain for an executive session after the formal visit to clarify their findings and prepare recommendations which will be reported as consensus views. The draft report may be prepared by individual site visitors, by site visitor-staff teams (or by staff), but the conclusions should represent the team's views.

## IV-6 SITE VISIT GUIDELINES

### D. Feedback

Before the site visit ends, team members (or the Chairman) provide verbal feedback to the Coordinator with regard to the main findings of the site visit team, pointing out that their recommendations are subject to modification by the Review Committee and the National Advisory Council.

## 6-6 SITE VISIT REPORTS

### A. Draft Report

The draft report is outlined around the twenty review criteria and conclusions. After completion copies are mailed to all site visitors for comment, additions, deletions, etc. The final report with any changes should be returned to the coordinating Operations Officer within 7 days in order to allow time for preparation of final reports.

### B. Distribution of Final Report

Copies of the final site visit reports are made available to the members of the Review Committee. The Chairman of the visit presents a verbal report on the site visit findings when the application is reviewed by the full Review Committee. Subsequently, copies of the final report are made available to the National Advisory Council. (Usually the Council member who was at the site visit as the primary reviewer and spokesman for the team at the Council meeting.)

### C. Post Council Feedback (to Regions)

After the Council has made its recommendations, an advice letter is prepared and forwarded over the signature of the Director, RMPS, which embodies the site visit recommendations and modifications made by the Review Committee and accepted by the Council. As part of the RMPS feedback process, copies of the advice letter are sent to (1) the grantee institution, (2) the RAG Chairman, (3) members of the Review Committee, (4) members of the National Advisory Council, and (5) all participants of the site visit team. The advice letter to the RMP serves as the summary statement which reflects the deliberations and recommendations stemming from the full review process. This routine feedback in writing, provides the RMP with positive direction based on an in-depth review of its total program that can be shared by everyone involved in program direction and policy-making.

CHAPTER IV  
PROCEDURES FOR SUPPLEMENTS TO GRANTS

IV-7 PROCEDURES FOR REQUESTING SUPPLEMENTS TO RMPS GRANTS

IV-7 PROCEDURES FOR REQUESTING SUPPLEMENTS  
TO RMPS GRANTS\*

7-1 APPLICABILITY

The procedures contained in this section relate to submission of requests by Regional Medical Programs for supplementary funds under Title IX of the Public Health Service Act, and primarily to special procedures which apply when out-of-cycle supplementary requests are authorized by the Director, RMPS.

7-2 DEFINITION

A Regional Medical Program may request supplemental funds to support any activity eligible for support under Title IX and any future amendments thereto.

A supplement is an addition to the direct costs awarded as shown in Item 11g. of the most recent "Notice of Grant Award," and/or an addition to the recommended future support shown in Item 15 of such Notice.\*\* When supplementary funds are awarded, appropriate additional indirect costs may be authorized. (See Section 7-6, "Allowable Costs.")

7-3 TYPES OF APPLICATIONS

When supplementary funds are requested in a Region's normal review cycle, no special procedures are required. An anniversary application for funds for the 02 or the 03 year of support may request greater support than that recommended for the year in question as shown in Item 15 of the last Award Notice.\*\*\*

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\*Effective April 7, 1972

\*\*All references to the "Notice of Grant Award" refer to Form HSM-457, a copy of which is attached. Item 6 of the Award form shows the total period of support, and Item 7 shows the dates of the current budget period.

\*\*\*A triennial application, also, may request funds in excess of the prior level of support, but this would not be a supplement. A triennial application seeks funds for an additional period of continued support, while a supplement is an addition to an existing award.

## IV-7 REQUESTING SUPPLEMENTS TO RMPS GRANTS

RMPS in some cases will permit requests for supplemental funds to be submitted outside of the normal review cycle which has been established individually for each Regional Medical Program. Such out-of-cycle requests, however, may be submitted only when specifically authorized by the Director, RMPS, in a general announcement to all Regional Medical Programs. RMPS should not request individual exceptions to their normal review cycles and may not submit out-of-cycle applications in the absence of such an announcement.

### 7-4 DURATION OF SUPPORT

Supplementary funds may be requested for any length of time within the period of support specified in Item 6 of the last Notice of Grant Award. A single application may request an addition to the amount awarded for the current budget period (Item 11g.), and if needed, an addition to the recommended future support (Item 15). An award of supplementary funds may not include support for any activity beyond the ending date of the period of support shown in Item 6 of the current Notice of Grant Award.

Any funds needed to continue activities in the next period of support (beyond that shown in Item 6) may be requested in the normal triennial review cycle. This procedure is designed to channel review and funding of activities into the regular review cycle as quickly as possible. Unless otherwise specified in an award or other communication, it should not be inferred that RMPS requires termination of an activity at the end of the current period shown in Item 6. Regional Medical Programs should, however, keep in mind that grant support for any activity generally should be for a limited period. Thus, an important factor in considering supplemental proposals should be the likelihood of the activity either terminating or becoming self-sustaining within several years.\*

Support may also be requested for less than the remainder of the currently approved period. For example, if there were two and one-half years remaining in a Region's triennial period, and additional funds were being requested for an activity that would be completed in 18 months, the application would only request supplementary funds for the six months remaining in the current budget period (Item 7 of the last Notice of Grant Award) and for the next 12 months, and not for the remainder of the triennium.

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\*The National Advisory Council has suggested that ordinarily RMPs should plan to support specific activities for no more than 3 years. Regional Advisory Groups should carefully deliberate concerning any possible longer term commitments in order to assure maximum flexibility in the use of RMPS grant funds.

7-5 ACCOUNTING AND REPORTING

When awarded, supplementary funds may be mingled in appropriate accounts with other RMPS grant funds for the activity or activities in question. Normal accounts should be maintained for specific activities, but it is neither necessary, nor desirable to account for or report expenditures of supplementary funds separately from funds previously awarded.

All normal accounting, expenditure and reporting requirements prevail with respect to any activity funded in whole or in part through a supplementary award. Progress and expenditure reports for such activities would be submitted in the usual manner, and no special procedures would be required.

7-6 ALLOWABLE COSTS

When out-of-cycle requests for supplements are authorized by the Director, RMPS, the announcement of such supplements may contain special requirements with respect to costs allowable for the applicable activities. Unless specified otherwise in such announcement, the following cost principles apply to both in-cycle and out-of-cycle requests for supplements.

A. Direct Costs

Supplementary funds may be requested for any eligible RMPS direct cost category. Such funds may be requested to cover the costs of new or previously unfunded activities, costs of expanding existing activities. Supplementary funds may be requested for core, operational activities, or unanticipated additional costs of existing activities.

B. Indirect Costs

When requested, applicable indirect costs will be authorized in connection with an award of supplementary funds. Where the supplementary request includes additional funds for an existing activity, indirect costs for the supplement will be calculated on the same basis as the indirect costs for the original grant (i.e., salaries and wages only, or total applicable direct costs) using the currently applicable rate(s) for the institution(s) involved.

C. Developmental Components

Since the amount of any developmental component is calculated as a percentage of direct costs, it should be noted that the award of supplemental funds for core or operational activities does not automatically authorize an RMP to increase the amount of any previously approved Developmental Component. Any such increase has to be requested and specifically approved.

7-7 OUT-OF-CYCLE SUBMISSIONS

A. Authorization and Announcement

In certain circumstances, RMPS may from time to time authorize the submission of out of cycle requests for supplementary funds. In such cases, authorization for out-of-cycle submissions will be provided through a general written announcement to all Regional Medical Programs. The announcement will include:

1. deadlines for submission where different from the usual dates for each Council cycle;
2. a general description of any special class or type of activity to be funded;
3. criteria for development of proposals;
4. any necessary special instructions.

B. Application Requirements

The announcement by RMPS that supplementary funds are available does not necessarily mean that a special application is required prior to initiating an activity. Unless otherwise specified, activities for which it is announced that supplementary funds are available can be funded locally through rebudgeting or through support beginning in the next budget period. In the latter case, funds to support the activity would be included in the next in-cycle 02, 03 year, or triennial request. Where funds are rebudgeted, the normal requirements for reporting such changes apply.\*

When the availability of supplementary funds is announced, all Regions may apply on equal terms whether in-cycle or out-of-cycle. When it is announced that supplementary requests will be considered during a particular review cycle, any Region which is preparing or has already submitted an application for the cycle in accordance with its regular anniversary date may (1) amend its application, or (2) submit an additional request, or (3) both, in accordance with the deadlines or any other conditions stated in the RMPS announcement.\*\*

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\*See instructions for Page 16, "Financial Data Record," form No. RMP-34-1.

\*\*As a general rule, an RMP should follow what it considers to be the most sensible course of action under the circumstances. Where there is any question as to the best procedure, Regions are advised to contact the appropriate Operations Branch staff.

## IV-7 REQUESTING SUPPLEMENTS TO RMPS GRANTS

### 1. Example

To illustrate the above points, consider the case of a triennial or anniversary application submitted in its normal cycle for the June Council. In accordance with the usual schedule, the application would be received on March 1 and funded on September 1. If, however, on March 15 (after the regular application was submitted) RMPS were to announce the availability of out-of-cycle supplements, the RMP in the example could prepare a supplementary request for additional funds to cover the last months of its current budget period. If the Region's in-cycle request were for the 02 or 03 year of a triennium, the supplemental application could include funds needed to continue the activities (for which the supplement is requested) for the remainder of the approved period of support, Item 6 of the last award. An alternative would be to begin the new activity concurrently with the next budget period, in which case the regular application could be amended in accordance with whatever special deadline was set for out-of-cycle supplementary requests.

### C. Method of Review

The method of review of out-of-cycle requests for supplemental funds will be determined by the Director, RMPS, in each instance where such requests are authorized. The particular method of review chosen will depend upon:

1. the nature of programmatic activities for which support is requested;
2. existing Council and RMPS policies;
3. existing delegations of authority by the Council.

### D. Review Schedule for Out-Of-Cycle Supplementary Requests

Out-of-cycle supplementary requests, when authorized, will be reviewed in accordance with the following schedule. The earliest beginning dates for awards pursuant to such requests are shown in the table below. Later beginning dates, if desired, may be requested in an application.

| <u>Council<br/>Review Dates</u> | <u>Submission<br/>Deadline</u> | <u>Earliest<br/>Beginning Date</u> |
|---------------------------------|--------------------------------|------------------------------------|
| February                        | per announcement               | March 1                            |
| June                            | per announcement               | July 1                             |
| October                         | per announcement               | November 1                         |

- IV-7 REQUESTING SUPPLEMENTS TO RMPS GRANTS

E. Local Review by the Regional Medical Program and Comprehensive Health Planning

1. RAG Review

Like all other applications submitted to Regional Medical Programs, out-of-cycle requests for supplements must first be reviewed by the applicant RMP in accordance with its established local review processes. No application shall be submitted to RMPS unless it has been reviewed and recommended by the applicant RMP's Regional Advisory Group.

2. CHP Review and Comment

Out-of-cycle applications are also subject to the requirements of Section 904(b) of the Act relating to opportunity for review and comment by Comprehensive Health Planning "B Agencies." In any case where special deadlines for submission announced by RMPS do not permit the usual 30 days for review and comment required by RMPS and CHP policy, the applicant RMP is responsible for working with the appropriate "B Agencies" to insure that they are afforded an opportunity to comment prior to Regional Advisory Group review within the shorter time period afforded by the special deadlines.

7-8 APPLICATIONS AND AWARDS

A. Format and Content of Out-of-cycle Applications

Unless otherwise specified in a special announcement, requests for supplemental funds should be submitted on the standard Regional Medical Program Service Application Form, RMP-34-1.

For out-of-cycle applications, only the following pages of the RMP Application Form (RMP-34-1) need to be submitted:

1. Page 1

Submit one Face Page for the entire application. Show only the additional funds needed on line 7a. (I.e., sometimes a supplementary request will involve additional funds for an existing activity.)

2. Page 2

Submit one Assurances and Certifications page for the entire application. This page should be signed personally by the required individuals including the Chairman of the Regional Advisory Group. Actual signatures are needed even though the same individuals may have signed the original application for which the supplementary funds

IV-7 REQUESTING SUPPLEMENTS TO RMPS GRANTS

are being requested. In completing this page of the application, for a supplementary request, show the dates on which it is signed, not the dates of the original submission for the period in question.

3. Page 3

Submit one Organization and Performance Site Data page for each operational activity for which supplemental funds are requested. If performance sites are not known at the time of application, indicate this in the first data block under Item 10.

4. Page 11

Complete for any applicable program staff activities to be supported with the additional funds, otherwise do not submit.

5. Page 12

Same as above for Page 11.

6. Page 15

Submit one page 15 for each operational activity for which supplemental funds are requested.

- a. Out-of-cycle submissions authorized for specific activities: Describe the proposed activity. Show how it fulfills or deviates from each of the characteristics enumerated in the authorizing announcement by RMPS. Describe how the funds requested will be applied. Use continuation sheets as necessary, and be as concise as possible.
- b. Expansion of an existing activity: Describe the activity as expanded and show how it differs from the existing activity. Provide the most recent information on progress to date in Item 11 of page 15 ("Progress"), and give the dates of the period covered by the information. (Item 11 of page 15 is left blank if the supplemental funds are requested for new activities.)
- c. All supplementary requests: Complete item 12 on Page 15 for all supplements requested for operational activities. Enter information relating to the approved period of support for which the supplement is being requested. In the event that the activity would continue into the next period of support and receive support for less than a full year during the current period, it would be desirable to outline proposed progress for the first year of

- IV-7 REQUESTING SUPPLEMENTS TO RMFS GRANTS

the next triennium, and to indicate this in the narrative with the dates for the period entered in Item 12.

7. Page 16

- a. Funds requested for Program Staff: Submit the Financial Data Record form for Program Staff (Core) Activities where additional funds would be provided for Program Staff through the proposed supplement. In addition, complete page 16 for each operational activity to be supported in whole or in part with supplementary funds.
- b. Increased funds for existing Operational Activity: If the proposed supplement involves an increase in the budget of an existing activity, show the total budget as revised, not the difference between the original budget and the new request.
- c. Increase for Part of Budget Period: Where the requested supplement for a given activity would begin part way through the current budget period shown in Item 7 of the last Award Notice, complete one page 16 for the next year of the project if it is to be continued even if the next year were in the next triennium. In the latter case indicate in a footnote that the particular data pertains to the succeeding period of support and is submitted for information only.

B. Descriptor Codes

Each Regional Medical Program is responsible for insuring that the descriptors for its various activities are kept current for Program Staff (Core) planning and feasibility studies as well as operational activities. Where a Descriptor Coding Sheet has been submitted previously no additional Descriptor Coding Sheet is necessary unless changes have occurred. When any change has occurred, complete the entire Descriptor Coding Sheet for the activity as modified--not just the changes from the previous submission. Submit a Descriptor Coding Sheet for any new core planning or feasibility studies, or operational activities for which funds are requested.

C. Awards

Awards for supplemental funds will be issued in the form of a "Notice of Grant Award" which incorporates all necessary changes. Such award will supplant any previous "Notice of Grant Award" for the period.

IV-7 REQUESTING SUPPLEMENTS TO RMP'S GRANTS

7-9 ATTACHMENTS

- A. Notice of Grant Award
- B. Operational Activity Summary (RMP 34-1, Page 16)

HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

NOTICE OF GRANT AWARD

Under Authority of Federal Statutes and Regulations, and HSMHA Policy Standards Applicable to the Following Grant Program:

3. SUPERSEDES AWARD NOTICE dated \_\_\_\_\_  
except that any conditions or restrictions previously imposed  
effect unless specifically rescinded.

4. PROJECT IDENTIFICATION NO. \_\_\_\_\_ 5. ADMINISTRATIVE \_\_\_\_\_

6. PROJECT PERIOD  
From \_\_\_\_\_ Through \_\_\_\_\_

7. BUDGET PERIOD  
From \_\_\_\_\_ Through \_\_\_\_\_

8. TITLE OF PROJECT (OR PROGRAM) (Limit to 53 spaces)

9. GRANTEE (Name and Address)

10. DIRECTOR OF PROJECT (PROGRAM OR CENTER DIRECTOR  
COORDINATOR OR PRINCIPAL INVESTIGATOR) (Name & \_\_\_\_\_)

11. APPROVED BUDGET FOR HSMHA FUNDS

| BUDGET CATEGORIES<br>For items identified by<br>Asterisk*, see remarks | FINANCIAL<br>ASSISTANCE<br>A | DIRECT<br>ASSISTANCE<br>B |
|--|------------------------------|---------------------------|
| a. PERSONAL SERVICES   | \$ _____                     | \$ _____                  |
| b. PATIENT CARE  |                              |                           |
| c. EQUIPMENT   |                              |                           |
| d. CONSTRUCTION  |                              |                           |
| e. OTHER:<br>(Specify)   |                              |                           |
| _____  |                              |                           |
| _____  |                              |                           |
| _____  |                              |                           |
| ALL OTHER _____  |                              |                           |
| f. TRAINEE COSTS   |                              |                           |
| 9. TOTAL APPROVED<br>BUDGET  | \$ _____                     |                           |

12. SOURCE OF HSMHA FINANCIAL ASSISTANCE

a. APPROVED BUDGET (11 g. Col. A) \$ \_\_\_\_\_  
b. INDIRECT COSTS \$ \_\_\_\_\_  
(RATE \_\_\_\_\_ %  
Base: S&W - TADC of \$ \_\_\_\_\_) J  
c. TOTAL \$ \_\_\_\_\_  
d. LESS UNOBLIGATED BALANCE FROM  
PRIOR BUDGET PERIOD(S) \$ \_\_\_\_\_  
e. LESS CUMULATIVE PRIOR AWARD(S)  
THIS BUDGET PERIOD \$ \_\_\_\_\_  
f. AMOUNT OF THIS ACTION \$ \_\_\_\_\_

13. REQUIRED GRANTEE PARTICIPATION

- INSTITUTIONAL COST SHARING AGREEMENT  
EFFECTIVE DATE \_\_\_\_\_  
 INDIVIDUAL GRANT AGREEMENT \_\_\_\_\_ %  
 MATCHING AGREEMENT \_\_\_\_\_ %  
 OTHER \$ \_\_\_\_\_  NONE REQUIRED

15. RECOMMENDED FUTURE SUPPORT (Subject to availability)

| BUDGET YEAR | FISCAL YEAR | BUDGET PERIOD | TOTAL DIRECT |
|-------------|-------------|---------------|--------------|
|             |             |               |              |

16. ACCOUNTABILITY FOR EQUIPMENT

- CONDITIONALLY WAIVED  NOT WAIVED  \_\_\_\_\_

17. FINANCIAL MANAGEMENT OFFICIAL (Title & Address)

18. HSMHA OFFICIAL (Signature, Name and Title)

|                                |                    |   |  |   |
|--------------------------------|--------------------|---|--|---|
| 19. FOR HSMHA INFORMATION ONLY | a. PHS LIST NO.    | b. PAYMENT SYSTEM<br><input type="checkbox"/> HSMHA <input type="checkbox"/> R.O.<br><input type="checkbox"/> NIH | c. DIRECT ASSISTANCE FUNDS<br>FY _____ \$ _____<br>FY _____ \$ _____ | d. GRANTEE LOCATION<br>City _____<br>County _____ Comp. # _____ |
|                                | e. ACCOUNTING DATA |   |  |   |

|                                       |  |  |  |   |
|---------------------------------------|--|--|--|---|
| 1. TITLE                              |  | 2. IDENT. NUMBER (9-12)  | 3. DATE OF INITIAL ICAPS SUPPORT<br>MONTH (13-14) YEAR (15-16) |   |
| 4. SPONSOR (Institution/Organization) |  | 5. GEOGRAPHIC AREA SERVED (17-18)  |  | 6. EST. TERMINATE DATE OF RMPS SL<br>MO. (19-20) YEAR (21-22) |
| 7. DIRECTOR                           |  | 9. TARGET GROUP(S) (25-28)<br>A. CONSUMERS AND/OR PATIENTS<br>B. PROVIDERS (29-30) |  |   |
| 8. DISEASE CATEGORY (IES) (23-24)     |  |  |  |   |

10. SIGNIFICANT RELATIONSHIPS WITH OTHER FEDERAL PROGRAMS (Check all applicable)

|  |                                       |   |   |
|--|---------------------------------------|---|---|
| (31) A <input type="checkbox"/> OEO                        | (34) D <input type="checkbox"/> CHP-A | (38) H <input type="checkbox"/> MOD. CITIES | (42) L <input type="checkbox"/> NIH-INSTITUTES      |
| (32) B <input type="checkbox"/> EXP. HEALTH PLAN. & DELIV. | (35) E <input type="checkbox"/> CHP-B | (39) I <input type="checkbox"/> HMO         | (43) M <input type="checkbox"/> NIH-MANPOWER BUREAU |
| (33) C <input type="checkbox"/> OTHER NCHSR&D              | (37) G <input type="checkbox"/> CHP-E | (40) J <input type="checkbox"/> FDA         | (44) N <input type="checkbox"/> OTHER (Specify)     |
|  |                                       | (41) K <input type="checkbox"/> APPALACHIA  |   |

11. PROGRESS

| PERIOD       |                 |
|--------------|-----------------|
| FROM (45-48) | THROUGH (49-52) |
| MO. YR.      | MO. YR.         |
|              |                 |

12. PROPOSAL

| PERIOD       |                 |
|--------------|-----------------|
| FROM (53-56) | THROUGH (57-60) |
| MO. YR.      | MO. YR.         |
|              |                 |

A. WHAT WAS DONE?  
 B. WHAT ARE THE SIGNIFICANT OUTPUT DATA?  
 C. WHAT ARE THE BENEFITS OR FINDINGS?  
 D. WHAT PROBLEMS WERE ENCOUNTERED (IF ANY)?  
 E. IF RMPS SUPPORT HAS BEEN OR WILL TERMINATE EXPLAIN WHY AND WHETHER ACTIVITY WILL BE CONTINUED WITH OTHER SUPPORT.

A. WHAT ARE THE GENERAL OBJECTIVES?  
 B. WHAT WILL BE DONE IN THE ABOVE PERIOD?  
 C. WHAT RESOURCES WILL BE EMPLOYED?  
 D. WHAT SPECIFIC RESULTS ARE EXPECTED IN THE ABOVE PERIOD?

CHAPTER IV  
COMMUNITY BASED MANPOWER PROGRAM PROPOSALS

IV-8 GUIDES FOR REVIEW OF COMMUNITY BASED MANPOWER PROGRAM PROPOSALS

IV-8 GUIDES FOR REVIEW OF  
COMMUNITY BASED MANPOWER PROGRAM PROPOSALS \*

8-1 APPLICATION ESSENTIALS

1. Proposal is requesting funding in excess of \$50,000.
2. Proposal has approval of the Regional Advisory Group.
3. Proposal includes review and comment of the appropriate CHP agency, if not, explanation is given.
4. The area to be served is clearly defined and comprises a medical trade area.
5. Names of all institutions and agencies involved.

8-2 DOCUMENTATION OF NEED

A. Required Data

What sources of data have been used for planning to determine needs for health services? Do these include:

1. Number and characteristics of the population to be served;
2. Numbers, distribution, and utilization of health manpower providing services;
3. Numbers and kinds of institutions, agencies, both private and public, providing health manpower education and training opportunities; numbers and nature of their training programs.

8-3 OBJECTIVES

1. Objectives are stated in clear and measurable terms.
2. Objectives relate to the RMPS concept of the community based manpower programs.

8-4 PLANNING

1. The proposal is not in competition with similar efforts within the same geographical area.
2. Identification of the accredited education institutions, health care provider institutions and community health care and planning interests committed to the advancement of the program.

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\*See Subchapter X-7 for further discussion of manpower activities.

## IV-8 GUIDES FOR REVIEW OF COMMUNITY BASED MANPOWER PROGRAM PROPOSALS

3. Identification of the potential membership of a Coordinating/Governing Body group.
4. There is a plan for evaluating the developmental process.
5. An implementation scheme has been developed and appropriate sources of funding to support each phase has been identified.

### 8-5 ORGANIZATION AND DEVELOPMENT

- A. The Coordinating/Governing Body has been formed, its function formalized, and an administrative structure planned for management purposes.
  1. For established Bodies, by-laws are attached.
- B. Such a Coordinating/Governing Body is proposed.
  1. Draft by-laws are attached if available.
- C. The Coordinating/Governing Body represents a consortium of:
  1. At least one fully accredited institution of higher learning.
  2. Principal health care provider groups or institutions, including appropriate clinical resources.
  3. Consumer interests.
  4. Health professional societies.
- D. Evidence is provided of the degree of commitment of participating educational institutions, health service institutions, and other appropriate groups.

### 8-6 OPERATIONAL

- A. The operational phase of the proposal describes which of the following activities are to be undertaken in the current period.
  1. Setting of priorities based upon continuous appraisal of the relationship between community health service needs and production of health manpower.
  2. Designing education for both traditional and new health occupations to meet the particular health service needs of the area.

CHAPTER IV

IV-9 MANAGEMENT SURVEYS

B. Organization and Personnel Management

The staffing pattern and organizational structure of the RMP is reviewed. In addition, the adequacy and effectiveness of personnel policies are considered. The team ascertains the degree to which employees understand the policies and their own responsibility and relationships to related elements of the RMP. A review is made of office procedures relating to time and leave records, payroll procedures, and internal communication.

C. Development and Monitoring of Activities

Although the team makes no judgment on the professional aspects of projects, it inquires into the staff assistance provided in project development, review, and supervision. The team member covering this area is interested in the region's data collection and evaluation, guidelines available to project authors and reviewers, and staff participation in developing realistic project budgets. Under normal circumstances this review and analysis is the responsibility of the operations officer.

D. Fiscal Controls

No effort is made to conduct a deep financial audit. The survey team instead is concerned with what fiscal controls have been established, policies relating to disbursements, and fiscal reports required of the affiliates. A review is also made of documentation required of the affiliates to support payment and the written instructions that are available to them. If questionable uses of grant funds arise, they are pursued until proper action is determined by the team.

E. Purchasing

A review is made of the purchasing policies and the controls established to assure that they are followed. In the area of equipment, the team is concerned with inventory records, accountability for equipment and maintenance of it, and what provisions are made for its eventual disposal. The Affiliation Agreement, Articles of Incorporation, and any written documents between the RMP or grantee and affiliates are examined within the limitations of the team to determine if the RMP is adequately protected.

9-4 SURVEY REPORT

Upon returning to RMPS, each team member contributes a written report on his area of responsibility during the survey, and the team leader edits, rewrites, and combines the parts into a single survey report.

Copies of the written report are distributed to

- (1) Director, RMPS
- (2) Director, DOD
- (3) Chief of responsible operations branch
- (4) Office of Planning and Evaluation, RMPS
- (5) Coordinator
- (6) Chairman of Regional Advisory Group
- (7) Grantee institution
- (8) Office of Grants Management, HSMHA
- (9) Office of Grants Administration Policy, DHEW
- (10) DHEW audit agency

Recommendations made in the report are used

- (1) to correct the deficiencies identified,
- (2) to assist the operations desk in working with the region,
- (3) by the director in making management decisions concerning the region,
- (4) as part of the total review process, and
- (5) as information to be included in the site visit package.

Among other things, the findings may result in developing new RMPS policy and may be the basis for special studies by either the Grants Management Branch or some other office in RMPS. In addition the Office of Grants Administration Policy has used the reports as basis for reconsideration of indirect cost rates for grantees. Management survey reports also provide the HEM audit agency with information used to determine RMPS audit needs. By relying on RMPS management surveys, the audit agency has been able to limit their audits of RMPs.

9-5 Follow-up

Approximately six months after the report has been forwarded to the RMP and its grantee and after their written response

CHAPTER VI  
ADMINISTRATIVE AND ORGANIZATIONAL REQUIREMENTS

- VI-1 GRANT ADMINISTRATION REQUIREMENTS
- VI-2 ORGANIZATIONAL AND STRUCTURAL REQUIREMENTS FOR RMPs

CHAPTER VI  
ADMINISTRATIVE AND ORGANIZATIONAL REQUIREMENTS

VI-1 GRANT ADMINISTRATION REQUIREMENTS

CHAPTER VI  
ADMINISTRATIVE AND ORGANIZATIONAL REQUIREMENTS

VI-2 GRANTEE AND REGIONAL ADVISORY GROUP  
RESPONSIBILITIES AND RELATIONSHIPS

VI-2 GRANTEE AND REGIONAL ADVISORY GROUP  
RESPONSIBILITIES AND RELATIONSHIPS

2-1 INTRODUCTION

There are three major components of a Regional Medical Program at the regional level: the grantee organization; the Regional Advisory Group; and the Chief Executive Officer (often referred to as the RMP Coordinator) with his (or her) program staff. The responsibilities that each has and how they relate to and interact with one another are important factors in a successful Regional Medical Program. The following outline sets forth a framework for these responsibilities and relationships.

2-2 GRANTEE

A. Responsibilities of the Grantee Institution

The grantee organization shall manage the grant of the Regional Medical Program in a manner which will implement the program established by the Regional Advisory Group and in accordance with Federal regulations and policies. This shall include:

1. Initially designating a Regional Advisory Group in accordance and conformance with Section 903(b) (4) of the Act. Such designation includes selection of the Chairman until such time as the bylaws of the RAG have been approved. (This is a responsibility of the applicant organization which requests planning support for the establishment of an RMP.)
2. Confirming subsequent selection of RAG Chairmen.
3. Selecting the Chief Executive Officer on the basis of Regional Advisory Group nomination.
4. Receiving, administering, and accounting for funds on behalf of the Regional Medical Program.
5. Reviewing operational and other activities proposed for RMP funding with respect to:
  - a. their eligibility for and conformance with RMPs and other Federal funding requirements,
  - b. capabilities of affiliates to manage grant funds properly.

## VI-2 RAG/GRANTEE RELATIONSHIPS

6. Prescribing fiscal and administrative procedures designed to assure compliance with all Federal requirements and to safeguard the grantee against audit liabilities.
7. Negotiating provisional and/or final indirect cost rates for affiliates. (See Subchapter VII-3, 3-4.)
8. Providing the RMP with all administrative and supportive services that are included in the grantee's indirect cost rate. (See Subchapter VII-3, 3-1, C, and 3-3.)

### B. Responsibilities of the Chief Executive Officer

As its employee, the Chief Executive Officer-- the full-time person with day-to-day responsibility for the management of the RMP-- is responsible to the grantee; he is also responsible to the Regional Advisory Group which establishes program policy. His responsibilities include:

1. Providing day-to-day administrative direction for the program in accordance with the procedures established by the grantee and the program policies established by the Regional Advisory Group.
2. Providing adequate staff and other support to the Regional Advisory Group and its committees for effective functioning.
3. Developing the RMP staff organization and selecting program staff and supervising their activities.
4. Assuring both the effectiveness of operational activities and integration of all operational and staff activities into a total program.
5. Monitoring grant-supported activities to assure compliance with all Federal requirements.
6. Establishing and maintaining an effective review process in accordance with RMP requirements.
7. Maintaining appropriate relationships and liaison with RMPs, including HEW Regional Office staff. This shall include the dissemination of Federal program policies and requirements to staff, Regional Advisory Group, and other interested parties within the region and program to RMPs.

2-3 REGIONAL ADVISORY GROUPA. Responsibilities

The Regional Advisory Group (RAG) has the responsibility for setting the general direction of the RMP and formulating program policies, objectives, and priorities. More specifically, RAG responsibilities shall include:

1. Establishing goals and objectives for the Region's total program; setting priorities for both operational and program staff activities; and evaluating overall program progress and accomplishments.
2. Approving any applications submitted to RMFS.
3. Approving the RMP organizational structure and significant program staff activities.
4. Approving overall budget policy and major budget allocations.
5. Subsequent to its establishment (See 2-2, A., 1., above) procedures for selecting and appointing its own members; assuring appropriate representation on the Regional Advisory Group in accordance with the Act, RMP regulations, and policies; assuring its continuity; selecting and appointing its own officers (other than the chairman); and establishing an executive committee from its own membership to act on its behalf between RAG meetings.
6. Selecting the Chairman for confirmation by the grantee. (See 2-2, A., 2., above.)
7. Nominating the Chief Executive Officer for selection by the grantee. (See 2-2, A., 3., above.)
8. Developing, formally adopting, and periodically updating RAG bylaws which set forth duties, authorities, operating procedures, terms of office, categories of representation, method of selection, and frequency of meetings for the RAG and its committees.
9. Approving any delegations of authority, including those relative to specific budget allocations, to the Chief Executive Officer, its executive committee, and others.

2-4 IMPLEMENTATIONA. Effective Date

All RAGs must comply substantially with this Act by March 1, 1973.

## VI-2 RAG/GRANTEE RELATIONSHIPS

### B. Implementing Working Documents

Individual Regional Medical Programs are responsible for developing and maintaining the working documents necessary for implementing the policy. Such documents establish a basis for the required relationships and serve as evidence that the required relationships do, in fact, exist. Some examples of implementing working documents are: corporate charters; corporate or RAG bylaws; organizational, procedural and policy materials; the Coordinator's job description or contract of employment; and various agreements or contracts among the organizations participating in or involved with the RMP.

### C. Approvals

Although there must be documentary evidence of the required relationships, the written materials do not have to be submitted to RMPS unless requested. Regional Medical Programs and grantees, however, may call on RMPS at any time for advice relative to implementing the policy. While routine approval of the working documents by RMPS is not required, the Director, RMPS, may review such documents at any time and require any changes necessary to assure compliance.

### D. Effect on Existing Agreements

Fixed term contracts or agreements (e.g., the coordinator has a 3 year employment contract) in effect as of the date of this issuance shall be deemed to be in compliance with the policy until the expiration of the contract period. Other contractual arrangements affected by the policy should be altered accordingly by March 1, 1973. New or renewed contractual arrangements relating to the relationships covered by the policy must comply in all respects.

CHAPTER VI  
ADMINISTRATIVE AND ORGANIZATIONAL REQUIREMENTS

VI-3 AFFILIATION AGREEMENTS

### VI-3 AFFILIATION AGREEMENTS

the agency for both direct and/or indirect costs were not made in compliance with the regulations and policies of the granting or funding agency.

6. Hold the Grantee Institution harmless from any and all claims arising by reason of this agreement.
7. Acknowledge and agree that the ultimate disposition of equipment purchased with Regional Medical Program funds is the responsibility of the Grantee Institution, subject to the concurrence of Regional Medical Programs Service that it will continue to be used to further the objectives of the Public Health Service.
8. Certify that it will comply with Section 601, Title VI of the Civil Rights Act of 1964, 42 U.S.C. 20000d, which forbids discrimination to any individual on the grounds of race, color, or national origin, and also agree that on each construction project it will comply with the requirements of Executive Order 11246, 30 F.R. 12319 and the applicable rules, regulations, and procedures as prescribed by the Secretary of Labor. (See Subchapter IX-1, and VI-1, 1-2, C)
9. Assure that it will comply with the same assurances agreed to by the grantee with the funding agency, with specific reference to:
  - a. The Protection of Human Subjects Involved in Research Projects (See Subchapter VI-1, 1-3, A.)
  - b. Patents and Inventions (See Subchapter VI-1, 1-4, A.)
  - c. Humane Treatment of Research Animals. (See Subchapter VI-1, 1-2, I)
10. Agree that all income generated as a result of RMP grant supported activities will be the property of the grantee, until disposition instructions are received from the funding agency. (See Subchapter VII-4 and VI-1, 1-4)
11. Agree that continuation of this agreement is contingent upon the continued funding of the grantee by the funding agency, and decision by the RAG to continue support of the activity at the affiliated institution.
12. Agree that grant funds received from the grantee institution, will be expended in accordance with the budget agreed upon with the grantee for support of the approved activity, and that any deviations proposed from the approved budget will be subject to the approval of the grantee.

CHAPTER VII  
FINANCIAL MANAGEMENT POLICIES

- VII-1 GENERAL FINANCIAL MANAGEMENT PRINCIPLES AND REQUIREMENTS
- VII-2 ALLOWABLE COSTS
- VII-3 INDIRECT COSTS
- VII-4 GRANT RELATED INCOME
- VII-5 CONTRACTING BY GRANTEEES
- VII-6 PAYMENT SYSTEMS
- VII-7 GOVERNING PRINCIPLES AND REQUIREMENTS, DISCRETIONARY RMP  
FUNDING AND REBUDGETING AUTHORITY

CHAPTER VII  
FINANCIAL MANAGEMENT POLICIES

VII-1 GENERAL FINANCIAL MANAGEMENT PRINCIPLES AND REQUIREMENTS

## VII-1 FINANCIAL MANAGEMENT REQUIREMENTS

4. Grantees will also be responsible for advising the recipients of the proposed equipment that any transfer to such equipment is made conditionally upon compliance by the recipients with the obligation to use the equipment for the purposes for which the original grant was made during the entire useful life of the equipment. If the recipient of the proposed equipment does not fulfill this obligation, the Federal Government may exercise its right to recover its proportionate share of the residual value of said equipment from the so designated recipient. The recipient of said equipment shall label the equipment to distinguish it from all other equipment within its facility, and keep appropriate records of the current status, location and eventual disposition of said equipment at the completion of its useful life.

D. Forms for Transfer of Equipment Title and Accountability

See attachment for suggested forms.

ATTACHMENT:

for 1-10 "Management of and Accountability for Equipment Acquired with RMPS Funds."

Suggested forms to be utilized to transfer title to and account for equipment purchased with RMPS funds.

- A. Communication from grantee to RMPS requesting transfer
- B. Communication from grantee to affiliate advising of approval of transfer
- C. Affiliate's certification re: continued use of equipment

VII-1 FINANCIAL MANAGEMENT REQUIREMENTS

B

To \_\_\_\_\_  
 (Affiliated Institution)

From Grantee Institution

Transfer of title and accountability for the equipment listed has been approved by the Regional Medical Programs Service.

You are advised that the following conditions apply:

1. The equipment will continue to be used for the furtherance of RMPS activities.
2. The equipment shall be labeled to distinguish it from all other equipment within the facility.
3. Appropriate records will be kept of the current status, location, and eventual disposition of said equipment at the completion of its useful life.
4. The Federal Government may exercise its right to recover its proportionate share of the original value if said equipment of the above three conditions are not met.

\_\_\_\_\_  
 Authorized Official, Grantee Institution

Equipment List

| <u>Item</u> | <u>I.D. No.</u> | <u>Description</u> | <u>Purchase Date</u> | <u>Original Cost</u> |
|-------------|-----------------|--------------------|----------------------|----------------------|
| 1           |                 |                    |                      |                      |
| 2           |                 |                    |                      |                      |
| 3           |                 |                    |                      |                      |
| 4           |                 |                    |                      |                      |
| 5           |                 |                    |                      |                      |
| 6           |                 |                    |                      |                      |
| 7           |                 |                    |                      |                      |

VII-1 FINANCIAL MANAGEMENT REQUIREMENTS

C

To

From

(Affiliate)

The

is

no longer receiving Regional Medical Program operational funding and requests the transfer of title to and accountability for the equipment listed. All of this equipment was purchased with RMPS funds under Grant Number \_\_\_\_\_

(Project No. and Title)

It is hereby certified that all of the equipment listed will continue to be used during its useful life for an activity which is approved by the Regional Medical Programs Service or supportable under Title IX of the Act. In the event the equipment at any time ceases to be used, the Regional Medical Programs Service, Grants Management Branch, will be notified.

\_\_\_\_\_  
Authorized Official, Affiliated  
Institution

From

To Grantee Institution

The above requested transfer is recommended for approval.

\_\_\_\_\_  
Coordinator or Director

\_\_\_\_\_  
RMPS Grant

CHAPTER VII  
FINANCIAL MANAGEMENT POLICIES

VII-2 ALLOWABLE COSTS

## VII-2 ALLOWABLE COSTS

### 2-1 GUIDE MATERIALS RELATING TO COSTS

Allowable costs under the RMP program are those specified in this Sub-Chapter (VII-2) and in the following HEW Guides.

1. "A Guide for Colleges and Universities--Establishing Indirect Cost Rates for Grants and Contracts with the Department of Health, Education, and Welfare."  
(OASC-1, Revised)
2. "A Guide for Non-Profit Institutions, Cost Principles and Procedures for Cost Rates for Grants and Contracts with the Department of Health, Education, and Welfare."  
(OASC-5, Revised)
3. "A Guide for State Government Agencies--Establishing Cost Allocation Plans and Indirect Cost Rates for Grants and Contracts with the Department of Health, Education, and Welfare." (OASC-6)
4. "A Guide for Hospitals--Establishing Indirect Cost Rates for Research Grants and Contracts with the Department of Health, Education, and Welfare." (OSAC-3)

### 2-2 ALLOWABLE COSTS

#### A. Use of List of Allowable and Not Allowable Costs

The list of allowable and not allowable costs furnished in Section B, below, covers those items most frequently encountered. The stated policies apply unless otherwise specified in a Notice of Grant Award, or other communication from RMPB. Omission of a particular item of cost is not intended to imply that the omitted item is either allowable or not allowable.

#### B. Allowability of Frequently Encountered Cost Categories

##### 1. Alteration and Renovation

Allowable. (Also see Chapter VII, 1-4, A, 3; Chapter VII, 13-2, A and B; and Chapter VIII.)

##### 2. Audiovisual Materials--(See B, 20, "Films and Videotapes.")

##### 3. Bonding Costs--Allowable. (See Chapter VII-1, 1-9, "Bonding Requirements.")

4. Basic Education (Training)

Allowable for student support (tuition, stipends, etc.) and associated costs for training of new types of health personnel. Student support for basic education and training in established medical and allied health professions (including internships and residencies) is not allowable. The training institution may be reimbursed for services rendered to an RMP activity by residents, interns or other students.

A health profession is considered established if a Board of Schools of the AMA Council on Medical Education, or some similarly recognized mechanism, has been set up to approve schools, outline standards for admission, curriculum requirements and certification procedures, and/or if definitive formal educational programs in the particular health occupation have already been instituted in the educational and training systems of hospitals, technical schools, junior and senior colleges.

Training of new types of health personnel is that training which relates to newly developing technologies or new modalities of diagnosis and treatment for which no standard curriculum is yet recognized, no minimum national standards for certification or licensure are yet established and which is not generally part of the regular offerings of the health-related educational and training system of hospitals and/or technical schools, junior and senior colleges.

5. Bonus Payments -- Not allowable6. Books and Periodicals -- Allowable7. Communications

Costs incurred for telephone services, local and long distance telephone calls, telegrams, radiograms, postage and the like, are allowable, provided that such costs are not treated as indirect costs.

8. Computers

Allowable. Grant funds may be used to purchase computer time, or if the needs of the program are sufficient, the rental of a computer as with all other activities, the costs of acquiring computer capability must be measured against the benefits to be derived.

9. Computer Assisted EKG Analysis

Not allowable to implement, equip or operate new computer assisted electrocardiographic systems (CAE). Limited funding is allowable, however, specific organizational phases of CAE system implementation. Such funding may assist in: establishing working relationships between participants, provision of technical consultation, and evaluation of the CAE system.

## VII-2 ALLOWABLE COSTS

- c. The medical personnel of the Uniformed Services of the United States (excepting commissioned officers of the Public Health Service) hired as consultants have prior written authorization from their commanding officers to work on the grant supported activity and to be paid for their efforts.

In addition, travel or other supporting costs but not consultant fees for Federal employees may be paid when consultative assistance is required from a Federal program other than RMPS. (For example, if an RMP needed consultation from an Office of Education employee, it could pay his travel and subsistence in the event that the OE's travel funds were limited.)

### 23. Films and Videotapes

Allowable provided that the film in question is intended for viewing by restricted audiences. Grant funds may not be used to produce films or videotapes for viewing by the general public without prior approval of the Regional Medical Programs Service. While there is no universal rule for determining whether the intended audience for a motion picture should be regarded as "general" or "restricted" the following situations are routinely considered as involving the general public: (See Chapter 1-450 of Grants Administration Manual.)

- a. Broadcast on commercial or educational public television
- b. Showing in commercial movie houses
- c. Showing in public places such as airports, waiting rooms, bus or railroad depots, vacation resort facilities, etc.
- d. Showing to civic associations, schools (except when used as a teaching tool in a classroom setting), clubs, fraternal organizations, or similar lay groups.

Films and videotapes produced with RMPS grant funds shall acknowledge grant support and clearly indicate that the material in question does not necessarily represent the views of the Federal Government. (Also see VI-1, 1-4, B,C, & D.)

### 24. Foreign Travel-- See; "Travel," this Subchapter.

### 25. Fringe Benefits

The grantee's share of fringe benefits, including leave, policies, uniformly charged as a direct cost on an actual rather than an estimated basis, and charged in proportion to salary charged to the grant.

27. Home Dialysis Training

See "Kidney Disease Activities," this Subchapter. (Also see Subchapter X-2.)

28. Honoraria

Not allowable. An honorarium is a payment or reward, the primary intent of which is to confer distinction on or to symbolize respect, esteem, or admiration for the recipient.

29. Kidney Disease Activities

Allowable and not allowable costs of various specific categories of kidney disease activities are outlined below. Kidney disease programs are expected to be fully operational independently from RMPS support after the third year of grant support. (See Subchapter X-2 for further requirements.)

- a. Dialysis and Transplantation Facilities for Children -- Start-up costs are allowable for pediatric end-stage renal activities in selected areas of need.
- b. Education -- Training and continuing education of physicians postgraduate renal nurses, and other allied health professionals to improve care for patients with end-stage renal disease is allowable, subject to the requirements and limitations of RMPS policies relating to educational and training activities. (See "Basic Education (Training)," and "Training Costs," this Subchapter. Also see "Public Education," below, in this Section.)
- c. Home Dialysis Training-- Allowable where there is a demonstrated need. Home dialysis training programs must be affiliated with a transplantation program and provide or have access to acute dialysis backup.
- d. Low-overhead Limited-care Dialysis-- Allowable for the development of home dialysis training programs where there is a demonstrated need. Such programs must be affiliated with a primary care program and have access to acute medical resources.
- e. Organ Procurement Activities-- Allowable for start-up of a Region's organ procurement activities.
- f. Organ Procurement and Communication Activities -- Allowable. Such activities must provide optimal use of harvested organs through sharing among many transplant centers serving several areas. These activities should, like other kidney disease activities, become self-sufficient over time as RMPS funding is reduced and eventually withdrawn. It is, however, more difficult for these activities to be financed by third-party carriers, and the costs of managing the organ- procurement network may be added to the individual cost per organ harvested.
- g. Public Education -- Allowable for limited support for appropriate public education activities which are clearly related to specific output of the end- stage renal program.

VII-2 ALLOWABLE COSTS

44. Training Costs

Allowable. Grant funds may be used for the payment of stipends and other benefits related to training in connection with RMP activities. Maximum allowances are set forth in the following schedule:

|   | Per Annum<br>Stipend | Dependency<br>Allowance | Per<br>Diem | Travel |
|---|----------------------|-------------------------|-------------|--------|
| Conferences and Seminars*                     | none                 | none                    | yes         | yes    |
| Short-Term Training*                          | none                 | none                    | yes         | yes    |
| Long-Term Training*                           |                      |                         |             |        |
| College level but less than Bachelor's Degree | \$2,400              | \$600                   | none        | none   |
| post Bachelor's, but less than a Doctorate    |                      |                         |             |        |
| 1st year post Bachelor's                      | \$2,400              | \$600                   | none        | none   |
| 2nd year post Bachelor's                      | \$2,600              | \$600                   | none        | none   |
| 3rd year post Bachelor's and beyond           | \$2,800              | \$600                   | none        | none   |
| Postdoctorate                                 | negotiable           | \$600                   | none        | none   |

- a. Stipends for long-term training which is less than a full twelve months are to be calculated on a prorata basis, and leave and holiday policies of the grantee institution are to be followed.
- b. Dependency allowances for those long-term trainees, who are in training for a full academic year, may be awarded an amount not to exceed \$600 per annum for each dependent who would meet the criteria developed by the Internal Revenue Service for dependency. (Consult IRS for details.)
- c. Reimbursement for per diem and travel for trainees should be made in accordance with the travel policies of the grantee institution, or in the absence thereof, in accordance with currently effective DHEW travel regulations. (See B, 35, "Travel.")

CHAPTER VII  
FINANCIAL MANAGEMENT POLICIES

VII-3 INDIRECT COSTS

## VII-3 INDIRECT COSTS

bookkeeping, whereas the usual research grant would rely on the central administrative mechanisms of the grantee institution for such services.

For the above reasons, then, it will usually be necessary to determine an appropriate RMP indirect cost rate for the grantee and each affiliated institution. In addition, the indirect cost rate determined for a given institution for RMP will usually be different from the indirect cost rate approved for other types of grants. The methods for negotiation and approval of indirect cost rates for: (a) RMP grantees; and (b) affiliated institutions receiving RMP support is discussed in the following sections.

### 3-3 NEGOTIATION OF INDIRECT COST RATES FOR GRANTEE INSTITUTIONS

#### A. Method of Negotiation

The Office of Grants Administration Policy, (OGAP), in the Department of Health, Education, and Welfare, has the responsibility for negotiating indirect cost rates with each grantee institution requesting indirect costs.

Each grantee which wishes to be reimbursed for indirect cost must submit an annual indirect cost rate proposal within six months after the last day of each of the fiscal years for which it receives an RMP grant.

Each institution's indirect cost rate proposal should propose as many indirect cost rates as are deemed necessary for the equitable allocation of indirect costs to its awards. For example, if the grantee conducts RMP activities at several different locations, it may propose separate rates for each, where appropriate (i.e., on-campus rates, off-campus rates, etc.).

Indirect cost rate proposals should be submitted to:

Division of Cost Policy and Negotiation  
Office of Grants Administration Policy  
Department of Health, Education, and Welfare  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Once an indirect cost rate has been negotiated by OGAP, it will be incorporated into an official negotiation agreement setting forth the results of the negotiation, indicating therein the applicable rate for RMP grants.

#### B. Provisional and Final Rates

The indirect cost rate negotiated by OGAP may be either a provisional or a final rate.

## VII-3 INDIRECT COSTS

A provisional indirect cost rate is a temporary rate established to allow the obligation and payment of funds RMPS grants, until such time as actual indirect costs can be determined and a final indirect cost rate established. Provisional indirect cost rates are subject to adjustment by OGAP at some future date. A provisional rate is used to compute indirect costs on grant applications and on grant reports of expenditures.

A final indirect cost rate is established after an institution's actual cost for a given accounting period (normally its fiscal year) are known. Once established, a final indirect cost rate is used as its current provisional rate.

If RMPS makes an award to an institution that has in good faith negotiated an indirect cost rate with OGAP, that rate will be used on a provisional basis by RMPS, irrespective of the applicability of this rate to RMPS, subject to the finalization by OGAP of an indirect cost rate applicable to the RMPS grant.

### 3-4 NEGOTIATING INDIRECT COST RATES FOR AFFILIATES

#### A. Grantee Responsibilities

##### 1. Required Grantee Action

The grantee institution is responsible for negotiating indirect cost rates for RMP affiliates when:

- a. The affiliate has no established indirect cost rate and none is currently being negotiated with OGAP for any other HEW program.
- b. An indirect cost rate has been negotiated for specific programs of the affiliate other than RMP and is not applicable across the board to all HEW support

The grantee is also responsible for verifying the appropriateness for RMPS supported activities of any indirect cost rates previously negotiated with the affiliate by OGAP. In the case of any discrepancy, the grantee is responsible for informing OGAP and for establishing a special rate for the affiliate's RMPS supported activities.

##### 2. Cases in which the Grantee's Negotiation is not Required

The grantee is not required to negotiate an indirect cost rate for an affiliate when:

- a. There is an established rate for the affiliated institution which is applicable to all HEW support and determined by the grantee to be appropriate for RMPS supported activities.

## VII-3 INDIRECT COSTS

- b. OGAP is in the process of negotiating the affiliate's indirect cost rate for other HEW programs (in which case OGAP will simultaneously establish a rate for RMP support).
  - c. The grantee decides at its discretion to reimburse all of an affiliate's costs as direct charges to the grant.
3. Staffing for Indirect Cost Studies by the Grantee

A grantee's negotiation or verification of indirect cost rates for affiliates can be carried out by either the grantee's own financial staff or through the employment of qualified accountants or accounting firms as consultants. In addition, OGAP may be called upon for advice as necessary.

### B. Provisional and Final Rates for Affiliates

Where the grantee institution negotiates indirect costs directly with an affiliated institution, it will be the grantee's responsibility to negotiate both provisional and final indirect cost rates with each affiliate institution. Once a final rate is agreed upon between the grantee and an affiliate, it will not be subject to further review or change, and will be considered to be the final rate as if negotiated by OGAP.

Before finalizing an indirect cost rate, the following steps must be taken by the grantee to support the reasonableness of the finally established indirect cost rate:

1. Review the adequacy of the affiliate's procedures, the reliability of the records, and the effectiveness of their internal controls.
2. Review the completeness of the base used for distributing the overhead costs, including an evaluation of the reasonableness and applicability of the base utilized (i.e., direct labor hours, direct labor dollars, etc.) to the subject and purpose of the project to which applied.
3. Review the pool of indirect expenses for those expenses which may be fully or partially unallowable, based upon their nature or content.
4. Selectively analyze the remaining accounts in the overhead pool for applicability to the RMP activity. Eliminate from the pool any expenses where similar type expenditures were previously recovered as a direct charge. Do not automatically eliminate overhead accounts from the pool purely by expense nomenclature if items of the same expense category

### VII-3 INDIRECT COSTS

any accounts from the overhead pool, a review should be made of the expenses comprising the account to ascertain if these expenses are really similar to those included as direct charges. The basis for determining the specific areas to be selected for intensive review and testing, and the depth and scope of the review should be determined by a review of a listing of the account balances of the various indirect costs, comparison with prior periods, and with the current year's operating budget. The reviewer should obtain or prepare a schedule of indirect expense accounts for the period under review and select for thorough analysis those accounts which are significant in amount, vary from developed trends, or which, on the basis of nomenclature review, appear to be sensitive in nature and likely to contain questionable costs.

5. Reconcile the affiliated institution's overhead submission to their general books of account. Ascertain in relation to the nature of the project whether a special overhead rate is warranted for the RMP activity.
6. Where applicable review the reasonableness of the rates utilized for depreciation, and whether the depreciation was based upon acquisition value or appraised value of the institution's assets. Ascertain if large repair and maintenance expenses have been incurred which may be justifiably reclassified to a capitalization account rather than annually expended.
7. Determine whether fringe benefits are included in both the overhead pool and base, and evaluate the reasonableness of this procedure.
8. Ascertain whether any income accounts from the "Income Statement" should be an offset to any of the expense accounts in the overhead submission.
9. When RMP project activities are performed at off-site locations, determine whether a separate overhead expense is warranted at this off-site location. If such a study is available, evaluate the reasonableness of allocations contained therein. If not, evaluate the reasonableness of the application of the main facility's overhead rate to off-site activities.
10. After eliminating unallowable items, the remaining total expenditures should be segregated between: (a) expenditures applicable to overhead functions, and (b) expenditures for all other purposes (direct). Expenditures applicable to an institution's overhead function normally include Administration and General Expenses, Housekeeping, Laundry and Linen, Maintenance of Plant, and Provision for Depreciation.

### VII-3 INDIRECT COSTS

- (5) When the grantee submits the final SROEAS for a particular budget period, such Report should be annotated as the "final report." The final report should also indicate the balance of indirect costs claimed on the Report of Expenditures submitted for which no adjustment will be requested.

#### C. Processing of Indirect Cost Adjustments

When appropriate, each grantee shall submit a SROEAS to the Office of Financial Management (NIH) reflecting the necessary adjustments in indirect costs to be made by RMPS for each project or activity. Upon receipt of the SROEAS by the Office of Financial Management (NIH), a copy will be forwarded to the Grants Management Branch (RMPS), via the Office of Grants Management, HSMHA. The RMPS Grants Management Branch Staff will review the information submitted to determine whether or not the adjustments, as reflected, are correct. RMPS will then forward a transmittal memo to the Office of Financial Management, NIH, via the Office of Grants Management, HSMHA, along with the SROEAS, reflecting any changes that may be necessary.

Upon receipt of notification of approval, or exceptions, to the SROEAS submitted by the Office of Grants Management, HSMHA, the NIH will institute a payment or collection of funds. A single Treasury check or Bill of Collection will be forwarded to the grantee reflecting the net total dollars of indirect cost adjustments submitted and approved.

CHAPTER VII  
FINANCIAL MANAGEMENT POLICIES

VII-4 GRANT RELATED INCOME

## VII-4 GRANT RELATED INCOME

- c. requires a formal set of prerequisite courses prior to enrollment.
- d. is open to all students meeting the necessary prerequisites, subject to space availability.

### 4. Other Common Examples of Grant Related Income

Examples of grant related income that may result from RMPS supported activities are:

- a. sale of services such as laboratory tests or computer time.
- b. payments received from patients or third parties for medical or hospital services.
- c. fees received for personal services performed in connection with and during the period of grant support.
- d. lease or rental of films or videotapes and
- e. rights or royalty payments resulting from patents and copyrights developed or acquired by the RMP in connection with RMPS grants.

### 5. Gifts and Donations

Grant related income does not include contributions, gifts, donations or other grants given to an organization to further an RMPS supported activity. A contribution, gift or donation is distinguished from grant related income if the donor or the grantor neither expects, nor receives any goods or service in return for his financial support.

### 6. Investment Income

Interest or other income derived from investment of grant funds is not treated as grant related income. All investment income must be repaid to the Federal Government and may not be waived to or retained by a grantee or affiliate. (See 4-2, below)

## 4-2 USE OF GRANT RELATED INCOME

RMPS may, and ordinarily will, authorize the use of grant related income to further the purposes of the RMP. Grantees, however, are required to submit written requests for the disposition of net grant related income. Such requests should indicate, in sufficient detail, the expected sources and amounts of such revenues and plans for their use.

Where grant related income is expected to be generated during a budget period, a prospective plan for the disposition of such income in connection with RMP must be submitted as early as possible, based on estimates of sources and amounts of funds. Grant related income be spent within the budget period in which it is earned.

## VII-4 GRANT RELATED INCOME

After evaluating such plans, RMPS will advise the grantee of the amounts and authorized uses of grant related income waived to the grantee, and/or the amount to be refunded to the Federal Government, if any.

Grant related income can be used (where permission is requested and granted by RMPS) for purposes such as the following: (1) to assist in phasing-in community support for activities initiated by an RMP, (2) to expand successful operational or program staff activities, (3) to initiate additional activities within the scope of the program in accordance with Sub-Chapter VII-7, below, and (4) to continue kidney dialysis and transplant activities. Grant related income may be used only for allowable costs. (See VII-2)

### 4-3 SPECIAL RULES FOR CALCULATING INCOME FROM PATENTS AND COPYRIGHTS

RMPS grantees and affiliates from time to time derive income from patented or copyrighted materials--usually films, videotapes, or publications. Special policies apply to the disposition of such income.

Any proceeds from the sale of patented or copywrited materials developed with grant funds must be credited to the grant account and returned to RMPS up to the total amount of direct costs of the grant expended for development of the materials. RMPS cannot waive repayment of the proceeds of grant developed, patented, or copywrited materials (as it can in the case of other grant related income.) (See 4-2, above.) Earnings accruing to the grantee or affiliate from patented or copywrited materials in excess of the applicable amount of direct costs are not grant related.

In the case of a single purpose activity, the sole purpose of which is to produce the patented or copywrited materials in question, the amount expended to develop the material is the total direct cost of the activity. This is the cost that will be used to determine the maximum repayment in such cases.

Where the development of patented or copywrited materials is incidental to a grant awarded primarily for other purposes, the direct costs of developing the item in question should be based upon the time, effort and materials directly attributable, and a reasonable estimate of any other costs. The maximum amount of repayment in such cases will be negotiated on an individual basis.

### 4-4 REPORTS, RECORDS AND ACCOUNTABILITY

The grantee is expected to maintain or require affiliates to maintain adequate records to support the computation of net RMP grant related income.

The grantee is accountable to RMPS for itself and all affiliates for the Federal share of any grant related income. The Federal share is the percentage of the total cost of an activity...

CHAPTER VII  
FINANCIAL MANAGEMENT POLICIES

VII-5 CONTRACTING BY GRANTEES

## VII-5 CONTRACTING BY GRANTEES

When completed the Request for Bids can be disseminated to potential bidders through advertising in appropriate publications or through direct notification by mail.

### B. Evaluation of Bids

Bids submitted should be evaluated from (1) a technical and (2) a business standpoint.

#### 1. Technical Evaluation

The technical evaluation of bids should be based on the evaluation criteria contained in the "request" and a rating or weight should be assigned to each criterion. The technical rating and the accompanying narrative of evaluation generally should cover:

- a. The Contractor's understanding of the scope of work as shown by the scientific and technical approach proposed.
- b. Availability and competence of experienced scientific and technical personnel.
- c. Availability of necessary facilities.
- d. Experience or pertinent novel ideas in the specific branch of science involved.
- e. The contractor's willingness to devote his resources to the proposed work.
- f. The contractor's proposed plan for achieving the quality of performance required.
- g. The reasonableness of the proposed manhours, validity of subcontracting, and the necessity of proposed travel.

After the offers are rated, a narrative statement should be prepared expressing the strength or weakness of each proposal and any reservations or qualifications that might bear on the selection of the source of negotiation or award.

#### 2. Business Evaluation

The business evaluation usually centers around cost analysis and analysis of the contractor's financial strength and management capability. Elements considered in cost analysis generally include direct material and labor costs, subcontracting, overhead rates, general

financial strength and management capability include

## VII-5 CONTRACTING BY GRANTEEES

organization, past performance, reputation for reliability, availability of required facilities, cost control, personnel practices, financial resources, etc.

### C. Contract Issuance

#### 1. Type of Contract

Once it is decided to issue a contract, a decision should be made by responsible grantee personnel as to the most effective contract instrument available, fixed price, or cost reimbursement.

The influencing factors in selecting and negotiating a contract are:

- a. Type and complexity of the product or service.
- b. Stability of the design.
- c. Prospective period of the contract performance.
- d. Adequacy of the contractor's estimating and accounting system.
- e. Urgency of the requirement.
- f. Degree of the competition.
- g. Availability of the comparative cost or pricing data, market prices, and wage levels.
- h. Administrative cost to both parties.

#### 2. Negotiation

Once the type of contract is determined, negotiations normally commence between the representative of the grantee institution and the proposed contractor. The contract negotiation will usually entail:

- a. Reaching agreement with a proposed contractor on the technical requirements--which is included in the workscope (if there is a true change in the requirements, all offerors must be given an opportunity to revise their proposals.)
- b. Reaching an agreement on the type of contract--the objective is to negotiate that type of contract and price which includes a reasonable amount of cost responsibility and risk to the contractor, and which is consistent with the performance.

- c. Reaching an agreement on the pricing and all other provisions which will condition his performance of the contract.
- d. Setting forth all terms and conditions in a mutually acceptable contractual document which includes terms and conditions required in relation to (1) civil rights (See Subchapter VI-1, 1-2, C, and Chapter IX); and (2) wage rates and related matters as specified in Section 904 of the Act. (See Subchapter VI-1, 1-2, B 4.)
- e. Justifying and documenting the contract negotiated.

#### D. Contract Administration

Once the contract is issued and performance commences, the grantee institution should assign a project officer to administer the contract. This function will normally entail the following:

##### 1. Monitoring of Performance

The project officer should be responsible for providing technical assistance and monitoring the performance of the contract. It is essential that he monitor a contractor's progress closely and identify problems that threaten contract performance so that remedial measures may be taken if necessary. The contractor should usually be required to submit periodic progress reports which could be used by the project officer to evaluate contractual progress. These reports should provide the project officer with most of the information necessary regarding the progress of the work.

The terms of the contract govern and they can only be modified by the Project officer after he has reached an agreement with the contractor.

##### 2. Contract Modifications

During the administration of a contract, different types of modifications may be necessary to incorporate new requirements or to handle contingencies which may develop after contract placement. The project officer must be careful in distinguishing between a modification and a new contract.

##### 3. Property Administration

When property is provided by a grantee to a contractor, the project officer should be called upon to advise or

to be advised. The project officer should be advised of the

- a. In determining the necessity for the property to be provided.

- b. In determining the kind and quantity of property required and the period of use.
- c. In ensuring proper utilization of property.

4. Inspection and Acceptance

The project officer must ensure that the work performed under the contract is measured against the work statement. If performance does not meet contract requirements, it is incumbent upon the project officer to identify deficiencies, and plan for remedial action that can be taken.

Once final acceptance of the work effort by the project officer has been accomplished, the contractor is no longer responsible for unsatisfactory effort. This concludes performance by the contractor, except for administrative details relating to contract closing.

5. Contract Closing

A contract is completed when all services have been rendered, all articles, material, reports data, exhibits, etc., have been delivered and accepted; all administrative actions accomplished; and final payment has been made to the contractor.

E. Final Audit and Close-out

Upon the physical completion of the contract, action should be taken to provide assurance that:

1. All services have been rendered.
2. All articles have been delivered and accepted.
3. All payments and collections have been accomplished.
4. Release from liabilities, obligations, and claims have been executed by the contractor.
5. All administrative actions have been completed, including disputes, protests, litigation, determination of final overhead rates, release of funds, etc.

Before final payment is made under a cost-reimbursement type contract, a representative of the grantee institution should verify the allowability and reasonableness of all costs reimbursed. When appropriate, verification of total costs reimbursed can be obtained from the DHEW audit agency in the form of a final audit report. Similar verification of actual costs must be made for fixed price contracts when costs incentives or price redetermination is involved.

CHAPTER VII  
FINANCIAL MANAGEMENT

VII-6 PAYMENT SYSTEMS

## VII-6 PAYMENT SYSTEMS

### 6-1 INTRODUCTION

In an effort to minimize the impact of withdrawals on the public debt level and the creation of additional related financing costs, the U.S. Treasury has issued regulations governing the flow of Federal cash to recipient organizations. These regulations provide that the amount of cash in the hands of recipient organizations should not at any one time exceed one month's funding requirement for support of Federal activities. Grant payments are usually authorized by either (1) letter of credit, or (2) a monthly cash request procedure.

The Office of Financial Management, NIH, acts as the centralized payment point for authorizing payment for support of RMPs grant activities.

### 6-2 LETTER OF CREDIT

A "Letter of Credit" is a document which can authorize a grantee for an RMP to submit payment vouchers through its local commercial bank to a Federal Reserve Bank or branch for deposit of cash on an "as needed" basis in a grantee's bank account. The letter of credit is a commitment, certified to by an official of DHEW, which specifies a dollar amount available to a designated grantee.

The Letter of Credit can only be used when a grantee meets the following criteria:

1. Annual aggregate Federal financing exceed \$250,000.
2. Federal and grantee business relationship will exceed one year.
3. The supported program is not a loan or construction project.
4. Reimbursement of actual costs is not a program requirement.

until actual disbursements are anticipated. Disbursements and related cash requests or draws can be made during periods subsequent to the close of budget period or the Federal fiscal year as long as the encumbrances, obligations, or accrued expenditures were incurred in accordance with the terms of the grant award. In short, the grantee will not lose funds if actual payments from grant funds are made after the close of the budget period or Federal fiscal year.

6-5 REQUESTS FOR INFORMATION AND ASSISTANCE

Additional information and/or forms necessary to effect payment may be obtained by contacting the:

National Institutes of Health  
Office of Financial Management  
Grant Accounting & Financial Reports Branch  
Westwood Building, Room 550  
Bethesda, Maryland 20014

Checks for FIPS grants are issued by NIH not RMPs. In the event of any payment problems grantees should contact the Office of Financial Management, NIH, directly.

CHAPTER VII  
FINANCIAL MANAGEMENT

VII-7 GOVERNING PRINCIPLES AND  
REQUIREMENTS, DISCRETIONARY  
FUNDING AND REBUDGETING AUTHORITY

VII-7 GOVERNING PRINCIPLES AND REQUIREMENTS:  
DISCRETIONARY RMP FUNDING AND REBUDGETING AUTHORITY\*

7-1 APPROVAL AND FUNDING AUTHORITY

An RMP, at its discretion, may fund any eligible operational or program staff activity (including new activities) or rebudget funds within the total direct costs awarded subject to the principles and requirements set forth below.

7-2 PRINCIPLES

The following principles shall be generally applicable in all situations:

A. Consonance With Federal Requirements

No activity shall be undertaken that is contrary to Title IX of the PHS Act and other applicable legislation, regulations, written Departmental, HSMHA, and RMP policies, and/or specific conditions of the grant.

B. Applicability of Local RMP Procedures

Any activity undertaken pursuant to the authority conferred by this policy shall be subject to the regular review, approval and funding requirements of the particular RMP, the grantee (where different), and the Regional Advisory Group.

C. Current Regional Advisory Group Approval

Any operational activity initiated by an RMP within its discretionary authority must have current RAG approval. That is, it must be approved by the RAG in the budget period during which it is initiated or the immediately preceding one. If not, the activity must be reapproved by the RAG before it can be undertaken. Likewise, any reapproved program

staff activity must have current RAG approval in accordance with the policies or normal administrative procedures of the RMP.

D. Activities Jointly Funded by Two or More RMPs

Any activity which involves, anticipates, or requires funding by more than one RMP during the total anticipated RMPS support period requires prior RMPS approval for such funding (but not for the technical designs or details of the activity).

E. Obligations of Funds Derived From Grant Related Income

No grant related income may be expended without prior RMPS approval.

F. Resolution of Questions Regarding Discretionary Funding Authority

When there are any substantive questions or doubts as to the scope and applicability of the discretionary funding and rebudgeting authority, the grantee or the Coordinator on its behalf shall communicate with RMPS for advice and guidance.

7-3. REQUIREMENTS

A. RMPs Approved for a Triennial Period

RMPs approved for a triennial period must obtain prior approval from the Director, RMPS for any proposed program or operational activity involving:

1. Alterations and renovations in excess of \$25,000 total Federal direct costs per activity, or any new construction regardless of amount.
2. Research or other activities involving the use of human subjects. (Programmatic approval by RMPS is required in addition to approval by NIH of an institutional plan for safeguarding the rights and welfare of human subjects. See Subchapter VI-1,1-3, A).
3. HMO related feasibility studies.
4. End-stage treatment of kidney disease (e.g., dialysis, transplantation and supportive facilities and services). See Subchapter X-2, 2-6.

5. Other specialized activities as identified by HSMHA/RMPS.

B. RMPS not yet Approved for a Triennial Period

RMPS not yet approved for a triennial period must obtain prior approval from the Director, RMPS for:

1. Any activity enumerated above except that any alterations and renovations and new construction regardless of costs must be submitted.
2. Any new operational activity not generally covered by its program as approved by the Council.

7-4 NOTIFICATIONS

RMPS should be notified immediately whenever an activity is initiated which has not been funded previously. The following documents should be submitted:

1. The budget for the new activity on RMPS 34-1, Page 16.
2. Revised budgets for any activity from which funds have been withdrawn, again on RMPS 34-1, Page 16.
3. A brief description of the activity on the applicable form, RMPS 34-1, Pages 6, 9, 11, 12, or 15 as appropriate.
4. The appropriate descriptor sheet.

In all cases normal procedures for notifying RMPS of rebudgets should be followed. Rebudgeting procedures are described in the instructions for RMPS 34-1, Page 16.

CHAPTER VII  
FINANCIAL MANAGEMENT

VII-8 THE DEVELOPMENTAL COMPONENT

## VII-8 THE DEVELOPMENTAL COMPONENT

### 8-1 PURPOSE

Where requested, a Developmental Component to provide additional flexibility in the use of Regional Medical Program funds may be awarded to Regional Medical Programs on the basis of maturity, adequacy of program, and administrative competence.

A Developmental Component is that part of an award to a Regional Medical Program for which the Region is required to delineate in advance only its general program objectives and priorities for expenditure of the funds. In awarding a Developmental Component, the National Advisory Council delegates to the Regional Advisory Group authority to fund specific activities without prior approval.

The Developmental Component provides the Regional Advisory Group with an opportunity to support relevant activities without delay. Among other things, funds provided through a Developmental Component enable a Regional Medical Program to devote attention to unforeseen problems, to take advantage of new opportunities as they arise, and to participate in appropriate activities supported through Federal and other grants as awarded.

### 8-2 AMOUNT AND DURATION

The Developmental Component may not exceed 10% of the annual direct cost funding level, excluding carryover, during the year in which the application is submitted or 10% of the current year's direct costs, whichever is lower. In the first case, if the applicant is in its 03 year, and is requesting funds for its 04 year, then the direct costs for the 03 year are the basis for computing the maximum amount of the Developmental Component. If the approved direct costs for the 04 year were less than those for the 03 year, then the Developmental Component would be based on a percentage of the 04 year award.

Approval of a Developmental Component does not necessarily require that additional funds be awarded since ability to award additional funds depends, in part, on the availability of appropriations.

A Developmental Component remains in effect for the duration of the triennium for which it was approved. The amount for any given year is determined by applying the approved percentage to the appropriate direct cost figure as explained above. Fluctuations in the amount of the Developmental Component resulting from annual variations in approved direct costs do not require Council action or special staff approval.

Where no additional funds have been awarded for an approved Developmental Component, the Regional Medical Program may rearrange its budget to include a Developmental Component up to the maximum permitted amount (i.e., take money previously budgeted for specific activities and rebudget into the Developmental Component).

There will be no carryover of unexpended Developmental Component funds from one year to the next.

### 8-3 APPLICATION

No Developmental Component will be approved unless it is specifically requested by a Regional Medical Program, approved by the Regional Advisory Group, and formally recommended for funding by the National Advisory Council. A Regional Medical Program may apply for a Developmental Component in any year of a triennium on its anniversary date for a period not exceeding the remainder of the triennium. For example, if an RMP applies for a Developmental Component in its "triennial" application and the Developmental Component is not approved, it may apply again in the following year, or the year after that, etc., but only on its anniversary date. All requests for approval of a new Developmental Component whether in a "triennial" application or during a "continuation" year will be referred to the National Advisory Council for consideration.

Where a Regional Medical Program has requested or been approved for less than the maximum allowable percentage for a Developmental Component, it may request an increase on its anniversary date in any year. A request to increase a Developmental Component over the previously approved level, likewise must be considered by the Council.

The following items should be covered in a request for a Developmental Component in an application:

1. The general objectives and priorities for which Developmental Component monies will be used.
2. Any specific uses of Developmental Component funds which appear extremely likely or possible at the time of application.
3. Mechanisms for developing or taking advantage of opportunities to use Developmental Component funds for the stated objectives (i.e., relationships with other organizations, communication channels, etc.).

4. Plans for evaluating the effectiveness of activities funded under the Developmental Component.
5. Procedures for allocating and monitoring Developmental Component funds. (See next section.)

#### 8-4 ADMINISTRATIVE PROCEDURES

Each Regional Medical Program requesting or approved for a Developmental Component must establish written administrative procedures for allocation, use and monitoring of Developmental Component funds. These procedures must be formally reviewed and approved by the Regional Advisory Group. As a minimum such procedures should cover the following:

1. Authorization for funding - In order to facilitate expeditious use of Developmental Component funds, procedures for funding should be kept as simple as possible. The procedures should explain how Developmental Component funds are formally obligated for specific activities by a Regional Medical Program. (Examples: "Awards shall be made in writing, state the amount and duration of funds obligated and be signed by the Coordinator and Chairman of the Regional Advisory Group;" or "All awards must be specifically approved by the Regional Advisory Group;" or "Awards under \$X,XXX may be approved by the Coordinator.")
2. Accounting - Accounting procedures should require the establishment of separate accounts for the Developmental Component and its subsidiary activities when funded. The Developmental Component should be clearly identified as the source of funds for such accounts. Where Developmental Component funds and other funds are mingled in support of an activity, it is only necessary to indicate the total amount of Developmental Component funds allocated to the activity. In such cases, it is not necessary to break down line items to show Developmental Component funds and other funds.
3. Monitoring of specific activities - Monitoring procedures should provide for the assignment of staff to be responsible for following progress and activities funded under a Developmental Component. Such procedures should also provide for periodic financial and progress reports to core (quarterly at least) and the review of such reports by appropriate staff and advisory bodies.

A copy of the full text of a Regional Medical Program's procedures for administering a Developmental Component shall be filed with the Regional Medical Programs Service as part of the initial request for a Developmental Component. Unless changes are made, such material only needs to be submitted once. Subsequent applications can make reference to the material on file.

8-5 INDIRECT COSTS FOR THE DEVELOPMENTAL COMPONENT

No additional funds will be awarded to cover indirect costs generated through the Developmental Component. Indirect costs associated with implementation of activities funded under a Developmental Component, however, are allowable and can be paid in accordance with existing negotiated rates with DGAP or with or by the grantee institution. The total amount of direct plus indirect costs for such activities, however, may not exceed the amount awarded for the Developmental Component.

8-6 RELATIONSHIP BETWEEN THE DEVELOPMENTAL COMPONENT, CORE AND OPERATIONAL PROJECTS

Ordinarily a given activity should not be funded under a Developmental Component for more than 24 months. Within that period of time such activities should either (a) be completed; (b) become a regular part of core activities; (c) become an operational project; or (d) be spun off and supported through other sources of financing. Where activities initially funded under a Developmental Component are transferred to core or operational status, they will no longer be charged against the Developmental Component, thus increasing the unobligated balance for the Developmental Component which may then be used for new purposes. It is, therefore, to the advantage of an RMP to turn over Developmental Component money quickly. The decision on when or whether an activity initially funded under a Developmental Component has achieved operational status is the responsibility of the Regional Advisory Group.

8-7 REPORTS

As discrete activities are funded under the Developmental Component, such activities must be reported immediately to the Regional Medical Programs Service by submitting a description of the activity on Form 11, 12 or 15, as appropriate, and a copy of Form 16, Financial Data Record, for each. Form 16 should be completed to show the proposed budget for the activity. Forms 11, 12 and 15 should also be used for reporting progress on funded Developmental Component activities in the annual application submission. Such activities should be identified in the "Project Title" or text as being funded in whole or in part through the Developmental Component.

CHAPTER VIII, FIGURE 1

OUTLINE OF RMPS CONSTRUCTION REQUIREMENTS

| TYPE OF APPLICATION  | RMPS FUNDING LIMIT PER FY | APPLICATION PROCEDURE   | APPROVAL LEVEL           | TYPES OF PROJECTS  | ELIGIBLE COSTS   |
|--|---------------------------|---|--------------------------|--|--|
| <u>Alteration &amp; Renovation</u><br>Triennial under \$25,000 | None                      | Prescribed by Local R&P   | Local RAC                | <ul style="list-style-type: none"> <li>a. Converting existing new use - MAJOR</li> <li>b. Rearrangement of interior partitions, appurtenances &amp; utilities - MINOR</li> <li>c. Provision of built in equipment for above</li> </ul> | <ul style="list-style-type: none"> <li>a. RMPS share limited to 90%</li> <li>b. Indirect cost rate allowable if based on total direct costs</li> <li>c. Many specific prohibitions (See text, Chapter VIII, 1-3, D &amp; E)</li> </ul> |
| Other, under \$25,000  | None                      | Descriptive letter to RMPS including cost estimate  | RMPS                     |  |  |
| Triennial over \$25,000  | None                      | Descriptive letter to RMPS including cost estimate  | RMPS                     |  |  |
| Other, over \$25,000   | None                      | Descriptive letter to RMPS including cost estimate  | RMPS                     |  |  |
| <u>NEW CONSTRUCTION</u>  | \$5 million               | <ul style="list-style-type: none"> <li>a. Informal discussion with RMPS</li> <li>b. Submission of formal proposal on HEW-537 &amp; consideration by Council<br/><i>NA</i></li> <li>c. If approved follows FECA procedures, Contact FECA Regional</li> </ul> | Council & Director, RMPS | <ul style="list-style-type: none"> <li>a. Construction of new buildings.</li> <li>b. Completion of unfinished space</li> <li>c. Provision of built-in equipment for above</li> </ul>   | <ul style="list-style-type: none"> <li>a. RMPS share limited to 90%</li> <li>b. Indirect cost rate not allowable</li> <li>c. Costs defined in approved application</li> </ul>  |

FIGURE 2  
COST ESTIMATE OUTLINE

A. ESTIMATED COSTS OF RMP'S ALTERATION AND RENOVATION PROJECT

|  | TOTAL COST | REQUESTED FROM<br>RMP'S |
|--|------------|-------------------------|
| 1. Demolition .....  | \$ _____   |                         |
| 2. General Construction .....  | \$ _____   |                         |
| a. Carpentry   | \$ _____   |                         |
| b. Masonry   | \$ _____   |                         |
| c. Sheetmetal  | \$ _____   |                         |
| d. Painting  | \$ _____   |                         |
| e. Other   | \$ _____   |                         |
| 3. Plumbing .....  | \$ _____   |                         |
| 4. Heating, Ventilation, and Air Cond..                              | \$ _____   |                         |
| 5. Electrical Work.....  | \$ _____   |                         |
| 6. Architect's and Engineer's Fees ...                               | \$ _____   |                         |
| 7. Other Costs (Specify)   |            |                         |
| _____  | \$ _____   |                         |
| _____  | \$ _____   |                         |
| _____  | \$ _____   |                         |
| 8. Total Construction Costs for<br>Alteration and Renovation Proj... | \$ _____   | \$ _____                |
| 9. Cost of Built-in Equipment .....                                  | \$ _____   | \$ _____                |
| 10. Total Project Costs (Lines 8+9)...                               | \$ _____   | \$ _____                |

B. SOURCES OF FUNDS

|                                     |  |          |
|-------------------------------------|--|----------|
| 1. Other Federal Programs (Specify) |  | \$ _____ |
| _____                               |  | \$ _____ |
| _____                               |  | \$ _____ |
| 2. State or Local Government .....  |  | \$ _____ |
| 3. Other.....                       |  | \$ _____ |

C. COSTS PER SQUARE FOOT

|  |  |          |
|--|--|----------|
| 1. Allowable Net Square Feet in<br>RMP Project.....  |  |          |
| 2. Cost per Net Square Foot, Exclud-<br>ing Fixed Equipment.<br>(Total costs, Line A, 8 - Line C, 1) |  | \$ _____ |

3. Sketch of the Project

An as-built drawing or single-line drawing showing the existing space and the remodeling to be accomplished.

4. Program of Requirements

a. The program of requirements states the function, space and total cost of the proposed remodeled space. It is the applicant's functional planning guide for his architect and should be prepared with consultation from representatives of the various participants in the project, the administration and management of the facility in which the space is located, and architectural-engineering advisors. The Program of Requirements should be written with the following specific, topical headings to facilitate review:

1. General Information
2. Description of the RMPS Functions to Occupy the space
3. A Schedule of Space
4. List of Equipment Proposed for the Facility
5. A Cost Estimate
6. Appendix (if applicable)
  - a. Special design problems
  - b. Description of the structural, and utility systems existing and proposed for the modified facility.
  - c. Supplements
    - (1) Access for physically handicapped
    - (2) Provision for requirements of the National Public Safety Code
    - (3) Historical site clearance

5. Submission of Architectural and Engineering Documents

The submissions will include one copy of each of the following documents:

1. The final cost estimate.
2. Coded architectural floor plans showing the final arrangement of space committed to RMPS activities.
3. The bidding documents, including final working drawings and specifications.
4. The design analysis report, describing the structural, heating, ventilation, and air conditioning systems, plumbing system, electrical power system and provisions to meet the various mandatory Federal requirements for access for physically handicapped, provisions for Public Safety Code and special clearances.

C. Related Requirements

1. Bidding Requirements

If the alterations and renovations are to be accomplished by the contract method, the award should be made on the basis of competitive bidding. See the FECA Regional Office Representative for procedures to be followed.

2. Force Account

"Force account" is used to describe the situation when the grantee manages the construction project rather than hiring a contractor. Force accounts are not recommended for RMP projects. However, some projects, usually those under \$10,000, may be acceptable for "force account" management. Consult with the FECA Regional Office staff before using force accounts.

D. Eligible Costs

The following costs are eligible for RMPS funding (90%).

1. The cost of any work related to the delivery and installation of built-in equipment.

2. Structural changes in or extension to the utility systems and refurbishing or refinishing of the building surfaces.
3. The cost of related architectural, engineering and consultant services.

E. Ineligible Costs

Alteration and Renovation Costs (as opposed to costs of new construction) which are not allowable are:

1. Moving costs (except that new equipment may be F.O.B. site).
2. Landscaping
3. Libraries, except for small reference rooms within or adjacent to RMP space
4. Dining facilities
5. Student and faculty lounges
6. Cafeterias
7. Lecture rooms (conference rooms may be included if need can be documented)
8. Site or building acquisition costs
9. Donated material or services
10. Legal fees, court costs, or costs for related services
11. Fund-raising costs
12. Interest on bonds or any other form of indebtedness
13. The cost of supplies or movable equipment
14. Fees for architectural or other professional services on designs which were abandoned
15. Any costs of a damage judgment
16. Any charge in excess of the net cost for materials, equipment or services when a grantee receives, or is entitled to a refund

17. The amount of any sales tax or excise tax when the institution is normally exempt from such taxes
18. Any cost of ceremonies
19. Any portion of those institutional costs which are normally considered to be indirect costs. However, when architectural and engineering professional design services are performed by the full-time staff of the applicant, they may constitute an allowable cost. In such instances, the institution must keep records to support these charges.

F. Eligible Activities

In order to be classed as alteration or renovation as opposed to new construction, a project must meet the following requirements:

1. The building or part of a building which is to undergo alteration and renovation must be owned or leased by the grantee and available for occupancy.
2. The building as altered or renovated must be suitable for the proposed use and the activities to be accommodated therein.
3. The building must be a completed structure. (i.e., It must be enclosed and under roof, and include all basic power, plumbing and ventilating outlets.)

1-4 NEW CONSTRUCTION

A. Procedures for Applying

All proposals for new construction must be specifically reviewed by the National Advisory Council. No proposal involving new construction should be submitted without first discussing the proposal with the appropriate RMPS Operations Branch staff.

Formal applications for new construction should be submitted on the standardized application form (HEW 537) - "Application for Federal Assistance for Construction of Health and Educational Facilities" which is delineated in HEW Grants Administration Manual, Chapter 4-54.

B. Approval Process

No funds will be awarded for new construction unless recommended by the National Advisory Council. Subsequent to approval by the National Advisory Council from RMPS as to the availability of funds for the construction project, a detailed application for new construction should be submitted by an applicant on HEW Form 537 to the RMPS Regional Program Director who will establish liaison between the applicant and the Facilities Engineering Construction Agency Representative in the HEW Regional Office (see Chapter ).

The Regional Office Representative of the Facilities Engineering Construction Agency in cooperation with Regional and Headquarters RMPS staff, will review the HEW Form 537 to ascertain the extent of compliance with the architectural and engineering standards applicable to the specific facility.

RMPS responsibility for application approval shall include the determination of project mission space eligibility; changes to projects which affect program objectives and fiscal plans; reviews, approvals, and other required actions as related to moveable equipment, administrative and legal budgets and costs, approval of requests for release of Federal funds, and final closeout including determination of final Federal funding support.

1-5 MISCELLANEOUS CONSTRUCTION REQUIREMENTS

A. Accounting for Construction Costs

Accounting for costs of construction and alteration and renovation shall be in accordance with the accounting policy of the grantee institution, consistently applied to all sponsors, regardless of the source of funds. The grantee must maintain accounting records to reflect that at least 10% of the project cost has been paid from the institution or other non-Federal funds. The cost of the facility, including construction project costs, must be kept in a prime account so that the grantee can furnish the following upon request:

- a. Total receipts
- b. Total disbursements

- c. Balance in the account
- d. Cost data as prescribed in the cost estimate outline.

B. Bonding Requirements

The applicant should require that the successful bidder for the proposed construction (inclusive of alteration and renovation) project furnish evidence

1. That a performance bond in the amount of 100 percent of the bid price has been secured. No contractor may be required to purchase bonds from a specified agent or company.
2. That a labor and material payment bond in the amount of 100 percent of the bid price has been secured. No contractor may be required to purchase bonds from a specified agent or company.
3. That adequate fire, workmens' compensation, public liability, and property damage insurance has been secured for the life of the contract. No contractor may be required to purchase insurance from a specified agent or company.
4. Of an assurance that no subcontractor will be employed on the project who is on the U.S. Comptroller General's list of ineligible bidders.
5. Of a one-year warranty covering materials and workmanship.

C. Content of Drawings

The final working drawings for the proposed project should include evidence of:

1. Access to the space by the physically handicapped.
2. Air pollution problems, if any that are to be encountered or created by the completed space.
3. Noise abatement control.

D. Mandatory Labor Standards

All construction contracts financed with Federal grant-in-aid funds under Title IX, Public Health Service Act, (RMPS), as amended, must conform with the Copeland Act (Anti-Kickback), the Equal Employment Opportunity Executive Orders, the Davis-Bacon Act, the Contract Work Hours Standards Act, and the Civil Rights Act of 1964. Grantee institutions are responsible for insuring that grant-supported construction contracts are carried out in donformance with these Acts and Orders, and for insuring that monthly or final payrolls covering the period in question have been received. Failure to comply with these Acts and Orders may lead to the withholding or withdrawal of Public Health Service grant funds.

E. Change Orders

RMPS participation in change orders is limited to 2% of the cost of the construction contract, subject to prior RMPS approval, to insure that the national limitation of \$5 million per fiscal year is not exceeded.

F. Payment for Construction

Payments are made on the basis of completed construction. The reports of construction progress are submitted to RMPS periodically for review and approval. Payments are authorized by RMPS based on the percentage of the construction work completed. Five percent of the grants is withheld until a final inspection has been completed by a RMPS representative.

G. Standards of Construction and Equipment

Facilities or portions thereof constructed with RMPS assistance must comply with the applicable standards of construction and equipment prescribed in Departmental Regulations with respect to the type of facility being constructed. For example, a hospital would comply with standards promulgated for the Hill-Burton program. A research laboratory would comply with standards prescribed for the NIH Health Research Facilities Construction program, etc.

H. Compliance With Local Requirements

Facilities or portions thereof constructed with RMPS assistance must comply with all applicable local codes, licensure laws, certificate of need and other applicable State and local requirements.

I. Recovery

CHAPTER IX  
CIVIL RIGHTS

## IX CIVIL RIGHTS

### IX-1 TITLE VI

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 grounds 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 Title 45, Code of Federal Regulations.

It is the responsibility of each grantee to insure that its own policies and those of each affiliated agency (institution) which receives funds or participates in the Regional Medical Program is in compliance with Section 601 of Title VI of the Civil Rights Act of 1964.

### IX-2 EXECUTIVE ORDERS

In addition, each grantee and each affiliated agency (institution) shall comply with the requirements of Executive Order 11246, 30 F.R. 12319, as amended and superseded by Executive Order 11375 and 11478, respectively, and the applicable rules, regulations, and procedures as prescribed by the Secretary of Labor.

Executive Order 11246, prohibits employment discrimination by Government contractors or Federally-assisted construction contractors, and requires them to take affirmative action to remedy the effects of past discrimination.

Executive Order 11375 prohibits discrimination based on sex by Federal Government contractors, and subcontractors and nonfederally-assisted construction projects.

Executive Order 11478 is the most recent Presidential directive dealing with this subject. This Order, which supersedes and strengthens previous Presidential Orders, reaffirms governmental policy both to assure equal opportunity in Federal employment to all persons regardless of race, color, religion, sex, or national origin and "to promote the full realization of equal employment opportunity through a continuing affirmative program in each executive department and agency."

CHAPTER X - SPECIAL REQUIREMENTS

X-1 - SECTION 910

X-2 - GUIDELINES AND REVIEW PROCEDURES  
FOR KIDNEY DISEASE ACTIVITIES

X-3 - RMP HEALTH MANPOWER ACTIVITIES

X-4 - EMERGENCY MEDICAL SERVICES

CHAPTER X  
SPECIAL REQUIREMENTS

X-1 SECTION 910

## X-1 APPLICABILITY AND OPERATION OF SECTION 910

### I-1 BACKGROUND

Section 910 was added to the original RMP legislation, P.L. 89-239, when the Act was extended and amended in 1968. At that time, the authority was limited to grants for "services needed by, or of substantial use to, any two or more Regional Medical Programs." When the Act was again amended and extended in 1970 by P.L. 91-515, Section 910 was extensively modified. As amended, it provides authority to contract specifically under Title IX (the RMP Legislation), and permits support of various specific types of activities and special projects by Regional Medical Programs and other organizations.

Public Law 91-515 expanded Regional Medical Programs in certain areas while at the same time retaining the major features of the previous legislation. Among other things, it expanded the purposes of the program through the addition of kidney disease. It provided for medical data exchange as an eligible activity in addition to research, training and demonstrations. It provided for fostering of regionalization through institutional and provider linkages. It explicitly identified "prevention" and "rehabilitation" as eligible areas of endeavor and cited improvement of quantity and quality of manpower as specific program goals. Public Law 91-515 also added as new program objectives the strengthening of primary care as well as the improvement of health services for persons residing in underserved areas.

Section 910 provides additional authority and means for carrying out the purposes of the program including the expanded purposes outlined above. Possible uses of this authority specifically identified in Congressional reports include:

1. Providing training for personnel required by Regional Medical Programs such as educational and evaluation specialists,
2. supporting training activities for specific types of personnel required to meet national needs, perhaps as an adjunct to training carried on by individual Regional Medical Programs,

3. Facilitating short-term developmental work of potential benefit to all Regional Medical Programs such as medical record systems,
4. Providing interregional support of such activities as communications networks, data collection systems and training and evaluation efforts;
5. Supporting integrated kidney dialysis-transplantation programs and associated communication and transportation mechanisms.

1-2 EXPLANATION

A. Purposes

Because the original title of Section 910, "Multi-program Services," was retained unchanged in the amended legislation, P.L. 91-515, a casual reader might be led to assume that the current Section 910 relates only to activities conducted by two or more Regional Medical Programs when, in fact, activities of a much broader nature are authorized.

The purposes of Section 910 are to develop improved national capability for delivery of health services, as well as to facilitate interregional cooperation. This represents a considerable broadening of the original Section 910 which was, in fact, limited to multiprogram services.

B. Contract Authority

Prior to the passage of P.L. 91-515, the Regional Medical Programs Service was able to make contracts under Section 301 of the Public Health Service Act which contains general authority for the Service to enter into contracts. The Congress, however, felt that it would be desirable to include specific contract authority within Title IX and placed this in Section 910. Under this authority, the Regional Medical Programs Service may contract with RMPs, with other public or nonprofit agencies or institutions or with profit-making firms. For contracts, National Advisory Council approval is not required.

C. Grants under Section 910

Grants may be awarded to Regional Medical Programs or to other organizations or institutions. Grants, however, may be awarded only to public or nonprofit groups, and only when recommended by the National Advisory Council.

D. Categorical Emphasis

Not all of the provisions of Section 910 are related to the categorical diseases, Heart Disease, Cancer, Stroke, Kidney Disease and other related diseases. Section 910(a)(1) which provides for programs, services and activities of substantial use to two or more Regional Medical Programs is not limited to these diseases and could be used, for example, to support training of staff specialists needed by Regional Medical Programs, themselves, or for development or improvement of data systems, communication networks, etc.

Likewise, research, studies and investigations relating to utilization of manpower in the delivery of health services under Section 910(c) are not limited to the categorical diseases.

While Section 910(a)(5) which provides for the conduct of cooperative clinical field trials does not contain a reference to the categorical diseases, both Senate and House reports on the RMP Legislation clearly indicate that such activities are to be related to such diseases.

Training under Section 910(a)(4) must be "specifically related" to the covered diseases.

1-3 REQUIREMENTS FOR RMP'S

A Regional Medical Program does not have to submit a special application to carry out activities authorized by Section 910, nor do such activities have to be identified specially in the RMP application submitted in the regular review cycle.

No special approvals by RMPs are required for those types of activities authorized by Section 910 except where prior approval would be required by Subchapter VII-7. Special attention is called to Subchapter VII-7, 7-2, D which is applicable to activities jointly funded by two or more RMPs. If approval is required, RMPs should contact the appropriate Operations Branch of RMPs.

Examples of circumstances in which no prior approval by RMPS is required (except where otherwise required as noted above) to carry out activities authorized by Section 910 include:

1. activities carried out by program staff
2. activities carried out through subcontracts or pooled funds with one or more other types of organizations
3. activities carried out by affiliates.

1-4 SPECIAL PROJECT GRANTS TO ORGANIZATIONS OTHER THAN RMP'S

A. Eligibility

Any public or nonprofit private agency or institution or combination thereof is eligible to apply for a special project grant under Section 910. Any group not a Regional Medical Program requesting such support must submit a special project grant application

B. Consultation

Where an organization or institution other than a Regional Medical Program wishes to submit an application for a special project grant under Section 910, the prospective applicant should consult with RMPS prior to developing a formal proposal. This will help the applicant to gauge the extent of RMPS' interest in the type of activity proposed. RMPS can also advise on the desirability of making a special project application rather than teaming up with one or more RMPs to fund the activity through the regular RMP mechanism.

C. Forms for Special Project Applications Under Section 910

Applications for special project grants under Section 910 should be submitted on HSM-550-1, "Grant application for Health Services." (See attached Exhibit). Copies of this form are available on request from the Regional Medical Programs Service.

Follow the instructions for the form, but omit job descriptions and biographical sketches. If needed, these will be requested.

Do not solicit or include in the application perfunctory letters of endorsement. Pledges of financial or staff support for the project should be attached if available, as well as any substantive comments received from Regional Medical Programs or Comprehensive Health Planning Agencies. It is considered desirable that Special Project proposals under Section 910 be submitted to several RMPs for comment prior to submission to the Federal government. Any views with respect to the usefulness of the project to RMPs will assist RMPs in reviewing applications. CHP review and comment is not required for special project grants under Section 910.\*

In completing the application, enter the following in the "Program" block in the top left hand column on Page 1 of HSM-550-1:

REGIONAL MEDICAL PROGRAMS SERVICE  
Special Project Grant Application  
Section 910

Send 25 copies of the completed application to Regional Medical Programs Service, HSMHA, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland, 20852.

D. Review of 910 Special Project Grant Applications

Special project grants under Section 910 shall be approved only after staff review, review by the Regional Medical Programs Review Committee and affirmative recommendation by the National Advisory Council on Regional Medical Programs. The amount awarded shall be within the amount recommended by the Council. The Committee and Council meet on a regular schedule three times a year. Where necessary, the Review Committee may be assisted by appropriate consultants, and site visits may be conducted when deemed appropriate by staff or the review groups.

Applications will be referred to the Committee and Council at the discretion of the Director, RMPs. In general, special project applications will not be referred to the Committee or Council in those cases where the Director determines after staff review (a) that the subject

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\*Review and comment by CHP "B" agencies is required by Section 904 of the Act for regular RMP applications.

matter of the application is of no interest to the program, or (b) that the proposed activities could best be carried out through the Regional Medical Programs and the regular RMP grant mechanism. In such cases, the applicant will be notified immediately.

E. Review Schedule

Special project grant applications under Section 910 will be received and reviewed in accordance with the following schedule:

| <u>Submission<br/>Deadline</u> | <u>Committee<br/>Review Dates</u> | <u>Council<br/>Review Dates</u> | <u>Earliest<br/>Beginning Date</u> |
|--------------------------------|-----------------------------------|---------------------------------|------------------------------------|
| November 1                     | January                           | February                        | March 1                            |
| March 1                        | May                               | June                            | July 1                             |
| July 1                         | September                         | October                         | November 1                         |

F. Duration of Support

Support for Special Projects under Section 910 may be requested for up to seven years. Ordinarily, support will be recommended for no more than three years at a time.\*

Approved applications shall be funded annually, contingent on satisfactory progress and the availability of appropriations. Continuation shall be submitted on HSM-550-1. Continuation applications should be submitted no later than 45 days prior to the close of the budget period for which funds have been awarded. (i.e., the date shown in Item 7 of the Notice of Grant Award issued for the project.) The continuation application shall include an estimated expenditure report (page 12 of HSM-550), and a progress report (page 13 of HSM-550).

Unless otherwise specified, RMPS policies relating to eligible costs, financial management, accounting, record keeping, reporting, wage rates (in the case of construction) and other aspects of grant administration apply to special project grants.

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\*The National Advisory Council has taken the position that Regional Medical Programs, themselves ordinarily should plan to support specific activities for no more than three years.

CHAPTER X  
SPECIAL REQUIREMENTS

X-2 GUIDELINES AND REVIEW PROCEDURES FOR  
KIDNEY DISEASE ACTIVITIES

X-2 GUIDELINES AND REVIEW PROCEDURES FOR  
KIDNEY DISEASE ACTIVITIES\*

2-1 BACKGROUND

Nowhere in medicine does the same gap exist between technology and delivery as in the area of treatment of patients with end-stage renal disease. Technological developments in recent years have made possible the rapid expansion of programs to provide patients with hemodialysis in institutional settings. Innovations which allow self-dialysis by the patient in his home, or in a low overhead facility, vastly extend the utilization of delivery resources, and reduce the cost to the patient. Techniques of organ harvesting, preservation, and transplantation have made renal homotransplantation a service entity, no longer a research tool.

It is estimated that of the approximately 50,000 persons who die each year from kidney disease, 7,000 to 10,000 are suitable candidates for chronic hemodialysis and/or renal transplantation, and that an additional 10,000 to 20,000 might benefit from each treatment. At present, the annual increment of new patients being offered treatment for terminal kidney disease is probably not more than 3,000.

2-2 CURRENT RMPS PROGRAM EMPHASIS FOR KIDNEY DISEASE PROPOSALS

Although national priorities for kidney disease programs will be established and modified over time as appropriate by a panel of renal authorities, for the present it is necessary to focus on improvement and expansion of the delivery of care to end-stage kidney disease patients. RMPS is primarily concerned with the development and implementation of kidney disease programs which will provide the therapeutic tertiary care services of dialysis and transplantation to patients who do not now have access to such life-saving care.

A. Essential Elements of Kidney Programs

The substance of kidney disease programs includes:

1. Procedures to assure early identification of patients in, or approaching a terminal stage of renal failure.
2. Rapid referral of such patients from the level of primary care (private physician) to tertiary care facilities for dialysis and transplantation.

Policy issued on 8/1/72 and clarified on 9/14/72

3. Early patient classification with regard to tissue type, and other pertinent factors.
4. Dialysis and transplantation facilities which assure treatment alternatives to both the patient and physician.
5. Effective cadaver kidney procurement operations, coupled with rapid kidney donor-recipient matching.
6. Selective training to meet the specific needs of the above program.

B. Outline of Program Characteristics

Characteristics of kidney programs include:

1. The patient has access to conservative management before kidney function has ceased.
2. The patient is registered in shared recipient rosters to assure optimum tissue matching, and maximum utilization of harvested cadaver kidneys.
3. The patient can be trained to carry out dialysis at home, or if not eligible for this mode of care delivery, has access to satellite dialysis, or in-center care.
4. Dialysis facilities encompassing all three of the above modes of dialytic treatment will serve, or be an integrated part of a system which serves a population of no less than 500,000.
5. The patient can gain access to transplantation if such therapy is his choice, with his physician's concurrence.
6. Transplantation facilities are centralized to:
  - a. limit duplication of high cost facilities and services.
  - b. assume maximum utilization of full-time transplantation surgeons. A full-time transplantation surgeon is a surgeon who is committed to the full time vocational conduct of planning, organizing and performing transplantation services.

- c. assure availability of complementary backup services required for special patient evaluations and treatment.
  - d. provide the coordinating point for patient referral, donor-recipient matching, patient data exchange and organ sharing.
7. Transplantation centers will serve populations of 3-4 million persons.
  8. Maximum utilization is made of services and facilities for kidney disease patients.
  9. Continued development of third-party payment mechanisms is pursued to support expanding kidney patient care services.
  10. Integration of renal disease patient services with other patient services and facilities is organized at all levels.
  11. Pediatric dialysis and transplantation services are coordinated with adult facilities to provide optimal use of services.
    - a. pediatric nephrology services do not necessarily have to be housed and extended within adult nephrology facilities. Normally competent outside counsel should be sought in determining the need for pediatric nephrology services. Because of the small anticipated pediatric nephrology case-load, support can be justified for only a few specialized children's units nationally.

#### 2-3 REVIEW PROCEDURES

The openly categorical nature of end-stage kidney disease activities, and the need to effectively coordinate integrated dialysis and transplantation systems indicate the need for continued central direction for development of a national program. Thus, applications for kidney activities will be handled in a manner different from other Regional Medical Program applications, but modified from the procedures followed heretofore.

A. Policy Preclearance

Immediately upon an indication of interest in the submission of a kidney proposal by a source within an RMP, the RMP should contact the appropriate RMPS Branch in the Division of Operations and Development (DOD). It is suggested that a brief abstract or letter of intent be submitted which outlines the nature of the prospective activity, the probable role the proposal would play in the Regional program, and the need which will be satisfied within the overall renal disease program of the Region. The Branch which serves the Region will utilize the Region's written inquiry to confer with staff of the Division of Professional and Technical Development (DPTD). RMPS will advise the Region whether it is desirable to proceed further. The RMP, of course, may accept or reject this advice.

B. Technical Program Review

Each application for RMP support of kidney disease activities (including applications for continuation of approved activities) requires a peer review by outside renal experts. Prior to submitting application for a renal disease program, the RMP is expected to obtain a technical review of the proposal by a group which has not participated in the program's development. The technical review group must be comprised of at least 3 renal authorities for new activities (or 2 for continuations) from outside the geographic area served by the Region. Payment of the costs of such consultant services will be made by the requesting RMP.

The Region may obtain the names of consulting renal experts by calling the appropriate Operations Branch for assistance. The Division of Professional and Technical Development maintains a list of renal consultants, and is responsible for coordinating their assignment. Should the RMP desire to choose its own review panel, the names and curriculum vitae of prospective consultants must be cleared with the DPTD.

Technical reviews of renal programs need not always be made by consultant site visits, but may be accomplished by mail when appropriate. The RMP will negotiate any compromise needed should conflicting technical advice be given by the technical reviewers.

To adequately review program progress after the first and second grant years, technical reviewers will need to be provided with a statement of the program undertaken in the first year, the comments of the initial reviewers, a complete statement on program achievements (including numbers of patients treated, program staff development, costs of treatment services), and related information as is indicated in 2-2A, above. The RMP submittal of the renal project report to RMPS should contain, in addition to the Form 15 summary statement and the RAG report, the review comments of the outside technical consultants.

C. Forwarding Proposals

Only those proposals which are recommended favorably by the local Technical Review Group (Section 2-3, B above) shall be eligible for consideration by RMPS. In addition, an opportunity must be provided prior to consideration of the proposal by the RAG for review and comment by the appropriate CHP agency(ies) as required by Section 904(b) of the Act.

The RAG shall consider any CHP comments and comment on the ability of the RMP to manage the kidney project without hindering the development of the overall RMP program, and the reasonableness and adequacy of the kidney budget proposed. The RAG is responsible also for indicating how major issues raised by the local technical review group will be resolved.

Since kidney proposals are reviewed separately at the national level, the RAG need not give priority ranking to kidney proposals in relation to other non-kidney operational activities. Kidney proposals shall be considered by RMPS in relation to national priorities.

The complete comments of the members of the Technical Review Committee, and any CHP agency comments, must be included in the forwarded proposal.

D. RMPS Staff Review

The initial review of kidney applications shall include:

1. the contribution of the project toward kidney program objectives.

2. the completeness and nature of the comments of the RAG (Section 2-3, C above).
3. comments of CHP agencies.
4. the preferred method of funding.

E. RMPS Review Committee

RMPS staff will summarize for the RMPS Review Committee available information as to how each kidney proposal proposes to support the National Kidney Program objectives, and the substantive points developed through local review processes by the Technical Review Committee, the RAG, and the CHP Agency. For those applications for which the RAG; CHP Agency; Director, RMPS, or RMPS Review Committee has indicated a concern apart from the technical merits of the project, the RMPS Review Committee will be asked to make a recommendation to the National Advisory Council.

The RMPS Review Committee specifically will not review on a technical basis the merit of the proposal, or establish formal numerical ratings for individual proposals.

F. Council Review

All kidney proposals shall be submitted to the National Advisory Council for final recommendation. In keeping with the categorical nature of the kidney disease program within RMPS, the Council will review and recommend funding levels for kidney proposals separately from the funding level of the specific RMP. Kidney program funding will be in addition to other RMP program funding.

2-4 PREPARATION OF APPLICATIONS

A. When to Submit

All kidney proposals must be submitted as part of the RMP's regular annual application in accordance with the Region's assigned anniversary date. Prior to July 1, 1973, kidney proposals may be submitted in accordance with Subchapter IV-7, Procedures for Requesting Supplements to RMPS Grants.

B. Routing of Proposal

Sponsors of applications for support of kidney disease projects should submit them to the appropriate RMP in the format which the RMP prescribes. An application involving 2 or more RMP's may be submitted where appropriate. In such cases, one RMP should be designated to act as "applicant" and submit a single application. Such applications must be approved by each RAG and shall include a description of mutually agreed upon arrangements for administration of the project. In view of the preliminary clearances which are called for in these guidelines, it may be helpful to develop and submit a letter of intent to the appropriate RMP's before an application is prepared.

C. Information Required

In addition to the summary information to be provided on the forms specified for applications, narrative should address in detail the program elements specified below. Descriptions which are comprised only of generalized narrative will not be acceptable; disease control needs and the applicability of the proposed program must be presented on the basis of solid data relating to patient populations and distribution, specification of existing services and resources, and clearly documented commitments of cooperation and participation from key persons and institutions. Assistance can be obtained from the program staff of the RMP.

Program elements to be addressed are:

1. the magnitude of the renal disease problem.
2. facilities and programs currently in operation and the needs they are meeting.
3. the needs which the new proposal will meet and how the program will integrate with existing programs to improve patient care services without duplication of existing services or facilities.
4. existing and potential sources of third-party payment for care and how these resources will be developed
5. the commitment of cooperating institutions, groups and health practitioners whose collaboration is essential to insure the success of the program.

6. training, when pertinent to the plan, which is directly related to the projects comprising the plan, or judicious expansion of existing programs.
7. the system or method of program evaluation which will be employed.
8. a decremental rate or proportion of Federal (RMPS) contribution to the program over time.
9. the program's phase-out as an RMP-supported activity.

2-5 ALLOWABLE COSTS

Program costs related to the Federal share of support should normally be identified with personnel and equipment requirements in tertiary care facilities.

RMPS will not fund ALG-related activities. Such funding may be allowed in the future if standardized production and testing is achieved and its efficacy is demonstrated.

2-6 AWARDS

Awards for kidney projects will be issued as a part of the total award to the Regional Medical Program. The amount allocated for the kidney activity will be specified in Item 14, under "Remarks", of the Notice of Grant Award, Form HSM-457. Unexpended balances of funds awarded for kidney activities may be rebudgeted only with prior RMPS approval as specified in Chapter VII, Section 7-3, A, 4.

In some cases, a kidney proposal may be approved by RMPS but unfunded. An RMP may fund such a kidney project through rebudgeting other RMP funds to the kidney activity. Rebudgeting of this nature should be undertaken only after the RAG has carefully considered the effect of such action on the remainder of the RMP program. Likewise, a kidney project may be expanded as determined by the RAG by rebudgeting of funds to the kidney activity in addition to those specifically earmarked for kidney in the Notice of Grant Award.

CHAPTER X  
SPECIAL REQUIREMENTS

X-3 RMP HEALTH MANPOWER ACTIVITIES

3-1 BACKGROUND AND INTRODUCTION

The Regional Medical Program Programs' reaffirmation of their commitment to improving the delivery of health services through accelerated efforts in health manpower education and utilization was one of the major outcomes of the National Coordinators' Conference in St. Louis. The manpower issue and the present and potential impact of the Regions in bringing about needed improvements was a central theme in the formal deliberation and informal discussions of the conference.

As the Coordinators cited examples of RMP success in the manpower area, one characteristic was notably apparent. Essentially, the impact of the Programs cited stemmed from their capacity to engage in activities through a consortium of providers and educational institutions who came together to plan and implement activities to meet health needs which could not be met by individual practitioners, professional organizations, hospitals and other institutions acting alone. As the Coordinators discussed the specific manpower issues of recruitment, education, distribution and utilization, it became further obvious that those RMPs which had successfully addressed these interrelated issues had done so from a base of community involvement. These RMPs had approached a solution to manpower problems through assisting communities to identify their needs and to link and relate total health resources in such a way as to ensure a better balance between the quantity and quality of manpower and locally determined needs for service. In the words of the report from the St. Louis Conference, "a community-based educational approach is actually a means of more universally systematizing the present educational efforts of RMPs, filling in the gaps and placing RMP effort on a more scientific basis linking health professions education with the health service needs of the communities they will serve."

The consensus of the Coordinators on the unique potential of RMPs in the area of manpower constitutes a challenge to proceed imaginatively and aggressively in extending their efforts to link education and service more closely.

In issuing this challenge, the role of the community appeared to be an essential element. As the same time, however, there was tacit acknowledgement by the Coordinators that a definition of the nature, degree and extent of involvement of the community is only now beginning to appear. They further agreed that the RMP experience over the past five years readily lends itself to the latter area of inquiry.

Based on the cumulative experience of the 56 Regions, RMPs which elect to expand their community-based manpower programs will undoubtedly proceed, as in the past, with due regard for the need for individualization of effort. Each area will, because of its local characteristics, differ from others in the extent and kinds of manpower needs, the breadth and depth of planning, educational and service resources, and in the manner in which they presently relate. These differences will be apparent very early as RMPs which are planning and implementing community-oriented manpower programs follow the classic steps which include determination of need, an inventory of existing resources, the development of specific objectives, an implementing scheme involving all participants, and an evaluation design.

In approaching the vast problems of health manpower, the Coordinators agreed that no one solution would suffice. They therefore focused on problems which realistically lend themselves to RMP intervention and solution. These included such issues as irrelevant education programs, personnel retention, maldistribution and inappropriate utilization of health manpower, fragmentation and obsolescence, citizen apathy and excessive costs.

### 3-2 OBJECTIVES

The following objectives appeared to emerge from the Coordinators' discussions of developing manpower programs that would more closely relate education to the health service delivery needs of an area:

1. Development of area health care manpower resources to meet community health service needs as defined by the community through the participation of educational institutions, health professionals, consumers and others.
2. Recruitment, training and employment of local citizens in health occupations.

3. Development of health education activities and programs for the general public.
4. Establishment of a professionally attractive environment which will promote retention of health manpower in communities which are currently underserved.
5. Provision of basic and continuing education, and in-service training for health manpower including appropriate clinical experience, particularly in medically underserved areas.
6. Improvement of the cost-effectiveness of education for health manpower by encouraging the phasing out of ineffective programs.
7. Development of opportunities for consumer inputs, where possible, in the development of health career opportunities.
8. Identification of problems for study in the areas of improving programs for continuing education and training.
9. Designing education, for both traditional and new health occupations, to become more responsive to the skills required by the health delivery team:

### 3-3 CHARACTERISTICS AND FUNCTIONS

If community-oriented manpower programs are to accomplish the foregoing goals and if they are to fit the description of the Coordinators as "more systematic" and more scientific" approaches to ongoing activities, a formalized structure is implied. This structure together with a set of characteristics and functions would be relatively comparable from one program to another. Drawing from experience thus far and from the general objectives as outlined above, a community which would warrant a concerted RMP effort would ordinarily, as a minimum, need the resources to engage in undergraduate and basic education for the health professions, residency training in primary care, continuing education and refresher training and to engage in health education of the public as well. Such a community would also be actively involved in manpower planning and priority setting through CHP and other appropriate agencies. Positive commitments should exist on the part of the principal providers and educational resources in the area with respect to the organization and development of the proposed manpower

Once established, a community-based program would have, or would secure, the resources to address itself to the manpower continuum of recruitment, production, distribution and utilization. In so doing, such a program would necessarily involve itself in such pertinent activities as recruitment of minorities and local residents for health careers, studies of licensure and related issues, programs designed to increase the knowledge of consumers regarding the health delivery system, experiments in interdisciplinary education, task analysis, equivalency and proficiency testing, and the like.

#### 3-4 ORGANIZATION AND DEVELOPMENT

RMP experience with community-based activities to date points up the fact that programs of this nature proceed in a gradual and sequential manner. To accelerate their current activities, most RMPs would require only a brief planning period. However, the organization and development phase may require several months where new or stronger linkages are to be established between the necessary participants from the educational and delivery systems.

Organizationally, a community-based program should include among its resources at least one fully-accredited institution of higher education willing and capable of conducting health manpower educational programs. In addition it should include one or more accredited hospitals and other patient care institutions, capable of and interested in providing sound clinical experience. Also desirable is the establishment of linkages with a wide range of other existing institutions and agencies such as community colleges, vocational and technical schools, the institutions for health professions education, and the many patient care facilities and services in the community.

In planning and developing the program care should be taken to involve and secure continuing participation by appropriate regional and local health organizations. This will help to insure consonance with other health planning in the area and to utilize existing established data sources.

#### 3-5 TYPES OF ADMINISTRATIVE STRUCTURES

The foregoing are necessary steps if programs for a defined area are to move from the organizational to the operational stage. In order to mold the many linked units of such a program into a cohesive, effective force for local health

services improvement, one or more administrative structures are possible. For example, it may be advisable to administer the program through a consortium of cooperating institutions and agencies or through a new corporation. In any case a suitable governing body is required to serve as the principal policy and decision-making group on behalf of the participating agencies and institutions. The establishment of either a consortium or corporation would provide a mechanism through which goals and objectives could be clearly defined, jointly agreed upon, and the program implemented.

CHAPTER X-4.  
SPECIAL ACTIVITIES

X-4 EMERGENCY MEDICAL SERVICES

## X-4 EMERGENCY MEDICAL SERVICES

### 4-1 DEFINITIONS

#### A. Medical Emergency

A medical emergency is an unforeseen event affecting an individual in such a manner that a need for immediate medical care (psychological and/or physiological) is created.

#### B. Emergency Medical Services

The term emergency medical services (EMS) refers to the services utilized in responding to the perceived individual need for immediate medical care in order to prevent loss of life or further aggravation of physiological and/or psychological illness or injury.

#### C. Emergency Medical Service System

A variety of human and physical resources are utilized in a predetermined sequence over the entire time period encompassing the medical emergency. These resources and their joint or individual responses to medical emergencies make up a community EMS system.

### 4-2 EVENTS CHARACTERISTIC OF MEDICAL EMERGENCIES

Listed below in sequence are events that can follow occurrence of a damaging incident that produces emergency medical patients. Not all students of the subject would concur in this breakdown of events. Some would combine some of these events and others might subdivide the list further. This list is a reasonable enumeration of points where medical emergency system failures may exaggerate rather than control losses from damaging incidents. Many of these steps are not recognizable as separate entities in response to certain kinds of medical emergencies. Many of these steps are ineffective where medical science cannot help the victim regardless of where he is taken. However, the medical needs of the victim must determine the manner of system response.

#### A. Pre Treatment Phase

1. occurrence
2. detection
3. notification
4. dispatch of emergency medical services
5. travel to site

B. Preliminary Care Phase

6. problem analysis
7. treatment
8. extrication
9. stabilization
10. loading
11. patient maintenance
12. selection of definitive care facility
13. transport - (continuing patient maintenance)
14. enroute notification of receiving facility
15. facility preparation for receiving patient(s)
16. delivery to definitive care facility

C. Definitive Care Phase

17. patient transfer
18. information transfer
19. patient evaluation (by facility staff)
20. triage
21. continuation of treatment
22. second stage diagnosis
23. emergency room treatment
24. intensive care
25. definitive diagnosis
26. definitive treatment

D. Recuperation Phase

27. recuperative care (ward)

E. Rehabilitation Phase

28. transfer (to extended care facility or home)
29. rehabilitative treatment
30. discharge
31. return to normal function (patient)

4-3 THE PRIMARY NEED

An EMS system provides services which directly effect the elements cited in the first three phases of sequential events occurring during a medical emergency. The capability of these resources, the quality of their performance and their accessibility are the factors that determine the outcome of their services. Every element and step in the system must be designed to foster patient recovery, facilitate definitive care and keep open the widest possible spectrum of medical options. Any element which adds to the cost, time, or manpower requirements of the system without commensurate improvement in one or more of these medical objectives is waste.

The technology and methodology for delivering high quality emergency medical care has been developed for each element of the EMS system. What is lacking, in most areas of the country today, is informed cooperative linkage of the elements for optimum effectiveness in performance.

The most significant progress in improving emergency medical services has been made in areas in which all elements of the system achieved common understanding of the services desired and their requirements by active cooperation.

Logic dictates that effective change will result from careful planning and implementation on a time-phase basis. Effective change can occur only in a receptive environment. A favorable community-wide environment must be created prior to implementation of changes in the EMS system. This requires the basic education of the general public as well as the continuing education of the health community with emphasis on the need for coordination and cooperation among providers and the community at large.

Serious consideration should be given to the utilization and improvement of existing resources in effecting change, rather than superimposing sweeping unilaterally designed changes in drastic conflict with the existing system.

#### 4-4 PROBLEM MAGNITUDE

Accidents are the leading cause of death among all persons one (1) to thirty-eight (38) years of age. Among persons of all ages, accidents are the fourth leading cause of death and in 1968, 114,864 persons died as a result of accidents.

The statistics depict only a portion of the total demand on the EMS system. The figures indicating demands generated by medical emergencies of non-accidental origin are not immediately available. These demands are greater in magnitude than those generated by accidents. Some victims of medical emergencies will die or suffer permanent impairment despite optimal medical care. Others will recover normal function without need for medical intervention. For many, emergency medical care will prevent death, control disability or reduce pain, discomfort or expense.

#### 4-5 STATE OF THE TECHNOLOGY

##### A. Principal Technological Developments

A multitude of technological aids have become available. Many of these developed from single purpose allocations of federal research funds. These grants and contracts were awarded on the basis of the scientific merits of the projects. Their relation to the entire EMS system and the economic base has not always

been considered. Among technological developments are such features as:

1. telemetric monitoring of life signs of patients in medical emergencies for physicians or other attendants at base hospitals
2. mobile coronary care units, popularly called heart-mobiles, and other elaborately specialized patient transportation or field care units
3. centralized rescue vehicle and ambulance dispatch systems equipped with single areawide request numbers and radio and telephone dispatch networks to control all patient transportation vehicles
4. vehicle to dispatch, vehicle to destination hospital and inter-vehicle radio communication
5. helicopter and fixed wing airlift to supplement ground medical, rescue and transportation, sometimes in aircraft equipped for administration of medical care en route
6. two way television communication between hospital

B. Utilization of New Technology

Due to the romantic appeal of these technological developments and the implied promises with which they are promoted, most efforts to make major improvements in community EMS systems have concentrated on installation of costly rescue and ambulance innovations.

Technical development in hospital emergency rooms has been carried out largely for specific hospitals under leadership of innovative, individual physicians but has not produced improvements easily transferred to other areas.

Efforts to improve hospital EMS often have culminated in purchase of underutilized equipment and have failed to coordinate the emergency capabilities of the separate departments within the hospital or to improve the coordination between hospitals and medical transportation services. Technology alone may multiply EMS expenditures without significant improvement in the outcome for victims of medical emergencies.

4-6 STANDARDS AND GUIDELINES

Standards have been promulgated by various professional organizations (Appendix A). The principles of these

standards have been generally accepted throughout the country. Generally, these statements are in agreement on basic principles of EMS operations. Appendix A contains a list of the most widely accepted of these documents.

Although they do not cover all aspects of the EMS system, these standards have been applied in a number of jurisdictions which have reported improvement. To our knowledge, there are no published reports that have been based on comparisons between emergency health service performance before and after application. It should be noted that such comparisons are very difficult to execute.

Conversion of any system from non-compliance to compliance with such standards is not accomplished outright. The length of the conversion period, the difficulty of assembling baseline data, etc., put such evaluation beyond the reach of many communities.

#### B. Model Statute

A model statute (prepared under the auspices of the National Safety Council) has evolved through the cooperative efforts of several organizations that have faced the EMS problem.\* Modified forms of this model have been accepted by a few states and are being considered by others. Legislative standards, similar in tone, though not identical, are applied as criteria of grant eligibility in the National Highway Safety Act. Like all model laws, this one presents difficulties to state legislatures because of the complexities of state codes and the existence of special interests that are not always in harmony with each other. The model law confines itself to regulation of ambulance services in general and therefore affects their non-emergency business as well as their emergency operations.

### 4-7 SOCIO-ECONOMIC OVERVIEW

#### A. Time Constraints

Medical emergencies may affect very large numbers of persons, as in a community-wide disaster, or they may occur to a single patient as in a heart attack. The damaging incidents may be sudden illness, accidents, poisonings, personal violence or natural forces. By definition, each patient needs medical care to control the outcome of his emergency. By definition, the time from onset to definitive treatment is a factor in the outcome. The process by which the given emergency victim may be brought to definitive control may have many steps as

outlined above. In every case, the medical procedures required are crucial to the outcome. Time lapses can determine the medical requirement and the outcome, but medical procedures can alter time tolerances. Emergency medical services must be time conscious, but they are dominated by the medical options. The most efficient emergency transportation conceivable is useless for patients who are dead on arrival, or die waiting for care in a hospital.

#### B. Responsibilities of Providers

Providers of medical care in any community have inescapable responsibilities related to emergency medical services. They need to work together to (1) assure effective functioning of their emergency care, (2) assure that ambulance and other ancillary services protect the medical care options as far as possible for each victim; and (3) protect the emergency medical services against unnecessary demands and other abuses.

The providers of medical care jointly have other responsibilities for their communities' emergency medical care systems. They are best qualified to determine the point of diminishing returns in emergency medical service expenditure. This is the point at which additional expenditures for such services will yield less benefit in control of death and injury than would the same amounts invested in alternative disease prevention or control services.

Their unique situation enables providers of medical care to appraise and monitor existing emergency medical services. Their position permits identification of phases of hospital emergency systems, transportation services, rescue operations and other elements of the total system which are malfunctioning. The relative priorities of the problems presented by malfunctions can also be determined by providers. Time and funding priorities of attacks on these problems can be recognized, permitting selection of the most realistic or alternative modes of attack on each. They can provide essential expertise to communities assessing the EMS system.

#### C. Financing and Regulation

The medical functions of emergency medical services systems and the requirements imposed by medical necessity operate within social and economic constraints. Each part of the system has its own needs for manpower, facilities, equipment, supplies and supportive services. These needs can be satisfied only to an extent commensurate with the funds and options available.

##### 1. Public Regulation of Services

Private, volunteer, and public agency operated units in an emergency medical service system have rudimentary

characteristics of public utilities. They are regulated to degrees that vary among jurisdictions. Personnel qualifications, equipment configurations, fee schedules and operational practices may be regulated by law. In almost every state in which such regulation has been attempted, only ambulance services or their equivalents are controlled by statutes directed to emergency medical services. Hospital emergency personnel and functions employed in EMS are usually not affected by special emergency medical service legislation. In many states, enforcement of and compliance with the laws regulating ambulance services have not been ideal.

## 2. Financing

Community subsidization occurs in several forms. Most obvious are the emergency rooms of publicly-owned and community hospitals. Ambulance services may be operated by some of these hospitals or by such agencies as fire departments or volunteer ambulance and rescue companies. In money-losing proprietary ambulance services, losses are paid by the public through higher prices for the services that make up the owner's principal businesses.

## 3. Cost Effectiveness

Most community emergency medical service evolved in a piecemeal fashion. The ambulance phase of EMS has often been the target of piecemeal subsidization. The use of costly devices of limited effectiveness, such as heartmobiles and helicopters, has been introduced in some areas without adequate consideration of their economic effects.

Hospital based emergency services too often have been neglected. Demands for emergency services have produced hospital budget squeezes. Economic and staffing problems have produced competence squeezes in emergency rooms. Hospitals have been led to buy and develop equipment and facilities that are under-utilized. Community demands have pushed some hospitals out of the emergency care business, or, in some cases, have forced emphasis on emergency services to the detriment of other operations.

## D. Access To Services

Many medical emergencies still become the responsibility of the nearest person who will attempt to use whatever resources are at hand.

Many population groups feel that they have special problems of access to emergency medical services. In some areas, this is In others, these groups simply share a common problem of inadequate services. The situation in emergency medical services of all kinds is turbulent. It cannot be solved by unilateral action of the providers.

E. Summary

Development of an adequate community emergency medical service system requires creative contributions from many community oriented talents. It also requires a base of hard knowledge and rigorous control of sentimentality.

4-8 POLICY AND RESPONSIBILITY

The character and performance of emergency medical services in the United States is community determined. No legislative basis exists for State or Federal Government imposition of a system operated by a public agency. In general, the national policy may be said to be reliance on community responsibility.

Community control may operate through piecemeal individual or group responses to perceived needs, through approaches planned on a system-wide basis, or through some combination of these two styles. A community-wide approach to developing emergency medical services under a comprehensive plan seems to yield the most viable balanced system, particularly when included in a concept of improving access to health care at all levels.

In the process of community self-management, emergency medical needs make up one of many demands upon attention and resources. It is most apt to find its proper place in the array of community concerns when it receives truly representative and informed attention.

4-9 COMMUNITY MANAGEMENT

The process by which a community assumes and exercises management of its emergency medical services has many elements and may take many forms. The relative emphasis placed on individual elements and the order and way in which they are taken may legitimately vary. Experience has shown, however, that successful management processes have certain essential characteristics. Successful management of emergency medical services is most likely when the management process is:

A. Community Powered

Led by influential volunteer or locally appointed groups with the strong involvement of medical care professionals, business people, public administrators and legislators.

B. Community Specific

Concerned with a defined area and population, preferably a medical service area or local political unit in which public and professional medical feelings of unity and responsibility already exist.

C. Informed About

1. Pertinent Legislation and Regulations

Elements of State codes which may affect emergency medical services may include health and medical, business, tax, incorporation, liability, insurance, transportation, property and other laws.

2. Character and Magnitude of the Basic Problem

Local demographic, occupational, geographic, climatic, economic, cultural and other characteristics tend to individualize the patterns of disease, accident, violence and natural forces that make up the workload of emergency medical service requirements in each community.

3. Performance Evaluation

Ideally, a cause-specific and service-specific comparison of untimely death and disabilities sustained, with the lowest levels of these events that might have been achieved by application of the best medical measures known to "be practice-ready." Access time, that is the time from onset of the medical emergency until qualified initial treatment is provided, is a major factor.

4. Resources

All manpower, facilities and equipment potentially directly useful to emergency medical services, classified and cross-classified by:

- a. Activity status
- b. Deployment
- c. Effectiveness in terms of patient outcomes for participating resources

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- d. Control, in terms of ownership
- e. Response mechanisms
- f. Funding
  - (1) Revenue
  - (2) Other
- g. Reinforcement of capabilities of neighboring communities for massive or specialized needs

#### 5. Relative significance of medical emergencies

Comparison between untimely death, disability, and cost as compared with other health problems and with non-health problems presenting demands on community funding resources.

#### D. Explicitly Decisive on:

##### 1. Emergency medical service pattern desired for local and shared use:

- a. Kinds
- b. Quantities
- c. Deployments

##### 2. Controls desired:

- a. Ownership - a single type or a mix of types
- b. Response mechanism
- c. Quality controls

##### 3. Funding patterns desired (by sources, amounts, and modes of payment of each):

- a. Revenues
- b. Others

##### 4. Identification and re-ordering of phases of emergency medical services that must be changed to achieve the desired pattern

##### 5. Relationships to other components of health care delivery systems

#### 4-10 THE ROLE OF RMP IN COMMUNITY ACTION ON EMERGENCY MEDICAL SERVICE

##### A. Reasons for RMP Involvement

Emergency medical service is a highly visible part of the health care delivery system. Community decisions on emergency services inevitably affect all other aspects of health care.

The validity of emergency medical services is dependent on the community's recognition of the priority of medical emergencies among the community's responsibilities.

For these reasons, the Regional Medical Program has an obligation to take part in emergency medical service considerations. This obligation exists regardless of the origin of the community's initiative on the medical emergency problem.

B. EMS Responsibilities of RMPs

The Regional Medical Program is responsible for:

1. Mobilization of health care providers fully representative of the health care delivery system.
2. Cooperation with other public and private agencies in assembly and presentation of all available and pertinent information.
3. Directing and presenting staff studies to:
  - a. Demonstrate the medical imperatives of emergency services.
  - b. Relate medical emergencies to other problems of the community.
  - c. Compare feasibility, probable outcomes, and cost in dollars, manpower and time of alternative proposals for improvement of emergency medical services.
  - d. Assure representation of all interested segments of the community and of various planning agencies in the decisionmaking process to foster maturity and equity in decisions.
  - e. Implement and/or upgrade training and continuing educational programs provided that:
    - (1) Support for continuation of these programs will be provided beyond the RMP project period. The source of this support must be identified prior to an award.
    - (2) The training and continuing education plan is compatible with or part of any Area Health Education Center program.

C. Financial Assistance

The Regional Medical Program is the development arm of the community's decisionmaking process. In addition to the types of services represented above, the Regional Medical Program may assist in obtaining grants or loans to implement community decisions from areas authorized to disburse such resources.

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Such assistance will be confined, however, to requests that have fully informed approval of the decision making body. The community's emergency service plan cannot be considered viable until its discernable income and operational requirements are shown to be in prospective balance by a specified date.

4-11 APPENDICES

- A. "Emergency Medical Service Standards Guidelines and Protocols."
- B. "Federal, Financial, and Other Assistance for EMS."

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APPENDIX A

EMERGENCY MEDICAL SERVICE STANDARDS, GUIDELINES AND PROTOCOLS

1. American Academy of Orthopaedic Surgeons, Committee on Injuries, Emergency Care and Transportation of the Sick and Injured, Chicago, Illinois, 1971
2. American Medical Association, Commission on Emergency Medical Services, Developing Emergency Medical Services - Guidelines for Community Councils, Chicago, Illinois, 1970
3. Bulletin, American College of Surgeons, Essential Equipment for Ambulances, Chicago, Illinois, May 1970, pp. 7-13
4. Division of Medical Sciences, National Academy of Sciences, National Research Council, Advanced Training Program for Emergency Medical Technician - Ambulance, Washington, D.C., September 1970
5. Division of Medical Sciences, National Academy of Sciences, National Research Council, Medical Acquisitions For Ambulance Design and Equipment, Washington, D.C., 1969
6. Division of Medical Sciences, National Academy of Sciences, National Research Council, Training of Ambulance Personnel and Others Responsible for Emergency Care of the Sick and Injured at the Scene and During Transport, Washington, D.C., 1968
7. Health Care Facilities Service, U.S. Department of Health, Education, and Welfare, Hospital Outpatient Emergency Activities - Functional Programming Guidelines, Rockville, Maryland, August 1971
8. Joint Commission on Accreditation of Hospitals, Accreditation Manual for Hospitals, pp. 69-76, Hospital Emergency Services, Chicago, Illinois, December 1970
9. National Highway Traffic Safety Administration, U.S. Department of Transportation, Basic Training Program for Emergency Medical Technician - Ambulance, Course Guide and Course Coordinator Orientation Program, Washington, D.C., January 1971
10. National Highway Traffic Safety Administration, U.S. Department of Transportation, Basic Training Program for Emergency Medical Technician - Ambulance, Instructors' Lesson Plans, Washington, D.C., January 1971

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11. National Highway Traffic Safety Administration, U.S. Department of Transportation, Refresher Training Program for Emergency Medical Technician - Ambulance, Course Guide, Washington, D.C. March 1971
12. National Highway Traffic Safety Administration, U.S. Department of Transportation, Refresher Training Program for Emergency Medical Technician - Ambulance, Instructors' Lesson Plans, Washington, D.C., March 1971

## X-4 EMERGENCY MEDICAL SERVICES

### APPENDIX B

A 1970 study by the Division of Medical Sciences, National Academy of Sciences, National Research Council indicated that more than 25 federal agencies have some role and/or resources for supporting comprehensive emergency medical services. Available support ranges in scope from limited consultation to substantial financial assistance. The following is a partial list of those agencies:

1. Appalachian Regional Commission  
Appalachian Regional Health Program
2. Department of Defense
  - a. Office of Civil Defense
  - b. Department of the Army
    - (1) Directorate of Military Support
    - (2) Office of the Surgeon General
3. Department of Health, Education and Welfare
  - a. Health Services and Mental Health Administration
    - (1) Federal Health Programs Service  
Division of Emergency Health Service
    - (2) National Center for Health Services  
Research and Development
    - (3) National Institute of Mental Health
    - (4) Office of Comprehensive Health Planning  
Division of Community Health Services
    - (5) Regional Medical Programs Service
  - b. National Institutes of Health
    - (1) Bureau of Health Professions, Education and Manpower Training  
Division of Allied Health Manpower  
Division of Nursing  
Division of Physician Manpower
    - (2) National Institute of General Medical Sciences
    - (3) National Institute of Neurological Diseases and Stroke
  - c. Office of Education
    - (1) Vocational Education and Research Program
    - (2) Division of Manpower Development and Training
  - d. Social Security Administration
4. Department of Labor
5. Department of Transportation
  - a. National Highway Traffic Safety Administration
    - (1) Division of Emergency Medical Programs
  - b. National Highway Administration

APPENDIX B

6. Office of Economic Opportunity
7. Office of Emergency Preparedness
8. Small Business Administration
9. Veterans Administration

DPTD  
revised

CHAPTER X

SPECIAL REQUIREMENTS

X-2 GUIDELINES AND REVIEW PROCEDURES FOR  
KIDNEY DISEASE ACTIVITIES

## X-2 GUIDELINES AND REVIEW PROCEDURES FOR KIDNEY DISEASE ACTIVITIES

### 2-1 BACKGROUND

Nowhere in medicine does the same gap exist between technology and delivery as in the area of treatment of patients with end-stage renal disease. Technological developments in recent years have made possible the rapid expansion of programs to provide patients with hemodialysis in institutional settings. Innovations which allow self-dialysis by the patient in his home, or in a low overhead facility, vastly extend the utilization of delivery resources, and reduce the cost to the patient. Techniques of organ harvesting, preservation, and transplantation have made renal homotransplantation a service entity, no longer a research tool.

It is estimated that of the approximately 50,000 persons who die each year from kidney disease, 7,000 to 10,000 are suitable candidates for chronic hemodialysis and/or renal transplantation, and that an additional 10,000 to 20,000 might benefit from each treatment. At present, the annual increment of new patients being offered treatment for terminal kidney disease is probably not more than 3,000.

### 2-2 CURRENT RMPS PROGRAM EMPHASIS FOR KIDNEY DISEASE PROPOSALS

Current program emphasis is aimed at addressing the service delivery problems of kidney disease. It recognizes the fact that a finite amount of funds are available for attacking this problem. The framework of this program is based upon a comprehensive regional plan covering the multiple aspects of renal disease. The matrix of the system requires the establishment of primary, secondary, and tertiary care mechanisms for the identification, referral, and treatment of the patient with kidney disease. The realities of currently available treatment for end-stage renal disease necessitate the establishment of a limited number of tertiary kidney disease centers with the technical expertise and service capabilities to provide comprehensive care to a large number of patients on a regional basis. Studies concerning physical resources and available monies, compared with projected costs and cost effectiveness data, show that any effort aimed at treating end-stage kidney patients must be linked with such tertiary centers in order to provide a complete spectrum of high quality care at a price which can be reasonable borne by the public.

Although national priorities for kidney disease programs will be established and modified over time as appropriate by a panel of renal authorities, for the present it is necessary to focus on improvement and expansion of the delivery of care to end-stage kidney disease patients.

RMPS is primarily concerned with the development and implementation of kidney disease programs which will provide the therapeutic tertiary-care services of dialysis and transplantation to patients who do not now have access to such life-saving care.

A. High Priority Kidney Disease Activities

As is further explained in section 2-6, kidney activities will receive RMPS support in the form of "separate" decremental funding which provides less RMPS funding each subsequent year of program operation as developed third-party sources of funds support an increasing share of the program cost. Kidney disease programs are expected to be fully operational and independent from RMPS support after the third year of grant support, or sooner.

Separate funds are available for the following program areas:

1. Transplantation - RMPS funds will be provided on a decremental basis for establishing programs in transplantation in areas of need. Direct patient-care costs are not appropriate for support.
2. Organ Procurement Activities - RMPS will finance the start-up of a region's organ-procurement activities in the framework of decremental RMP funding with assumption of costs by other sources over time.
3. Tissue Typing - RMPS will pay for start-up costs in this activity provided that the tissue-typing labs are not redundant and duplicative. Tissue-typing costs also must be assumed by other sources of funds.
4. Organ Procurement and Communication Activities - These are designed to provide optimal use of harvested organs shared among many transplant centers over several regions. These activities should also become self-sufficient by the time RMPS seed money is withdrawn. It is, however, more difficult for these activities to be financed by third-party carriers and the costs of managing the organ-procurement network may be added to the individual cost per organ harvested.
5. Home Dialysis Training - RMPS will provide seed money for the development of home dialysis training programs where the need has been demonstrated. Such programs must be affiliated with a transplantation program and provide or have access to acute medical resources.

6. Low Overhead Limited-Care Dialysis - Where documented regional needs exist, RMPS will support the development of low-cost limited-care programs having access to acute medical care resources and affiliated with a tertiary care program.
7. Satellite Dialysis Facilities - Where appropriate, RMPS may support the development of satellite-dialysis resources to serve the backup needs of patients who are geographically removed from the tertiary-care facilities.
8. Dialysis and Transplantation Programs for Children- RMPS will provide the start-up costs for pediatric end-stage renal activities in selected areas of need. Since an estimated total of only 600 children each year are believed to be good candidates for dialysis and transplantation, we anticipate providing support for only a few highly centralized pediatric nephrology units. As with adult facilities, pediatric nephrology units must be based on a decremental RMP funding sequence, with assumption of costs by non-RMPS sources in time.
9. Education - RMPS will support, when appropriate to the goals of a comprehensive renal program, training in continuing education of physicians (excluding fellowships), postgraduate renal nurses, and other allied health professionals aimed at improving care for patients with end-stage renal disease. RMPS is not the appropriate source for support of degree or certificate-oriented programs, such as A.A., R.N., and M.D. programs; internships, residencies, and fellowships also are not suitable for RMP support.
10. Public Education - RMPS will provide limited support for appropriate public education activities which are clearly related to specific output of the end-stage renal program.

With respect to the renal programs initiated prior to issuance of the Guidelines, they should be brought into conformity with these priorities as soon as possible. This does not mean that nonconforming activities should be dropped in a precipitous manner, but they should be phased out as RMPS-supported work in an orderly way within a year.

#### B. Essential Elements of Kidney Programs

The substance of kidney disease programs includes:

1. Procedures to assure early identification of patients in, or approaching a terminal stage of renal failure.

2. Rapid referral of such patients from the level of primary care (private physician) to tertiary-care facilities for dialysis and transplantation.
3. Early patient classification with regard to tissue type, and other pertinent factors.
4. Dialysis and transplantation facilities which assure treatment alternatives to both the patient and physician.
5. Effective cadaver kidney procurement operations, coupled with rapid kidney donor-recipient matching.
6. Selective short-term training to meet the specific needs of the above program.

C. Outline of Program Characteristics

Characteristics of kidney programs include:

1. The patient has access to conservation management before kidney function has ceased.
2. The patient is registered in shared recipient rosters to assure optimum tissue matching, and maximum utilization of harvested cadaver kidneys.
3. The patient can be trained to carry out dialysis at home, or if not eligible for this mode of care delivery, has access to satellite dialysis, or in-center care.
4. Dialysis facilities encompassing all three of the above modes of dialytic treatment will serve, or be an integrated part of a system which serves a population of no less than 500,000.
5. The patient can gain access to transplantation if such therapy is his choice, with his physician's concurrence.
6. Transplantation programs will serve populations of 2-4 million persons.
  - a. A Transplantation Program has one or more hospitals doing transplantation surgery, one (1) tissue typing facility or contractual agreement, one (1) organ procurement

and sharing program, linkages to dialysis services (backup and home dialysis training), and should do a minimum of 25 transplants per unit per year and aim ultimately at 50-100 transplants per year and meeting the Region's needs.

7. Transplantation facilities are centralized to:
  - a. Limited duplication of high cost facilities and services.
  - b. Assume maximum utilization of full-time transplantation surgeons. A full-time transplantation surgeon is a surgeon who is committed to the full time vocational conduct of planning, organizing and performing transplantation services which will meet the transplantation needs of a large population.
  - c. Assure availability of complementary backup services required for special patient evaluations and treatment.
  - d. Provide the coordinating point for patient referral, donor-recipient matching, patient data exchange and organ sharing.
8. Maximum utilization is made of services and facilities for kidney disease patients.
9. Continued development of third-party payment mechanisms is pursued to support expanding kidney patient-care services.
10. Integration of renal disease patient services with other patient services and facilities is organized at all levels.
11. Pediatric dialysis and transplantation services are coordinated with adult facilities to provide optimal use of services.
  - a. pediatric nephrology services do not necessarily have to be housed and extended within adult nephrology facilities. Maximum utilization should be made of common facilities and staff, however.

D. Program Development

The project(s) forwarded for consideration must have been preceded by, or be a part of, a comprehensive renal plan. The comprehensive regional renal plan should not be confused with the grant application for RMP support of specific projects. The plan provides the

objectives and overall system; the projects represent successive steps over time to realize the comprehensive program based on the plan.

The comprehensive renal plan should identify and describe the:

1. Geographic area to be served.
2. Population area to be served.
3. Estimated or established number of renal patients.
  - a. If only estimated, how will accurate confirmation of this estimate be achieved?
  - b. How will patients gain entrance into the program?  
Are there any factors concerning minorities or patients with cultural, economic or environmental uniqueness effecting entrance into this system which must be considered?  
What are the selection criteria of the institutions within the region?
4. Existing personnel and facilities providing care, and the quantity and physical characteristics of the care being delivered by these facilities, such as, in-center dialysis, home- training programs, low overhead limited-care dialysis, transplantation, etc.
5. The proposed resources which are necessary to meet the regional needs identified by the parameters above.
6. The proposed program or project elements requiring specification are detailed in 2-4C.

## 2-3 REVIEW PROCEDURES

The openly categorical nature of end-stage kidney disease activities, and the need to effectively coordinate integrated dialysis and transplantation systems indicate the need for continued central direction for development of a national program. Thus, applications for kidney activities will be handled in a manner different from other Regional Medical Program applications.

### A. Policy Preclearance

Immediately upon an indication of interest in the submission of a kidney proposal by a source within the RMP, the RMP should contact the appropriate RMPS Branch in the Division of Operations and Development (DOD). A brief abstract or letter of intent should be submitted, which outlines the nature of the prospective activity, the probable role the proposal would play in the regional program, and the need which will be satisfied within the overall renal

disease program of the Region. If a comprehensive regional renal plan has not been forwarded, the letter should indicate the status of its development. The Branch which serves the Region will utilize the Region's written inquiry to confer with staff of the Division of Professional and Technical Development (DPTD). RMPS will advise the Region whether it is desirable to proceed further. The RMP, of course, may accept or reject this advice.

B. Technical Program Review

Each application for RMP support of kidney disease activities (including applications for continuation of approved activities) requires a peer review by outside renal experts. Prior to submitting application for a renal disease program, the RMP is expected to obtain a technical review of the proposal by a group which has not participated in the program's development. The technical review group must be comprised of at least three renal authorities for new activities (or two for continuations) from outside the geographic area served by the Region. Payment of the costs of such consultant services will be made by the requesting RMP.

The values of outside consultant review for the Region are multiple. Most importantly, it is designed to give the Region's decision-making body, the RAG, an objective evaluation of proposed or continuing kidney activities. This should permit the RAG to make sound decisions concerning approval, funding and relationships of these activities. Thoughtful consideration and resolution by the RAG of issues posed in the evaluation, should insure program effectiveness. The review also provides an opportunity for information exchange between the consultants and the Region's principals which should foster appropriate and compatible program development from region to region. This is most important when supraregional and national cooperation becomes an essential part of kidney programs.

C. Timing of Technical Reviews

There are three basic circumstances when outside consultation will be requested, two of which are required of renal program sponsors by paragraph B, above.

1. Renal program planning. Before a specific proposal has been developed, a Region may wish assistance in planning its regional program. (Not required, but frequently desirable)

2. A specific project or program has been developed and requires technical review so that the RAG is provided objective information to support its decision concerning approval or disapproval of the proposal. (Required)

3. A project(s) or program will be reviewed annually to ascertain progress. (Required)

D. Consultant-RMP Roles

RMPS supplies the Regions with the names of Renal Technical Consultants on request from the Regions. The outside Renal Technical Consultant services are official peer review services provided to the Regional Advisory Group (RAG) of a particular Region. The renal consultant is a private agent responsible for conducting his own negotiation on fee, time and site of consultation with the RMP which requests his services. The negotiated agreements reached between the consultant and the RMP represent a contractual arrangement between the two parties for consultant personal services.

Consultants who assist a Region in planning a program and/or projects should not participate in the technical review or progress assessments. Consultants who review the initial program or project proposals will frequently participate in the annual progress assessment. A minimum of three consultants will collaborate in the initial technical review; two consultants will perform the progress assessments.

Since the consultant's official relationship is with the RAG, a written report of the consultant's program review will be prepared for the RAG and presented to the RMP Coordinator (or Director). The reviewers' report should address organizational setting of the program, the specificity of outcomes, efficacy of program methodology (including evaluation activities), relationship of proposed to existing facilities or resources, development of other funding sources, and specifics of equipment and personnel. A recommendation section should clearly indicate suggested action, such as approval/disapproval, funding level, and changes or modifications necessary to merit RAG approval.

E. Reimbursement for Outside Consultant Services

Payment for Consultant review services cannot be a part of the renal program grant budget, nor can it be contingent upon successful project funding. The Region should negotiate the fee which it has established for such services, or an otherwise reasonable or mutually agreed-upon amount. RMPS typically pays a fee of \$75 per day (of for any part of a day), plus up to \$25 per diem, plus tourist-class, round-trip air or other appropriate travel mode. It is appropriate to pay an extra day's fee for study of a proposal and associated background material when the material to be absorbed is sizable.

F. Organization of Outside Consultant Reviews

Arrangements for renal program review and progress assessment should include:

1. Simultaneous visit to the sponsoring Region by the outside Consultants as a team.
2. A preconference meeting of the Consultants.
3. Joint Region-Consultant agreement on the program-related individuals to be interviewed.
4. Identification of additional program background information, and its provision as requested by the Consultants.

To adequately review program progress after the first and second grant years, technical reviewers will need to be provided with a statement of the program undertaken in the first year, the comments of the initial reviewers, a complete statement on program achievements (including numbers of patients treated, program staff development, costs of treatment services), and related information.

G. Forwarding Proposals

Only those proposals which are recommended favorably by the outside Consultants shall be eligible for consideration by RMPS. In addition, an opportunity must be provided prior to consideration of the proposal by the RAG for review and comment by the appropriate CHP agency(ies) as required by Section 904(b) of the Act.

The RAG shall consider any CHP comments and comment on the ability of the RMP to manage the kidney project without hindering the development of the overall RMP program, and the reasonableness and adequacy of the kidney budget proposed. The RAG is responsible also for indicating how major issues raised by the local technical review group will be resolved.

Since kidney proposals are reviewed separately at the national level, the RAG need not give priority ranking to kidney proposals in relation to other nonkidney operational activities. Kidney proposals shall be considered by RMPS in relation to national priorities.

The RMP submittal of the renal project report to RMPS must contain, in addition to the Form 15 summary statement and the RAG report, CHP agency comments, and the review comments of the outside technical Consultants.

H. RMPS Staff Review

The initial review of kidney applications shall include:

1. Program compliance with RMPS guidelines.
2. The contribution of the project toward kidney program objectives.
3. The completeness and nature of the comments of the RAG (Section 2-3G, above).
4. Comments of CHP agencies.
5. The preferred method of funding.

I. RMPS Review Committee

RMPS staff will summarize for the RMPS Review Committee available information as to how each kidney proposal proposes to support the National Kidney Program objectives, and the substantive points developed through local review processes by the Technical Review Committee, the RAG, and the CHP Agency. For those applications for which the RAG: CHP Agency; Director, RMPS, or RMPS Review Committee has indicated a concern apart from the technical merits of the project, the RMPS Review Committee will be asked to make a recommendation to the National Advisory Council.

The RMPS Review Committee specifically will not review on a technical basis the merit of the proposal, or establish formal numerical ratings for individual proposals.

J. Council Review

All kidney proposals shall be submitted to the National Advisory Council for final recommendation. In keeping with the categorical nature of the kidney disease program within RMPS, the Council will review and recommend funding levels for kidney proposals separately from the funding level of the specific RMP. Kidney program funding will be in addition to other RMP program funding.

2-4 PREPARATION OF APPLICATIONS

A. When to Submit

All kidney proposals must be submitted as part of the RMP's regular annual application in accordance with the Region's assigned anniversary date. Prior to July 1, 1973, kidney proposals may be submitted in accordance with Subchapter IV-7, Procedures for Requesting Supplements to RMPS Grants.

B. Routing of Proposal

Sponsors of applications for support of kidney disease projects should submit them to the appropriate RMP in the format which the RMP prescribes. An application involving two or more RMP's may be submitted where appropriate. In such cases, one RMP should be designated to act as "applicant" and submit a single application. Such applications must be approved by at least one RAG and shall include a description and affidavits of mutually agreed upon arrangements for administration of the project. In view of the preliminary clearances which are called for in these guidelines, it may be helpful to develop and submit a letter of intent to the appropriate RMP's before an application is prepared.

C. Information Required

In addition to the summary information to be provided on the forms specified for applications, narrative should address in detail the program elements specified below. Descriptions which are comprised only of generalized narrative will not be acceptable; disease control needs and the applicability of the proposed program must be presented on the basis of solid data relating to patient populations and distribution, specification of existing services and resources, clearly documented commitments of cooperation and participation from key persons and institutions, and specification of the outcome (quantified, insofar as possible) which the Region intends to achieve. Assistance can be obtained from the program staff of the RMP.

Program elements to be addressed are:

1. the magnitude of the renal disease problem.
2. facilities and programs currently in operation and the needs they are meeting.
3. the specific unmet needs which the new proposal will meet and how the program will integrate with existing programs to improve patient-care services without duplication of existing services or facilities.
4. existing and potential sources of third-party payment for care and how these resources will be developed.
5. the commitment of cooperating institutions, groups and health practitioners whose collaboration is essential to insure the success of the program.

6. increments of service increases, or numbers of patients treated which the program is designed to achieve.
7. training, when pertinent to the plan, which is directly related to the projects comprising the plan, or judicious expansion of existing programs.
8. the system or method of program evaluation which will be employed.
9. a decremental rate or proportion of Federal (RMPS) contribution to the program over time.
10. the program's phase-out as an RMP-supported activity.

2-5 ALLOWABLE COSTS

Program costs related to the Federal share of support should normally be identified with personnel and equipment requirements in tertiary-care facilities.

RMPS will not fund ALG-related activities. Such funding may be allowed in the future if standardized production and testing is achieved and its efficacy is demonstrated.

2-6 AWARDS

Awards for kidney projects will be issued as a part of the total award to the Regional Medical Program. The amount allocated for the kidney activity will be specified in Item 14, under "Remarks", of the Notice of Grant Award, Form HSM-457. Unexpended balances of funds awarded for kidney activities may be rebudgeted only with prior RMPS approval as specified in Chapter VII, Section 7-3, A.4.

In some cases, a kidney proposal may be approved by RMPS but unfunded. An RMP may fund such a kidney project through rebudgeting other RMP funds to the kidney activity. Rebudgeting of this nature should be undertaken only after the RAG has carefully considered the effect of such action on the remainder of the RMP program. Likewise, a kidney project may be expanded as determined by the RAG by rebudgeting of funds to the kidney activity in addition to those specifically indicated for kidney in the Notice of Grant Award.

III-1 DEFINITIONS

63. Operations Officer

title used to designate members of the staff of the Division of Operations and Development who assist and monitor assigned Regional Medical Programs.

64. Practicing Physician

any physician licensed to practice medicine in accordance with applicable State laws and currently engaged in the diagnosis and treatment of patients.

65. Program Staff (formerly "Core")

the staff employed by the RMP and their functions as contrasted with the staff and functions of operational activities. (See "Operational Activity.")

66. Provisional Indirect Cost Rate

a provisional indirect cost rate is a temporary rate established to allow the obligation and payment of funds RMP's grants, until such time as actual indirect costs can be determined and a final indirect cost rate established. Provisional indirect cost rates are subject to adjustment by OGAP at some future date. A provisional rate is used to compute indirect costs on grant applications and on grant reports of expenditures. (Also, see "Indirect Cost Rate," and Chapter VII-3.)

67. Publication Costs

those costs incurred for printing, distribution, promotion and general handling of publications, purchase of books, reprints, pamphlets, brochures, page costs, etc.

68. Region

1. Region

an individual Regional Medical Program

2. region

the area and population served by an RMP. (Also, see "HEW Region.")

69. Regional Advisory Group (RAG)

the advisory group designated to advise an RMP pursuant to Section 903(b)(4) of the Act.

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### III-1 DEFINITIONS

78. Self-Dialysis

dialysis performed by a trained patient at home or in a special facility with or without the assistance of a family member or friend.

79. Short Term Training

see "Training."

80. Staff Anniversary Review Panel

*that have been or are being reviewed*  
an internal RMPS staff committee appointed by the Director, RMPS, the primary function of which is to review applications for second and third year funding of applications and to rate Regions recommended for triennial support by the National Advisory Council. (Also, see Subchapter IV-3, 3-1.)

81. Supplies

expendable items which have an expected service life of less than one year. (Includes expendable items and spare parts.)

82. Tissue Typing

laboratory procedure used to determine the degree of compatibility between the donor organ and the recipient of a kidney transplant.

83. Training

1. Training Conferences and Seminars

presentations which are planned for full-time participation for periods from one full day to five consecutive days, or intermittently on a regular basis.

2. Short-Term Training

activities which are planned for full-time participation for more than five consecutive days, but not more than a single academic session (quarter or semester).

3. Long-Term Training

activities requiring full-time participation for more than a single academic session (quarter or semester).

## IV-9 MANAGEMENT SURVEYS

### 9-1 INTRODUCTION

The Grants Management Branch of the Division of Operations and Development, RMPS is responsible for conducting management surveys. These surveys are conducted by RMPS staff as a service to RMPs for the improvement of management. The survey team identifies and makes recommendations on areas which can be strengthened. Through this in-house type of review, ~~problems can be corrected before they affect a program adversely.~~ The reviews also assist the Regions in maintaining a high level of management capability and performance.

The survey's scope includes management practices of both the program staff and the grantee institution.

### 9-2 SURVEY PROCEDURES

#### A. Survey Team

The survey team usually consists of three people, (1) the team leader who is a member of the RMPS management survey staff, (2) the operations officer for the RMP, and (3) a grants management officer from either RMPS or the HEW Regional Office.

#### B. Preparation for the Survey

In preparing for a survey the team gathers as much information in advance as possible on the RMP. This involves discussions with the operations officer, the regional program director, and a review of RMPS files. Of particular value in preparation for the survey is the report on the verification of the RMPs review process, if such has been completed.

#### C. Survey Procedures

Surveys include interviews with RMP staff and review of documents. Selected advisory group members are also interviewed. Surveys normally are conducted for

*identified and RMPS management officials can be alerted to the need for corrective action*

## IV-9 MANAGEMENT SURVEYS

### I

three full days, beginning with a meeting with the coordinator and program staff and ending with an exit conference on the fourth day. During the initial meeting the coordinator gives the team a very broad overview of the RMP.

The team leader also explains to the coordinator and his staff how the survey will be conducted and each team member's responsibility.

Following the meeting each team member goes his own way to begin his part of the survey. Interviews are normally held with RMP employees at their desks rather than having employees come into a team room and appear before the entire team. Throughout the total review of management systems the team members must each be aware of an alert to other signals which they may receive since they also are reviewing internal communication within the RMP and the manner in which RMP business is directed, controlled and coordinated.

Each day throughout the survey the team meets and discusses its findings, conclusions, and potential recommendations. On the last morning the team meets with the Coordinator and representatives of the Regional Advisory Group and the grantee institution to present an oral report. -Nothing appears in the final written report of the survey team that has not been discussed at this meeting and that the RMP has not had an opportunity to rebut.

### 9-3 SCOPE OF SURVEY

#### A. Board and Regional Advisory Group

The composition and function of the Regional Advisory Group and Board of Directors of the grantee are examined to ascertain if the responsibilities of each have been identified, are properly divided, and are understood by both bodies. Committee activities are also reviewed to determine if members understand their missions, how well they coordinate relevant activities with other committees, and how effective the committees are. Program staff input in terms of providing information to committees is considered.

IV-9 MANAGEMENT SURVEYS

to the report has been received by RMPS either the operations officer or the regional program director conducts a follow-up visit to determine the adequacy of the region's implementation of recommendations.

9-6 GUIDE MATERIAL

The RMPS management survey activity is part of an overall department-wide effort to improve the quality of grantee management. As part of this departmental program, the Office of Grant Administration Policy in the Office of the Secretary has developed two guides for improving the quality of grantee management in financially dependent or independent organizations. (A financially dependent organization is one that receives 80 percent of its total support from DHEW grants.) Copies of these guides are available upon request from the Office of Grants Administration Policy, DHEW, 330 Independence Avenue, S.W., Washington, D. C. 20201. *of note*

## VI-1 GRANT ADMINISTRATION REQUIREMENTS

### 1-1 GENERAL RESPONSIBILITIES OF THE GRANTEE

The grantee is responsible for insuring compliance with all Federal requirements. Specifically every grant must be administered in accordance with (1) the Act, (2) the regulations thereunder, (3) other applicable regulations (i.e., Civil Rights), and (4) written Federal policies (e.g., the policies contained in this Manual). Grantees are also responsible for advising program staff, affiliates and all institutions and agencies participating in an RMP of the applicable Federal requirements and for instituting procedures to insure compliance.

Grantees are urged to safeguard their interests by requiring that institutions and agencies participating in the RMP execute a contract or affiliation agreement regarding the administration of RMP funds. It would be advisable for such an agreement to include appropriate references to the Act, regulations and this Manual, and, further, to provide for reimbursement of the grantee in the event of audit liabilities incurred by others in connection with carrying out the grant.

*x ref to  
VII - 5*

*have the  
approval of  
an attorney,*

### 1-2 ASSURANCES

The signature of the applicant's authorized representative on page 2 of the grant application provides assurance to the Federal Government that the grantee will comply with the required assurances discussed below.

#### A. Section 903

The following assurances are specified by Section 903(b) of the Act:

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1. reasonable assurance that Federal funds paid pursuant to any applicable grant will be used only for the purposes for which awarded and in accordance with the applicable provisions of the Act and the regulations thereunder;
2. reasonable assurance that the applicant will provide for such fiscal control and fund accounting procedures as are required by the Secretary to assure proper disbursement of and accounting for such Federal funds;
3. reasonable assurance that the applicant will make such reports in such form and containing such information as the Secretary may from time to time reasonably require, and will keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness and verification of such reports; and

VI-1 GRANT ADMINISTRATION REQUIREMENTS

4. a satisfactory showing that the applicant has designated an advisory group to advise the applicant (and the institutions and agencies participating in the resulting Regional Medical Program) in formulating and carrying out the plan for the establishment and operation of such Regional Medical Program which advisory group includes practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives from other organizations, institutions and agencies concerned with activities of the kind to be carried on under the Program and members of the public familiar with the needs for the services provided under the Program.

← Ref. VI-2

B. Section 904

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ref. to Det. →

The following assurances are specified by Section 904(b):

1. Federal funds paid pursuant to any applicable grant (a) will be used for the purposes for which paid and in accordance with the applicable provisions of Title IX and the regulations thereunder, and (b) will not supplant funds that are otherwise available for establishment or operation of the Regional Medical Program with respect to which the grant is made;
2. the applicant will provide for such fiscal control and fund accounting procedures as are required by the Secretary to assure proper disbursement of and accounting for such Federal funds;
3. the applicant will make such reports, in such form and containing such information as the Secretary may from time to time reasonably require, and will keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness and verification of such reports; and
4. any laborer or mechanic employed by any contractor or subcontractor in the performance of work on any construction aided by payments pursuant to any grant under this section will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 U.S.C. 276a--276a-5); and the Secretary of Labor shall have, with respect to the labor standards specified in this paragraph, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 FR. 3176; 5 U.S.C. 133z-15) and section 2 of the Act of June 13, 1934, as amended (40 U.S.C. 276c).

VI-1 GRANT ADMINISTRATION REQUIREMENTS

C. Civil Rights Assurance\*

A special assurance must be provided in relation to civil rights. Section 601 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 assistance.

No RMPS funds may be expended by or in behalf of any institution or agency which is not in compliance with Section 601. Compliance is signified by completion and submission of form HEW-441 (See Chapter IX.). The form only needs to be submitted once by any given organization. The Department maintains a list of organizations that have already filed a civil rights assurance.

Grantees are responsible for insuring that all affiliates and other institutions participating in the RMP submit HEW-441 where they have not already done so, and comply with the assurances given. In addition, all organizations participating in an RMP must comply with Executive Order 11346 as amended and superceded by Executive Order 11375 and 11478, respectively.

D. Animal Care Assurance

A special assurance relating to animal care must be submitted for any RMPS program staff or operational activity which involves the use of animals for research or other purposes. Such activities must be conducted in accordance with Departmental policies relating to animal care.

No RMPS funds may be used to support any activity involving the use of animals unless the grantee or other appropriate institution has filed a specific written assurance relating to animal care. The assurance must provide that the institution will evaluate its animal facilities on a continuing basis in regard to the care, use, and treatment of animals in a manner consistent with (1) standards established by the Animal Welfare Act (P.L. 89-544, as amended), (2) the HEW "Guide for the Care and Use of Laboratory Animals," and (3) other Department requirements. Where the applicable institution has previously submitted the required animal care assurance, no further action is necessary, since the assurance only needs to be submitted once.

*Consider  
omission  
of this  
para.*

Requirements relating to animal care are administered by the National Institutes of Health, not RMPS. Inquiries, assurances and other communications relating to animal care should be addressed to the Division of Research Grants, NIH, Bethesda,

\*See Chapter IX, CIVIL RIGHTS, which includes applicable regulations, Executive Orders, forms, and instructions.

## VI-1 GRANT ADMINISTRATION REQUIREMENTS

### 1-3 POLICIES RELATING TO SAFEGUARDING OF INDIVIDUALS

#### A. Protection of Human Subjects

Where applicable to any RMPS supported activity, a plan for the protection of human subjects must be submitted and approved in accordance with Chapter 1-40 of the RMPS Grants Administration Manual. The plan must be applicable to the institution directly responsible for the activity in question (i.e., the institution identified as the project sponsor on pages 15 and 16 of an application, RMP-34-1). Where such plan is already in effect as noted in item 6 on page 3 of an application, no further approvals are necessary. (Also see Chapter VII-2, 2-2, B, 25, "Patient Care.")

A plan for the protection of human subjects is required when any individual would be "at risk" - exposed to the possibility of physical, psychological, sociological or other harm - as a result of RMPS supported activities. No RMPS funds may be expended for such activities unless the required plan has been approved.

Plans for the protection of human subjects are reviewed and approved by the National Institutes of Health, not RMPS. Inquiries relating to further requirements and instructions for submission of plans should be addressed to the Division of Research Grants, NIH, Bethesda, Maryland 20014. Copies of all correspondence should be sent to RMPS. No RMPS funds may be used for any activity involving human subjects, however, without prior RMPS approval in accordance with Subchapter VII-7.

#### B. Confidentiality of Information

Where applicable, RMPS supported activities must be conducted in a manner which insures that information obtained from or about individuals be treated confidentially to protect the individual's right to privacy. Clinical information, for example, may be used in statistical tables, but may not be disclosed in a manner that would identify the specific individuals from whom it was obtained.

### 1-4 GRANT GENERATED MATERIALS

#### A. Patents and Inventions

Patents or inventions made in the course of, or under, any grant must be promptly and fully reported to the Department in accordance with Department regulations (45 CFR, Subtitle A, Parts 6 and 8). No commitments or obligations may exist or be made which conflict with this requirement. An invention is any process, art or method, machine, manufacture or improvement thereof, which is new and useful and would not have been obvious to a person skilled in the art to which it relates.

VI-1 GRANT ADMINISTRATION REQUIREMENTS

The completion of item 5, "Inventions," on page 3 of a grant application, RMP-34-1, provides the notice required above. Notice of patents and inventions may also be provided by filing an "Invention Statement," form PHS 3945 (which is attached). The latter should be forwarded to the Grant Application and Document Control Office, Public Health Service, 9000 Rockville Pike, Bethesda, Maryland 20014. When notice of an invention has been provided either through the application or an Invention Statement, the reporting institution will be sent a "Grantee Invention Report" form which must be completed and returned to the appropriate office in accordance with instructions.

A final Invention Statement must be submitted on PHS 3945 for each operational activity after termination of RMPS support.

B. Publications

Publications relating to RMP activities may be produced without prior review or approval by RMPS, provided that the title page includes an acknowledgment of RMPS support and indicates that findings and conclusions do not necessarily represent the views of the Federal Government. (Also see Subchapter VII-2, 2-1, B, "Printing and Publication Costs.")

C. Copyright

When publications, films, or similar materials are developed with RMPS support, the <sup>grantee</sup> author is free to arrange for copyright without approval. Copyrighted materials are subject to a royalty-free, nonexclusive and irrevocable license to the Government to reproduce, translate, and publish them, and to authorize others to do so. (Also, see Subchapter VII-2, 2-2, B, "Films and Videotapes," and Subchapter VI-1, 1-4, D, below.)

D. Distribution of Films, Videotapes, and other Audiovisual Materials

1. Production Authority

Grantee or their affiliated institutions may produce and distribute audiovisual materials, or contract for such production and distribution of such audiovisual materials that have been produced with RMPS funds, provided that such audiovisual materials include the required acknowledgment of RMPS assistance and the disclaimer required by Subchapter VI-1, 1-4, B, above. (Also, see VII-2, 2-2, B, "Films and Videotapes.")

2. Ownership

Audiovisual materials produced for the grant with RMPS funds are the property of the Federal Government. In order for this, any contract entered into for the production and/or distribution of such audiovisual materials would have to be between the grantee and the distributing or producing organization.

Word distribution not deemed appropriate since sub-sections cover more than distribution

## VI-1 GRANT ADMINISTRATION REQUIREMENTS

### 3. Derived Income

Audiovisual materials produced with RMPS funds are copyrightable subject to the provisions of Subchapter VI-1, 1-4, C, above, regarding the reproduction and distribution rights of the Federal Government. Grantees should copyright audiovisual materials produced through grants, since the copyright would afford grantees a legal basis for receipt of any income derived from the distribution of such materials.

All royalties or other fees received by grantees or their affiliated institutions from the use of distribution of audiovisual materials produced with grant funds, up to the amount they charged to the grant for production of the audiovisual materials, must be refunded to the RMPS. In this regard, grantees shall be responsible for maintaining records for the receipt and disposition of the Federal share of income received from the distribution of these audiovisual materials in the same manner as required for the funds provided by the grant which gave rise to this income. Upon notification from a grantee that income has been generated from the distribution of the audiovisual materials, grantees will be advised as to the disposition of such funds. Any income received by a grantee or an affiliated institution from distribution of these audiovisual materials that is over and above the amount that is charged to the grant may be used by the grantee at its discretion. (See Subchapter VII-4, "Grant Related Income.")

### 4. Required Approvals

*Should be 1-1 →*

RMPS requires that its grantees comply with Chapter 1-450 of the HEW Grants Manual, entitled, "Use of Grant Funds for the Production of Motion Picture Films," which prescribes certain procedures which must be followed when motion picture films are produced with Federal grant funds. RMPS applies the provisions of this Chapter to all audiovisual materials produced in connection with RMPS support. Grant funds may be used without prior approval to produce audiovisual materials which are intended for viewing by restricted audiences in connection with a program or project conducted by a grantee or an affiliated institution. Prior RMPS approval is necessary, however, when the intended audience for the audiovisual materials to be produced would be available to general audiences. (See Subchapter VII-2, 2-2, B, "Films and Videotapes.")

Chapter 1-450, however, does not (1) restrict the distribution of these audiovisual materials once produced in accordance with the policy contained therein; and (2) is not applicable to audiovisual materials produced under other Federal grant programs.

VI-1 GRANT ADMINISTRATION REQUIREMENTS

1-5 RECORD KEEPING AND REPORTING

A. Accounting

Accounting for grant funds will be in accordance with generally accepted principles consistently applied, regardless of the source of funds. All supporting records of project expenditures must be compatible with RMPS reporting requirements.

B. Retention of Records

All grantees and/or their affiliated institutions are required to maintain grant accounting records, identifiable by grant number, until audit ~~by or~~ on behalf of the Department or five years after the end of the final budget period, whichever is less. Accounting records must contain adequate references for identifying and locating original documents in support of direct costs. These include invoices, checks, time records, and payrolls, etc.

omit  
omit  
word  
final

1-6 PROGRAM CHANGES

A. Change of Chief Executive Officer

RMPS must be notified whenever a new Chief Executive Officer (Coordinator) is appointed for an RMP. Such notification must also be given when any individual is appointed to act in such capacity when a vacancy exists.

B. Change of Grantee Institution

Insert  
Lead in  
that these requirements  
for new non-profit  
grantees, other  
than estab. educ.  
institutions.

1. General

If for any reason a grantee proposes to relinquish responsibility for a Regional Medical Program grant, it must immediately notify the Director, Regional Medical Programs Service. A change of grantee occurs most frequently when a new nonprofit corporation is established to administer an RMP. Where a change of grantee is contemplated, old and new grantees should, however, work out arrangements for completing and submitting necessary reports or other information, and for the smooth transfer of responsibilities.

2. Approval

Insert  
Upon request  
change in grantee  
may be required to  
be approved by  
Director, RMPS.

In the absence of any significant changes in program the Director, RMPS may approve a change of grantees. The Director, however, may request approval of the National Advisory Council when, in his judgment, such action is necessary. Where there is a change of grantee, a new Notice of Grant Award will be issued to the new grantee.

## VI-1 GRANT ADMINISTRATION REQUIREMENTS

### 3. Required Materials

The following materials must be submitted to carry out a change of grantee:

- a. Articles of Incorporation
- b. Corporate By-Laws
- c. Listing of the Board of Directors
- d. Listing of Officers of the Corporation
- e. Policy statements regarding Personnel, Staff Benefits and Travel Practices (as these are developed, in the case of a newly organized nonprofit corporation)
- f. Policy statements regarding fiscal and other handling, taxes, direct taxes, indirect costs, etc. (as these are developed, in the case of a new nonprofit corporation)
- g. Evidence of nonprofit status with the Internal Revenue Service
- h. DHEW Form 441 (Assurance of Compliance/Title VI of Civil Rights Act of 1964 if not previously submitted by the new Grantee institution. See Chapter IX, Civil Rights.)
- i. List of Members of the Regional Advisory Group (if different)
- j. Regional Advisory Group By-Laws (if different)
- k. OMS Circular A-95 clearance, state concurrence with the intent of the application for a planning grant
- l. A letter of concurrence in the change from the terminating grantee
- m. A final report of expenditure from the terminating grantee on form AMP-34-1 within 120 days of the termination date
- n. A final Invention Statement from the terminating grantee on form PHS-3945 within 120 days of the termination date (See Subchapter VI-1, 1-4, A.)
- o. Where applicable, a plan for the protection of human subjects covering the new grantee (See Subchapter VI-1, 1-3, A.)

*from existing corporate or current RAG by laws.*

VI-1 GRANT ADMINISTRATION REQUIREMENTS

*fidelity bond only - error of omission clauses.*

*require one-months normal draw of federal funds rather than \$100,000.*

p. Where applicable, an assurance relating to animal care covering the new grantee (See VI-1, 1-2, D)

q. A ~~performance fidelity~~ bond for no less than \$100,000 payable to the United States of America-DHEW-PHS-RMPS

r. A formal application signed by an authorized official of the new grantee and including the following:

(1) A new page 1 and 2 of RMP-34-1 including the signature of an authorized representative of the new grantee institution on page 2.

(2) A statement adopting the application of the original grantee and agreeing to any conditions of the award with respect to those activities to be assumed by the new grantee and clearly indicating which activities, if any will not be undertaken (i.e., in some cases, new RMPs have split off from an existing RMP and divided the ongoing activities between them)

(3) Appropriate pages of the application revised as necessary to reflect any significant changes from the original application submitted by the old grantee.

(4) Revised Budgets showing the amounts needed by the new grantee for the remainder of the current budget period and any revision of amounts estimated to be required for future periods of recommended support as shown in item 15 of the Notice of Grant Award issued to the original grantee

4. <sup>S.K</sup> Payments to the New Grantee

A system of payment for the new corporation must be established with the Office of Financial Management, National Institutes of Health, prior to processing any Notice of Grant Awarded to the New corporation. (See Subchapter VII-6.)

*list of equip transferred from old to new grantee*

C. Early Termination of Grant

1. By the Grantee

A grant may be terminated or cancelled at any time by the grantee upon written notification to the Director, Regional Medical Programs Service, stating the reasons for, and effective date of termination.

VI-1 GRANT ADMINISTRATION REQUIREMENTS

2. By RMPs

A grant, in whole or in part, may be revoked or terminated by the Director, RMPs, at any time within the program period whenever it is determined that the grantee has failed in a material respect to comply with the terms and conditions of the grant.

*ADD*  
1-7 HEW Appeal procedure

Change title to "Model"

VI-3 AFFILIATION AGREEMENTS

3-1 NEED FOR AGREEMENTS

By its nature, an RMP will involve a number of different institutions, organizations, and agencies in addition to the grantee. In order to assure accountability for Federal funds and conformance to other requirements, and to protect the grantee against audit liabilities by these additional agencies, an Agreement of Affiliation must be concluded between each affiliating institution (or agency) and the RMP grantee. Such an agreement will not be required nor appropriate in the conduct of business with (1) a profit-making organization by (subcontract), or, (2) where direct payment is to be made for the use of facilities or for services rendered on behalf of the Regional Medical Program. A minimal type of agreement is illustrated below.

change to "should usually"

eliminate "Sub"

A. Model Affiliation Agreement

That an Affiliated Institution, for and in consideration of mutual benefits, shall

1. Be cognizant of and comply with the intent and purpose of Title IX of the Public Health Service Act (P.L. 91-515) as set forth in Sections 903 and 904 of the Act or any amendments thereto.
2. Administer all grant funds received through the Grantee Institution of the Regional Medical Program in accordance with the regulations and policies of the granting or funding agency.
3. Comply with all rules, regulations, or policies as may be adopted by the Regional Advisory Group, an integral part of the Regional Medical Program.
4. Keep such records as may be required by the granting agency or the Regional Medical Program and provide such information, reports, or documents as may be required for the Grantee Institution or the Coordinator to administer the grant properly.
5. Assume sole responsibility of such program for reimbursement to the granting or funding agency a sum of money equivalent to the amount of any expenditures disallowed, should the granting or funding agency or an authorized auditing agency rule, through audit exception or some other appropriate means, that expenditures allocated to

in the philosophy of RMPs include at least the following points.

change 89-439a amended

VII-1 GENERAL FINANCIAL MANAGEMENT  
PRINCIPLES AND REQUIREMENTS

1-1 APPLICABILITY OF POLICIES

In the absence of any contrary provisions of the Law, regulations, or written and announced Federal policies, the policies of the grantee institution or the affiliate are applicable whichever is more restrictive.

1-2 UNIFORM TREATMENT OF GRANTS AND INSTITUTIONAL FUNDS

Institutional policies applied to the management of grant funds must apply equally to all institutional activities irrespective of the source of funds. This means that the institution must have the same policies for expenditures from grants as for expenditures for non-Federally supported activities.

1-3 UNIFORM TREATMENT OF SALARY SCHEDULES

No supplementation of normal salaries in accordance with institutional policies is permitted for employees who are paid from grants. (See Subchapter VII-2, 2-2, B, "Salaries and Wages.")

1-4 PRIOR APPROVALS

A. When Required

The following cost categories and types of activities require prior approval by RMPs before such costs may be incurred for the purposes indicated:

1. Foreign Travel
2. Certain categories of printing (See details under Subchapter VII-2, 2-2, B, "Printing and Publication Costs.")
3. Certain Types of Films and Videotapes (See details under Chapter VII-2, 2-2, B, "Films and Videotapes." Also, see Subchapter VI-1, 1-4, D, "Required Approvals.")
4. New construction (See Chapter VIII.)
5. Patient care
6. Certain classes of drugs (See Chapter VII-2, 2-2, B, "Drugs.")
7. End stage kidney disease (dialysis and transplantation)
8. Activities jointly funded by two or more RMPs (See Subchapter VII-7 7-2, D.)
9. Obligation of funds derived from grant related income (See Subchapter VII-7, 7-1, E.)

also ref to  
T-1

VII-1 FINANCIAL MANAGEMENT REQUIREMENTS

10. Experimentation or other activities involving use of human subjects (See Subchapter VI-1, 1-3, A, "Protection of Human Subjects.")
11. Alterations and renovations (See Subchapter VII-7, 7-3, A and B and Chapter VIII.)
12. Feasibility studies related to "Health Maintenance Organizations," (HMOs).
13. Any other cost or type of activity for which approval is required by (1) this Subchapter, (2) other requirement included in this Manual, or (3) the HEW Grants Administration Manual.

B. Nature of Approvals

The applicant or grantee is responsible for requesting approval as necessary. This may be done by letter to RMPS. In addition, inclusion of costs such as those enumerated in 1-4, A, above, in a final budget submitted to support an award constitutes prior approval unless otherwise specified in the award.

1-5 LIMITATION ON CONSTRUCTION COSTS

RMPS participation in the cost of construction (inclusive of alteration and renovation and built-in equipment) is limited to 90% of the total costs including, in the case of built-in equipment, the cost of delivery and installation. (Also, see Chapter VIII.)

1-6 ALLOCATION OF COSTS TO THE GOVERNMENT

A. Chargeable Costs

Costs incurred by the grantee or affiliate which are otherwise allowable, may be charged to a grant only to the extent that such costs have actually been paid or incurred in the course of bona fide transactions. This means that grant funds may not be used to reimburse an institution for donated services, space, equipment or supplies. Likewise, grant funds may not be used to reimburse an institution for space and equipment already owned by the institution. Depreciation for such space and equipment can be used to justify an indirect cost rate. Previously owned equipment, however, may be charged directly to a grant where withdrawn from a central stockroom in accordance with institutional policy. (Also see Chapter VII-2, 2-2, B, "Rental of Space.")

B. Determination of Necessary Expenditures

Expenditures for allowable costs required to carry out a Regional Medical Program within the total direct costs awarded

change in salary scales. Such studies should be supported by a synopsis of the salary levels of full-time professional and non-professional personnel employed by at least three major institutions of various types in the geographic area served by the RMP (e.g., hospitals, educational institutions, professional societies, voluntary agencies, etc.). RMPS will not consider salary levels paid by other Regional Medical Programs as appropriate support for salary levels established by an RMP in a different geographical area.

1-9 BONDING REQUIREMENTS

All non-profit organizations that are established solely for the receipt and administration of an RMP grant must obtain fidelity/or performance bond insurance which will assure RMPS of the proper performance and maintenance of Federal Funds.

A performance bond usually provides an assurance guaranteeing that the organization will perform its duties and faithfully account for the Federal funds awarded in accordance with the RMPS enabling legislation.

A fidelity bond, as distinguished from burglary insurance provides coverage solely for losses resulting from the dishonest acts of employees of an organization, while burglary insurance coverage other than such dishonest acts of employees of such organization.

Whether an organization secures either a fidelity or a performance bond, either must include the provisions of each, and copies of such must be furnished to RMPS prior to the issuance by RMPS of an initial grant award to such newly-established non-profit organization.

Provision should be made that both types of coverage continue for the length of RMPS support. The coverage secured must provide for payment of the amount of the coverage in the result of any defalcation to the United States of America - DHEW-PHS-RMPS. The fidelity bond should normally provide theft insurance in the amount of one month's normal draw of funds from the Federal treasury.

1-10 MANAGEMENT OF AND ACCOUNTABILITY FOR EQUIPMENT ACQUIRED WITH RMPS FUNDS

A. General Provisions

Title to equipment acquired with RMPS funds is normally vested in the grantee institution, irrespective of whether the equipment is acquired by the grantee or one of its affiliated organizations. Thus, although an affiliated institution purchases equipment with grant funds for a specific RMP activity, title to, and accountability for equipment is normally vested with the grantee institution for the life of the equipment.

Grantees, however, may request RMPS to grant permission for a

*leave out titles of bonds & only indicate what bonds should cover.*

*either partially or fully with . . . .*

*What about NID on major purchases.*

## VII-1 FINANCIAL MANAGEMENT REQUIREMENTS

purchased with Title IX grant funds from the grantee to either an affiliated institution or an institution not affiliated with the RMP, as long as there is an assurance that the equipment will be used in support of an activity specifically approved by the RMPS or an activity that would be supportable under Title IX of the PHS Act.

### B. Management Requirements

Grantees and their affiliates are expected to apply to equipment acquired with RMPS funds the same policies, procedures, and controls normally applied to all of their other equipment, provided that the following requirements are met.

#### 1. Acquisition

Grantees and affiliates are required to be prudent in the acquisition and management of equipment acquired with grant funds. Careful screening should take place to assure that equipment is needed and that the need cannot be met with equipment already in the possession of the institution. A grantee of an affiliate may be reimbursed for an item of equipment already owned by the respective institution only when such equipment is in an institution's central purchasing department and held in a central stock room for issuance and sale to a using activity.

For purposes of charging the grant, the cost of a single item or piece of equipment includes necessary accessories, duty, excise and sales taxes. If the institution policy provides that charges for transportation, protective in-transit insurance, and installation are a part of the cost of equipment, such charges may be included as direct costs of equipment.

#### 2. Sale or Trade

When equipment is sold by a grantee or an affiliate, the net proceeds of sale must be credited to the grant account. Equipment for which accountability has not been waived may be disposed of by the grantee after termination of the project period provided the grant account is credited with the fair market value as of the date of disposition of such equipment. The accounting obligation shall apply to that portion of new equipment that has been purchased by using accountable equipment as a credit or trade-in. (This is not applicable to equipment which has a residual value of less than \$100.)

*Requires RMB  
OMB approval.*

VII-1 FINANCIAL MANAGEMENT REQUIREMENTS

3. Lost, Damaged, or Destroyed Equipment

When accountability has not been waived, the grantee will be responsible, using other than RMPS grant funds, for replacement or repair of, or compensating the grant account for equipment that is lost, damaged, or destroyed due to negligence on the part of the grantee.

4. Depreciation and Use Charges

Depreciation or use charges for any equipment or portion of such equipment acquired with Federal funds may not be charged against RMPS funds either as a direct or indirect cost. The records of grantee institutions must therefore identify equipment purchased with RMPS funds to assure exclusion of such equipment from depreciation or use charges claimed for Federal participation.

C. Requests for Waiver of Title and Accountability

Once support of an activity is terminated, it is expected that the affiliated institution will continue to support the activity. However, when support of the activity is discontinued, the institution sponsoring the activity may no longer be affiliated with the grantee institution who has retained title to and accountability for the equipment purchased for the activity. In order to permit the institution supporting the activity to retain possession and obtain title to and accountability for such equipment, grantee institutions may relinquish title to, and accountability for such equipment, in the following manner:

1. The RMPS Grants Management Branch will entertain requests from grantees to transfer either title to or accountability for equipment, or both, to another institution upon termination of project support.
2. Upon receipt of such requests, RMPS will advise grantees as to whether their disposition of the equipment is approved, or if the RMPS has other plans for the equipment for which disposition instructions will be forwarded to grantees.
3. Grantees will be responsible for documenting their records, and advising the Grants Management Branch of the basis for the proposed action. This documentation should include as a minimum an itemization of the specific equipment to be transferred with signed disposition and receipt records by responsible parties of each institution and an assurance from the recipient institution that such equipment will be used for the furtherance of RMPS activities. Subsequent to approval by RMPS of the proposed action, grantees may make final arrangements for the transfer of title to or accountability for the proposed equipment or both.

*should be revised to indicate that equip. can be transf. within grantee instat.*

VII-1 FINANCIAL MANAGEMENT REQUIREMENTS

A

To: Regional Medical Programs Service

From: Grantee Institution

The requested transfer is recommended for approval. If approved by Regional Medical Programs Service, the affiliated institution will be advised at the time of transfer regarding its responsibilities for the making and use of such equipment, the maintenance of appropriate records, and the rights of the U.S. Government should the institution not fulfill its obligations as certified above.

*maintenance*

Authorized Office, Grantee Institution

VII-2 ALLOWABLE COSTS

RMPS funding is also allowable for specific CAE studies in Regions that have the technological expertise, facilities, and potential EKG volume necessary to support an economical CAE system. Such staff support may take the form of participation in assessment of needs; resources and priorities; technical consultation; organizational counseling; and institutional liaison.

CAE systems receiving RMPS support on or before March 7, 1971 will be continued under the terms of their current approvals. Addition support beyond the currently recommended period of support is subject to the restrictions stated above.

10. Construction - Allowable (See Chapter VIII.)

11. Consultant Fees

Consultant fees, including supporting costs such as travel and per diem, are allowable. (See this Subchapter, "Contracts," and "Salaries and Wages.") Consultant Services must be procured and compensated in accordance with institutional policies.

An employee of the grantee or affiliate not normally employed in connection with RMP may be employed as a consultant by a Regional Medical Program. In order to be paid as a consultant such individuals must perform services for the RMP beyond his normal work week as determined by institutional policy. An individual employed as a consultant by an RMP is acting as a private contractor in relation to the RMP and must be appointed as such. Consultants may be compensated directly for individual services rendered to the Regional Medical Program.

Employees of the grantee or affiliate paid for services rendered to a Regional Medical Program within their normal work week as determined by institutional policy are not to be considered consultants. The grantee or affiliate institution may be reimbursed in accordance with time or effort in connection with RMP for the salary of such employees. In such cases the individual employees receives his normal salary from the institution, and additional compensation is not allowable.

Consultant fees may be paid to members of the Regional Advisory Group who sustain a loss of salary due to the absence from their place of employment. Efforts should be made to hold such meetings at an opportune time to prevent the loss of salary.

*only to non-professionals*

When reimbursement of RAG members is contemplated for loss of salary, efforts should be made to limit payments to the minimum amount necessary to maintain the member's place of employment.

*should be expanded to include:*  
1) An employee of one RMP can be a consultant to another RMP during his normal work week, but only be paid travel & subsistence  
2) Individual perform consulting services on regular basis should be paid part-time salary basis.  
3) RAG members may not be paid consultant fees unless their services are required for other than their normal functions as a RAG member.

VII- 2 ALLOWABLE COSTS

12. Contingency Funds or Reserves--Not Allowable.

13. Contracts

Allowable in accordance with grantee institution policies. It is considered advisable to discuss proposed contracts in advance with the RMPS Regional Office Representative. (See "Consultant Fees," this Subchapter. Also See Subchapter VII-5, "Subcontracting by Grantees.")

*eliminate  
as useless  
discuss  
contract*

14. Dependency Allowances-- See "Training Costs," this Subchapter.

15. Direct Assistance

Allowable. At the Request of any recipient of a grant for a Regional Medical Program, the payments to such recipient may be reduced by the fair market value of any equipment, supplies, or services furnished by the Secretary to such recipient and by the amount of the pay, allowance, traveling expenses, and any other costs in connection with the detail of an officer or employee of the Government to the recipient when such furnishing or such detail, as the case may be, is for the convenience of and at the request of such recipient and for the purpose of carrying out the Regional Medical Program to which the grant is made.

16. Dialysis -- See "Kidney Disease Activities," This Subchapter

17. Drugs

Allowable. Grantees are encouraged to adopt policies and procedures which will ensure the most economical expenditure of funds for the acquisition of drugs and biologicals for research, training, or patient care, consistent with acceptable standards of identity, strength, safety, quality, purity, and effectiveness. When not contraindicated, drugs should be purchased under their nonproprietary or generic names. (See Chapter 1-50 of Grants Administration Manual.)

RMPS funds shall not be used without prior approval to purchase drug products classified "ineffective" or "possibly effective" by FDA. Lists of drug products that have been declared "ineffective" and "possibly effective" are available from the Office of Grants Management, HSMHA, Parklawn Building, Rockville, Maryland 20852. Classifications of drug products are available from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

VII-2 ALLOWABLE COSTS

18. Dues, Institutional

18 Costs of the grantee or affiliate institution's membership in civic, business, technical, and professional organizations are allowable.

19. Dues, Personal

Costs of personal memberships in civic, business, technical and professional organizations are allowable only to the extent that they are (1) limited to one individual per headquarters or major field installation of the Regional Medical Program; (2) can be purchased at a lower price than institutional membership; (3) are required to obtain publications necessary to the program.

20. Entertainment

Costs of amusements, social activities, entertainment, or incidental costs related thereto are not allowable.

21. Equipment

Rental and purchase of equipment, including diagnostic and treatment equipment, for the planning or implementation of a program is allowable. When acquiring major items of equipment, consideration of the relative advantages of lease versus purchase should be considered. (See Subchapter VII-1, 1-10.)

*including maintenance of, tax on, & delivery of equipment.*

22. Federal Employee Compensation

Grant funds may generally not be used to pay fees and supporting costs to U.S. Government employees regardless of their employment or pay status, except that grant funds may be used to pay consultant fees to U.S. Government employees when:

a. These employees are medical personnel of the Uniformed Services of the United States (excepting commissioned officers of the Public Health Service) qualified to provide the kind, type, and extent of medical services approved in the grant award.

b. Adequate numbers of qualified civilian medical personnel are not available to provide the kind, type, and extent of medical services approved in the grant award and medical personnel of the Uniformed Ser-

in addition to those qualified civilian medical personnel, if any, who are available.

- h. Satellite Dialysis Facilities -- Allowable where appropriate to serve the backup needs of patients who are geographically removed from tertiary care facilities.
- i. Tissue Typing -- Allowable for start-up costs provided that the tissue typing labs are not redundant and duplicative.
- j. Transplantation -- Allowable for establishment of transplantation programs in areas of need. Direct patient care costs are not allowable.

30. Legal Fees

Allowable when separately incurred specifically for a grant-related purpose, such as establishment of a new corporation to administer the RMP or the development of new nonprofit educational consortia. Where legal fees are incurred by the grantee or affiliate on a "retainer basis," however, they may be reimbursed only through the indirect cost allowance and may not be charged directly to the grant.

Low-overhead Limited-care Dialysis

See "Kidney Disease Activities," this Subchapter (Also see Subchapter X-2.)

32. Patient Care

Allowable for hospital, medical and/or other care of patients which is incidental to research, demonstration or training activities. No patient shall be furnished hospital, medical, or other care at any facility unless he has been referred to such facility by a practicing physician, or dentist as appropriate.

No experimentation with human subjects shall be carried out without specific prior approval by RIMS. In addition, activities of this nature shall be conducted only in accordance with a plan for the protection of human subjects approved by the National Institutes of Health. (See Subchapter VI-1, 1-3, A, "Protection of Human Subjects." Also see Subchapter VII-1, 1-4, A.)

33. Insurance

Allowable for premiums on liability insurance to cover personnel or equipment directly connected with the program.

34. Meals

Allowable within institutional policies provided that costs

alcoholic beverages or entertainment may be charged to the grant account. Meals may not be charged separately where per diem is paid.

*Should be expanded since single purpose nonprofit organization may not have IDC rate & have legal services provided on retainer basis.*

*out of alphabetical order*

VII-2 ALLOWABLE COSTS

35. Organ Procurement

See "Kidney Disease Activities," this Subchapter. (Also see Subchapter X-2.)

36. Organ Procurement and Communication Activities

See "Kidney Disease Activities," this Subchapter. (Also see Subchapter X-2)

37. Printing and Publication Costs

Allowable, except that any grant activity which would require printing in excess of 5,000 units of one page or 25,000 units in the aggregate of multiple pages must be considered as printing substantially for the Government and must be done through regular Government channels. (See Grants Administration Manual Chapter 1-463. Also see Subchapter VI-1, 1-4, B and C.)

38. Recruitment Costs (for recruiting staff for RMP activities)

Allowable only for full-time employment on RMPs supported activities, if payment of such costs is normally made by the grantee, or affiliate, regardless of source of funds. Costs may include moving the individual, his family, dependents, and household goods. Costs of relocating an employee must be credited to the grant account when the employee resigns within 12 months after employment for reasons within his control. Not allowable for individuals recruited for part-time or temporary employment.

change household goods to personal belongings.

39. Recruitment, Health Careers (as a program staff or operational activity)

Not allowable for direct recruitment of individuals into health careers. RMP program staff activities related to stimulating, planning and coordinating health careers recruitment by appropriate institutions and agencies in the area served by the RMP, however, is allowable. RMPs are encouraged to use staff assistance to stimulate cooperative efforts between professional associations, clinical resources, educational institutions and other appropriate agencies to provide new opportunities for recruitment into health careers and to plan health careers recruitment activities as part of and coordinated with the overall manpower strategy for the area served.

40. Rental of Space

Allowable when charges are made in conformance with normal grantee policies regardless of the sources of funds. No rental charge may be made for space owned or controlled (managed or administered) by the grantee or by an affiliate;

in indirect cost. Also, when an organization transfers a facility to a third party through sale, lease, or otherwise,

## VII-2 ALLOWABLE COSTS

and then leases the facility back from that third party, the lease costs which may be charged to the grant may not exceed the equivalent of the "cost of ownership"

### 41. Salaries and Wages

Allowable for time spent on a grant-supported activity. (See Chapter VII, 1-8, "Salary Comparability Studies.") No supplementation of base salary is permitted. (See B, 9, "Consultant Fees," above.) Salary and wage rates must be in conformity with those permitted by institutional wage and salary scales and policies. RMP program staff salaries should be reasonable and not exceed the salaries of full-time personnel with equivalent responsibilities in major medical institutions in the Region. Direct charges for professionals must be supported by either:

- a. An adequate appointment and workload distribution system, accompanied by monthly reviews performed by responsible officials and a reporting of any significant change in workload distribution of each professional (i.e., an exception reporting system) or
- b. A monthly after-the-fact certification system which will require persons in supervisory positions having firsthand knowledge of the services performed to report the distribution of effort (i.e., a positive reporting system). Such reports must account for the total salaried effort of the persons covered. A system which provides for the reporting only of effort applicable to Federally-sponsored activities is not acceptable.
- c. Direct charges for salaries and wages of non-professionals must be supported by time and attendance and payroll distribution records.

An employee or consultant may receive additional compensation for services performed for an RMP, where such services are performed within the individual's full-time work week. (See B, 9, "Consultant Fees," above.)

The grant may be charged in proportion to the percentage of time or effort an individual devotes to the grant within his full-time work week.

### 42. Satellite Dialysis Facilities

(See Chapter VII, 1-8, "Salary Comparability Studies," and Subchapter A-2.)

### 43. Stipends

VII-2 ALLOWABLE COSTS

45. Transplantation

See "Kidney Disease Activities," this Subchapter. (Also see Subchapter X-2.)

46. Taxes

Allowable only for those taxes which an organization is required to pay in connection with employment, services, travel, renting, or supplies.

47. Travel

Allowable when travel is required in connection with RMP activities. No foreign travel may be charged to an RMPS grant without prior approval by RMPS. Institutional policies will govern travel expenditures and reimbursement of individuals for travel, except that less than first class air travel must be used when available. In the absence of institutional travel policies the HEW travel regulations apply.

Tuition and Related Costs for Employees of RMPs and Affiliates

Allowable for employees of a Federally supported activity when such employees can contribute more effectively to the conduct of the activity by obtaining training related to the purpose of the activity.

Tuition is not allowable for training courses taken by an RMP employee to acquire basic skills unless provided as an institutional fringe benefit, or as part of an institutional program to upgrade the skills or knowledge of employees with economically or educationally disadvantaged backgrounds.

*Foreign travel should indicate that it does not include Canada, but does include Mexico, not appl. partially to Hawaii Rmp.*

## VII-3 INDIRECT COSTS

### 3-1 NATURE OF INDIRECT COSTS

#### A. Definition and Elaborations

Indirect costs are those costs of an institution which are not readily identifiable with a particular project or activity, but nevertheless are necessary to the general operation of the institution and the conduct of the activities it performs. Indirect costs are not peculiar to government sponsored activities, as they are generated to some extent by all business ventures. Indirect costs are normally calculated as a percentage of either (a) direct salaries and wages, or (b) total direct costs exclusive of capital expenditures. Indirect costs are paid as a lump sum to the institution and may be used for general institutional purposes without further accounting to the Federal Government. (Also, see Subchapter VII-1, 1-6, C.)

"earned by"  
rather than  
pl & lump sum.

#### B. Examples of Usual Types of Indirect Costs (Also see Chapter VII, 1-6, C)

The following type expenses of an institution are normally considered as indirect costs, and are reimbursed to an institution by means of an indirect cost rate:

1. The cost of operating and maintaining buildings and equipment--which usually includes: heating, air conditioning, lighting, service cleaning and maintenance contracts, and minor repairs.
2. Depreciation--which usually includes writing off the cost of buildings and equipment over their estimated useful life.
3. Salaries of administrative officials concerned with general management of the institution--usually include the personnel employed in central executive offices, the purchasing office, the public relations office, and the accounting and finance departments.
4. General telephone expenses--which usually include the monthly rental and usage charge for all telephone and long distance calls by the administrative staff.
5. General travel, supplies, and other expenses--which usually include all travel by the central administrative staff (not program staff), all supplies necessary for the operation and maintenance of the building, as well as the offices and facilities within the building, and the insurance, payroll taxes, other taxes, and any other fringe benefits, generated by the administrative payroll.

## VII-3 INDIRECT COSTS

### C. Incurrence of Indirect Cost

Where any of the above types of costs or other central service costs are used by a grantee or affiliated institution to justify an indirect cost rate in connection with RMP supported activities, the services for which the costs are incurred must actually be provided to the grant supported activity. (e.g., if all equipment and supplies for an activity are purchased by the RMP program staff, an affiliated institution sponsoring the activity could not include the costs of its central purchasing department as part of the justification for its indirect cost rate.)

### 3-2 FACTORS AFFECTING DETERMINATION OF RMP INDIRECT COST RATES

#### A. Guides for Institutions

Indirect cost rate is simply a device for determining fairly and expeditiously what proportion of an institution's overhead expenses should be charged to grant-supported projects or activities. The Department has issued separate guides for educational institutions, hospitals, State government agencies, and nonprofit institutions which set forth uniform principles for the establishment of indirect cost rates. (See Chapter VII-2, 2-1.) The cost principles set forth in the guide covering the specific type of institution receiving RMPS funds will be used as the basis for computing a submission for a proposed indirect cost rate.

#### B. Special Indirect Cost Rates for RMPs

Because of the complex organizational structure of RMPs, a single ICR applicable to all RMP-supported activities will ordinarily not be able to be developed. In some RMPs, program staff is employed by more than one institution and operational activities are carried on by various institutions which change over time as old activities are phased out and replaced by new activities under different sponsorship. For these reasons, RMP indirect cost rates, when requested, will have to be determined separately for the grantee institution and for each affiliate which receives RMPS funds either for support of program staff or operational activities.

While many RMP grantees and affiliates have approved indirect cost rates applicable to biomedical research projects, different indirect cost rates specifically applicable to RMPS-supported functions may have to be developed. In the case of RMP, many types of expenses ordinarily treated as general administration costs by the grantee for other types of grants are charged as direct costs to RMP. For example, many RMPs provide for their own purchasing, personnel administration, financial management and

S ←

*Cite this para  
in transmittal  
letter to manual*

## VII-3 INDIRECT COSTS

11. To obtain an indirect cost rate, the total amount of direct costs is divided by the total amount of indirect costs (after the exclusion of unallowable items). The resulting percentage is the indirect cost rate.
12. The resulting rate should be applied to the direct costs of the project to arrive at the allowable amount of indirect costs.

Full documentation of the above steps should be retained by the grantee institution as evidence that required procedures have been carried out.

### 3-5 PROCEDURE FOR EFFECTING SETTLEMENT OF DIFFERENCES BETWEEN PROVISIONAL AND FINAL INDIRECT COST RATES

#### A. Summary Report of Expenditure Adjustment Sheet

Chapter 1-80, of the DHEW Grants Administration Manual entitled, "Award and Payment of Indirect Costs on Project Grants," relates to the award and payment of indirect costs on grants and the method for effecting settlement of claims for unrecovered indirect costs resulting from the establishment of final negotiated rates. Chapter 1-80 specifies that "A Summary Report of Expenditure Adjustment Sheet (SROEAS) shall be submitted by each grantee to the Office of Financial Management (NIH) reflecting the necessary adjustment (upward or downward) in the indirect costs to be made on each grant by operating agency and appropriation." The format for ~~an~~ SROEAS is illustrated in Chapter 1-80.

*drop* Whenever the Grantee for a Regional Medical Program submits a Report of Expenditures, using provisional indirect cost rates, for either their own or an affiliated organization, and a final rate is subsequently established by the Office of Grants Administration Policy, for either their own or an affiliated organization, RMPS will expect the grantee to initiate a SROEAS to process any adjustments resulting from the difference between provisional and final indirect cost rates.

*both* As indicated in 3-4, above, grantees are responsible for negotiating final as well as provisional indirect cost rates for affiliated institutions, that do not have an OGAP established indirect cost rate. When establishing final indirect cost rates for affiliates, RMPS grantees shall report the difference between the final and provisional indirect cost rates in accordance with procedures specified in 3-5, below. AN SROEAS must be submitted to reflect final rates that are lower than the provisional rate, as well as those that are higher.

*drop* When a final rate is established that is different from the provisional rate, it is ~~not~~ necessary to revise any previously submitted

### VII-3 INDIRECT COSTS

expenditure reports which include an amount for indirect costs based on the provisional rate. All adjustments <sup>up</sup> or down) in the amount of indirect cost paid will be made on the basis of the SROEAS.

*direct rate* →

Since the Office of Grants Administration Policy reminds the grantee, or affiliated institutions as appropriate, with its covering letter transmitting the executed indirect cost negotiation agreement, upward adjustments for increased indirect costs will not be considered if a SROEAS is not submitted within this time limitation. RMPS shall consider that the date of this one year grace period shall start with the effective date of the earliest negotiation agreement processed by the Office of Grants Administration Policy, which establishes a final indirect cost rate for the applicable budget period, for an institution participating in the grant.

#### B. Special Requirements for RMPs

In addition to the requirements imposed by Chapter 1-80 of the Grants Administration Manual, there are additional requirements that must be followed by Grantees for a Regional Medical Program when preparing a SROEAS.

These are:

- (1) The SROEAS must reflect indirect cost adjustments to the RMP grant, separately from those indirect cost adjustments applicable to all other grants of the grantee institution.
- (2) The initial SROEAS submitted for a particular budget period should reflect as many adjustments as are necessary, and can be processed within the one year grace period.
- (3) When appropriate, addenda to a SROEAS should be processed for those institutions whose indirect cost rates were not finalized at the time of submission of the initial SROEAS for a particular budget period.
- (4) The grantee should indicate on the initial SROEAS submitted, how many of their affiliates were reimbursed indirect costs, based on either an indirect cost rate established by their own organization or the Office of Grants Administration Policy. This will serve to inform RMPS (a) as to which affiliates' indirect costs adjustments were included on the initial SROEAS submitted and which affiliates' indirect cost adjustments would be expected to be processed on addenda to the initial SROEAS, and (b) inform RMPS as to when the total amount of indirect cost adjustments were processed by the

## VII-4 GRANT RELATED INCOME

### 4-1 COMPONENTS OF GRANT RELATED INCOME

#### A. Definition and Elaboration

Grant related income is the Federal share of the net income derived by a grantee or affiliate from fees or charges made in connection with activities supported in whole, or in part, by an RMPS grant, or, where applicable, derived from the sale of items developed with RMPS grant support (e.g., publications, films, medical or other devices). (See 4-4, below)

Net income is income derived from an RMPS supported activity less any direct or administrative cost relating to the generation of such income.

"t"  
Credits or receipts (e.g., refunds, rebates, discounts, adjustments, and other allowances) which offset or reduce an expense chargeable to a grant do not constitute grant related income.

#### B. Treatment of Commonly Occuring Items of Income

##### 1. Income from Construction

Where RMPS funds are awarded for construction of a facility, the income derived from the operation of the completed facility does not constitute grant-related income except where the income is generated through specific RMPS supported activities carried on in the facility.

##### 2. Income from Government Agencies

Income recieved from other RMPs or from Federal or other governmental agencies on jointly-supported projects is not grant related income. Income derived from fees, or charges, or sales (as discussed in 4-1, A, above) to such agencies, however, would constitute grant related income.

##### 3. Income from Educational Programs

Normally, tuition and related fees received by an educational institution for a regularly offered course are not considered to be grant related income. Tuition and related fees, however, received by an educational institution must be treated as grant related income when the course of instruction developed, sponsored, and supported by an RMP is not a regularly offered course. A regularly offered course is a course that:

VII-5 CONTRACTING BY GRANTEES

Correct numbering system

6-1. INTRODUCTION

In general, contracts may be used by grantee institutions for (1) awards to affiliates and/or, (2) purchases of equipment, supplies or services. The purpose of this Sub-Chapter is to outline recommended contracting procedures which will help to avoid audit problems.

The Sub-Chapter covers suggested procedures for both competitive bidding and for sole source contracts. Discussion of competitive bidding is necessarily more extensive than that relating to sole source contracts. It should not be inferred, however, that RMPS necessarily prefers or requires competitive bidding where contracts are used.

In making contracts, the grantee should follow its own institutional policies. Where the grantee has no formal contracting policies or where such policies are not as extensive as those outlined below, it is recommended that the procedures discussed in this Sub-Chapter be followed.

6-2 USE OF CONTRACTS BY RMPS GRANTEES

While the use of contracts for purchasing is generally well understood, their use by RMPS grantees as a mechanism for allocating grant funds to affiliates or other organizations for carrying out the purposes of the grant requires some discussion.

A. Distinction Between Affiliation Agreements and Obligation of Funds

Most RMPS grantees have some form of written affiliation agreement with the other institutions carrying out program staff and operational activities. In most cases, an affiliation agreement can be regarded as a memorandum of understanding between the grantee and other parties, but is not an award or obligations of funds. It usually does not commit specific amounts of grant funds to the affiliate, and the agreement usually has an indeterminate life for the duration of the affiliate's participation in the RMP program.

B. Obligation of Funds to Profit-making Organizations

While an affiliate must always be nonprofit, the grantee may make use of the services of profit making firms. Profit making firms may be paid from grant funds for the use of facilities, the purchase of equipment and supplies, and for services rendered. (These types of expenses are normally

## VII-5 CONTRACTING BY GRANTEEES

### C. Required Allocations Through Contracts

Grantees can allocate funds to affiliates or others through either a contract or other instrument of commitment (i.e., a letter, a special purpose form, etc.) Contracts, however, must be used to allocate grant funds when:

1. The funds are provided to a profit making firm.
2. Material having a security classification is involved.
3. Payment of an amount in excess of actual costs (i.e., a profit or fee) is contemplated.

### D. Choice of Methods for Allocation of Funds by Grantees

Except where contracts are required as indicated in 6-2, C, above, the choice of whether grantees should allocate funds through contracts or other instruments is up to the grantee institution. Small purchases will usually be made through purchase orders in accordance with institutional policy.

In general, a contract is considered to be the most desirable mechanism for allocating funds when:

1. The funds are to be used for the purchase of a specified service
2. The funds are to be used for the purchase of a particular end product, such as a publication, report, or device.
3. Considerable direction and control by the grantee is required with respect to the manner of performance or timing of the work.
4. The funds must be formally obligated within a specific time period.

RMPS experience indicates that most grantees do not use formal contracts in allocating funds to affiliates to carry out specific activities. Usually, letters or other documents are issued by the grantee indicating the amounts, purposes and period for which funds are allocated, and the grantee relies on the understandings in the affiliation agreement to insure proper use of funds and compliance with federal and grantee requirements. Dealing with affiliates in this manner provides greater financial flexibility than the usual contract and enhances the RMPS concept of "cooperative arrangements" among the institutions participating in a Regional Medical Program.

The source of a proposal should not necessarily influence the choice of an award mechanism. For example, a contract is not necessarily required because the initiative for an activity originated with an affiliate.

## VII-5 CONTRACTING BY GRANTEEES

### E. Types of Contracts

Where contracts are used, these may be of two types, (1) fixed price, (2) cost-reimbursement. A fixed price contract may be used where a definite cost can be established in advance. A cost-reimbursement contract, therefore, specifies an estimated rather than an actual cost.

### F. Obligations and Expenditures

All contracts (and purchase orders) by grantees for RMP purposes constitute obligations of grant funds for Federal accounting purposes. Federal auditors have taken the position that other forms of allocations do not constitute obligations.

Where a grantee makes a contract which continues beyond the fiscal year of the grant, the funds are obligated immediately (even though actually paid out later) and would be shown in the entire amount of the contract on the expenditure report for the fiscal year in which the contract was initiated. Adjustments for any unexpended balance expenditure report for the subsequent fiscal year in which the contract terminated.

*Part of this sentence omitted in typing.*

## 6-3 RECOMMENDED CONTRACTING PROCEDURES

It is recommended that grantees follow the procedures recommended below when making contracts involving RMPS funds.

### A. Requests for Bids

Where competitive bidding is used, the grantee must prepare a "Request for Bids" to inform potential contractors. The "Request for Bids" should include the following information, as applicable:

1. A "scope of work" statement which includes (1) a broad, non-technical description of the work to be done or items or services to be purchased, (2) stages of work, technical specifications, reports, drawings and publications.
2. The period of performance.
3. The quantity needed.
4. A list of property to be furnished by the grantee or the contractor, if any.
5. Delivery requirements.
6. Reports required. (e.g., progress reports, etc.)
7. The initial dollar estimate of costs.
8. Required approvals and clearances.
9. Other necessary technical information or instructions.
10. A list of potential contractors, if known.

A Request for Bids should be worded to make more than one in-

statements can lead to unsatisfactory performance, delays, and disputes and possibly result in increased costs.

The Letter of Credit is only a fiscal device which authorizes a grantee to draw cash to pay for the Federal share of program and project disbursements. The Letter of Credit does not authorize the incurrence of those disbursements. A separate authorizing document, that is, the RMPS grant award, must be in the grantees possession before cash can be drawn. In other words, if the grantee has a Letter of Credit but has not received a RMPS grant award, then no withdrawals are authorized.

Charge  
to OFM,  
N.H.

To obtain a Letter of Credit, a grantee provides the paying agency with a forecast of expenditures for the next 12 months. Based on the forecast, a monthly renewable Letter of Credit will be established on behalf of the grantee through the Federal Reserve Branch which serves the grantee's local bank. To draw cash, the grantee then sends a Payment Voucher for the amount required to his bank. Cash withdrawals are limited to the monthly ceiling stated in the Letter of Credit. There is no carry-over of any unused ceiling amount. Each month stands by itself. The monthly ceiling is automatically renewed at the beginning of each month.

Eliminate  
Qualification

It is not considered to be advantageous for grantees to use the Letter of Credit payment system unless the grantee has more than one grant from HEW with aggregate HEW funding of at least \$5 million.

#### 6-3 MONTHLY CASH REQUESTS

Under the monthly cash request method of payment, the grantee institution requests grant funds monthly from the Office of Financial Management, NIE, based on anticipated cash expenditures for the next month. No payment will be issued (including the initial payment) until a monthly cash request is submitted.

#### 6-4 BASIS FOR DRAWING FUNDS

Treasury Regulations state that cash in the hands of recipients may not exceed at any time one months needs. Whether a grantee is utilizing the Letter of Credit or a monthly cash request to draw or request funds, at no time should cash be requested or drawn to cover unliquidated encumbrances, obligations, or accrued expenditures

## VIII - CONSTRUCTION, ALTERATION AND RENOVATION

### 1-1 INTRODUCTION

FMPS funds may be used for construction, alteration and renovation of facilities necessary to carry out regional medical programs. Under the Law funds for new construction may not exceed \$5 million in any fiscal year. This limitation applies to new construction only and not to alteration and renovation.

Under the Law, FMPS participation in both construction and alteration and renovation (including the costs of built-in equipment) is limited to 90% of the costs of such construction or equipment.

The HEW Grants Administration Manual requires that all costs of construction including those normally reimbursed as indirect costs must be allocated directly to the construction project. No indirect cost rate may be applied to the costs of construction.

Figure 1 is a schematic outline of the requirements discussed in this chapter. Consult the text for details.

### 1-2 CLASSIFICATION OF PROJECTS

#### A. Construction

Construction as defined in the Act means new construction of facilities for demonstrations, research, and training when necessary to carry out regional medical programs, alteration, major repair (to the extent permitted by regulations), remodeling and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing buildings.

#### B. New Construction

New Construction means the erection, installation or assembly of a facility, including the expansion, addition, extension of an existing facility which provides new floor space, cubeage, or applicable units of measurements; total replacement of a facility and/or

*identify that  
B & C actually  
part of A.*

see prior page

the physical relocation of a facility from one location to another. For buildings and structures, it may include site preparation, including demolition; excavation, landfill, utility system connections and extensions, site improvements such as roads, walks, parking areas, landscaping, and exterior or interior real property installed (built-in) equipment. Completion of unfinished space is to be treated as new construction

C. Alteration and Renovation - Definition

Alteration and renovation means work required to change the interior arrangements or other physical characteristics of an existing facility of installed (built-in) equipment, so that it may be more effectively utilized for its current designated purpose, or adapted to a changed use, as a result of a programmatic requirement. Alterations and Renovations may include work referred to as improvements, conversion, rehabilitation, remodeling or modernization.

Virtually all alterations and renovations supported through RMPS funds consist of rearrangement of space through relocation of non load-bearing walls or partitions and associated appurtenances, built-in equipment, and/or utilities. Alteration and renovation of this type should be classified as "Minor" in completing form RMPS-34-1, page 16, "Financial Data Record."

1-3 ALTERATION AND RENOVATION

A. When Approval is Required

Regions with triennial status do not require prior RMPS approval to initiate alteration or renovation in the amount of \$25,000 or less RMPS costs. In all other cases prior RMPS approval is required for alteration and renovation. (See Subchapter VII-9).

In requesting approvals two copies of the following documents are to be submitted:

1. Requests under \$25,000
  - a. Brief summary
  - b. Cost estimate

should include Ref. that info on H&R schedules on rebudgeting must be submitted to RMPS to satisfy FECA requirement.

c. Sketches of the project area showing present proposed arrangement

2. Requests over \$25,000

a. Program requirements

b. Submission of architectural and engineering documents

1. For activities involving alteration and renovation exceeding \$25,000 applicants should use the services of the DHEW Regional Grants Management Officer who will establish liaison between the applicant and the Facilities Engineering Construction Agency (FECA), which is responsible for evaluation of cost, functional design, and eligibility of the project.

B. Description of Information Required When Requesting Approval for Alteration and Renovation

1. Narrative Summary

The narrative summary is a statement of the proposed functional utilization of the space and equipment requirements which are developed and written by the persons who will use and be responsible for the working space. It is the foundation upon which the architect and engineer base their final drawings and specifications and is best prepared by a team representing the program, management, and architectural-engineer advisors.

The summary should describe in reasonable detail the need, character, and extent of the planned functions of the project to be housed in the altered or renovated space. However, since no single format best serves the wide variety of potential applications, each applicant is encouraged to prepare the narrative in a manner which best describes his program.

2. Cost Estimates

Figure 2 illustrates the format for submitting cost estimates.

*Should include that this info be submitted to RMB.*