
E001624

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
[redacted]
BUREAU HEALTH SERVICES RESEARCH AND EVALUATION

TO : Coordinators, Grantees, Members of the National Advisory Council

DATE: December 20, 1973

FROM : Acting Director, RMPS

SUBJECT: Highlights of November 26-27 National Advisory Council Meeting

Once again it is a pleasure to present the highlights of the November 26-27 National Advisory Council meeting. You will recall that the Council last met in July. During the July meeting, Council members were briefed on events since the initiation of the proposed phaseout and the subsequent one year extension of RMP. At that time, the Council recommended funding of RMPs in Fiscal 1974 based on staff reviews and annualized funding levels until a more regular review process could be reestablished. Using this authority $17.1 million was awarded to RMPs on October 1. An additional $24.136 million has recently been released for RMP grants and contracts. Application for these funds were reviewed at the present Council meeting for awards beginning January 1, 1973.

Because of the importance of some of the discussion and actions at this session I will outline the most important topics rather than give the usual play-by-play description of discussion and presentations.

I. Termination of RMP Activities

Both Dr. Kenneth M. Endicott, Administrator HRA, and Dr. Harold Margulies, Acting Deputy Administrator, addressed the Council on the period of support for RMP activities. Dr. Endicott advised Council Members to ignore uncertainties about budget periods when reviewing applications and Dr. Margulies reported on new understandings that apparently had been reached within HEW concerning the period for RMP expenditures. In doing so he noted that the new understandings, while based on high-level oral discussions, were still subject to change. In view of this information. the Council recommended an extension of the period during which RMPS funds may be spent. Contrary to expectations, however, there is no official change with respect to termination of RMP activities.

II. Options

Another understanding within HEW discussed by Dr. Margulies concerns the use of grant funds. While the purposes for which funds can be expended may be altered by new legislation, HRA and HEW still consider the five RMP options as high priority areas. They should be treated as areas of continuing emphasis, but not as exclusive areas of grant awards. Accordingly, all activities authorized by the Act and in the Mission Statement previously approved by the Council are eligible for support provided that they are within the purview of current council policies.

III. Policy Actions

The Council recommended three important policies.

Allocation of additional funds - All the FY 1974 funds apportioned by OMB for RMPS have been released and will be awarded by January 1, 1974. Because of the lawsuit by the National Association of Regional Medical Programs, Inc., there is a possibility that substantial additional funds will become available for award in Fiscal 1974. In order to prepare for such an eventuality, the Council approved a resolution (Enclosure, 1) which provides that:

1. any funds up to $81.9 million may be awarded by the Director RMPS, using the established formula ceiling method. ($81.9 million is the maximum anticipated amount of FY 74 funds.)
2. up to $10 million over the above amount can be awarded by the Director with notification to the Council.
3. award of all other additional funds would be subject to further recommendations by the Council.

Discretionary Funding Authority - The Council voted to modify the "Governing Principles and Requirements: Discretionary RMP Funding and Rebudgeting Authority" (Enclosure, 2) originally issued September 20, 1972. The revised policy will be transmitted formally in a NID in the near future. The revision removes the distinction formerly made between "triennial" and "anniversary" Regions with respect to rebudgeting authority. In approving the change, the Council asked that Regions be informed that the distinction may be reinstituted if the program continues. The phaseout and subsequent resumption of activities by RMPs, however, has made the difference between the old triennial and anniversary classifications irrelevant at the present time.

Resumption of review process certification and management assessment visits - The RMPS' plans in connection with management assessment and review process certification were discussed with the Council and their resolution supporting these activities is attached (Enclosure, 3).

Since over $41 million in FY 74 funds will be awarded for RMP grants and contracts, and since many structural and personnel changes have occurred in RMPs during the last year, the Regions' present ability to allocate, award and manage funds assumes great importance. At the time the phaseout was announced in January 1973, Management assessment visits had been carried out in all but 18 Regions,and these Regions will be among the first to be visited under the reconstituted activity.

In addition to management assessments, a few review process verification visits still remain to be completed. These and clearing up review process problems in compliance with RMPS standards will also receive priority attention.

IV. Special Reports

Overview of RMPs - Mr. Roland Peterson, Director, Office of Program planning and Evaluation, RMPS, presented statistical data on Coordinator changes, program staff, committee activity and categories of proposed RMP activities. These showed, among other things, that RMPs have retained about half the staff they had prior to phaseout and that about 75% of proposed activities are within the option areas. Mr. Peterson's data indicate that, in general, the Regions have attained a surprising degree of stability and renewed viability, considering the events of the last year.

Section 907 reports - Dr. Margaret Sloan, who is now an Assistant to Dr. van Hoek, reported on the outcome of RMPS' long-standing effort to carry out the provisions of Section 907 of the RMP statute. This has resulted in the publication of a seven volume inventory of services entitled Hospital Services for Selected Chronic Disease Patients. Copies have been mailed to all RMPs and will be sent to Council members. The inventory was developed through a questionnaire under a contract with the Joint Commission of the Accreditation of Hospitals. It covers 92% of the Nation's hospitals. Special runs can be made from the data contained in the inventory.

The JCAH Steering Committee felt that a list of outstanding facilities should be published only after actual site visitations to facilities. It was decided, therefore, that the public interest would be served best by publishing the basic data and criteria which could be applied by users to develop lists suitable to their particular needs.

Four criteria documents have now been completed. The kidney and stroke criteria appeared in the October 1973 JAMA. The heart disease and cancer criteria will be published in November and December respectively. These are tentative documents and comments and suggestions are invited. Address any comments regarding the criteria to Dr. Sloan at the Parklawn Building.

The American Cancer Society, American Hospital Association and JCAH are interested in keeping the data up to date and have discussed this with HRA. It is therefore possible that the inventory will be repeated in another year.

End Stage Kidney Disease Regulations - Mr. Matthew Spear, who has been on detail with others, developing standards for the new Social Security kidney reimbursement program, reviewed the Interim Kidney Regulations. Mr. Spear stated that medical care has now been extended to persons with end stage kidney disease who are fully covered by Social Security. Reimbursement for care under the Act was authorized to begin on July 1, 1973, and interim Regulations were promulgated on June 29th. (See Enclosure, 4) The Regulations blanket in coverage of existing end-stage renal services and provide coverage for new services only on an exception basis. The Regulations provide for (1) minimum utilization, (2) medical review, (3) facility affiliation and (4) cost containment.

All RMPS kidney activities must comply with the above regulations and conditions to that effect were placed on all kidney activities reviewed and approved at the present Council meeting.

V. Presentation by Dr. van Hoek

Dr. Robert van Hoek, Director Bureau of Health Services Research and Evaluation, discussed a number of matters of mutual interest to the Bureau and RMPs.

The Emergency Medical Services program which was initially lodged in the Bureau has now been transferred to the Health Services Administration.

There is a bill the the House (H.R. 11385) which would combine the National Center for Health Services R&D with the National Center for Health Statistics, but passage is not expected.

The Bureau has developed a lengthy program statement on health service research needs which have been mailed to all RMP Coordinators. In summary these Program needs are:

1. studies of planning licensure, and legislation especially certificate of need and planning mechanisms.
2. quality of health care including (a) assuring quality, (b) disseminating findings and (c) implementing the PSRO legislation, the quality aspects of kidney and HMOs (if legislation passes).

3. financing of medical care
4. productivity of the health care system especially in regard to manpower
5. data systems emphasizing improved medical record systems in ambulatory and institutional settings
6. long term care

Dr. van Hoek suggested that RMPs could assist the health service research and development effort in disseminating BHSR&E research findings and also in developing indices of standards of medical care and the effectiveness of medical care processes.

VI. Director's report

Contrary to the usual custom, I did not make a long report to the Council. To conserve time, which was needed for grant reviews, I sent a background memorandum to Council members prior to the meeting (See Enclosure, 5). At the meeting I did, however, briefly summarize the current budget picture (Enclosure, 6) and noted, as you already know, that additional funds may be forthcoming.

VII. Other matters

The Council reviewed applications from the 53 Regions during the closed portion of the meeting. The Council members considered the applications carefully and extensively discussed identified problem areas. Three Council site visits will be conducted during January as a result of the deliberations.

Dr. Sparkman and Dr. Reinschmidt attended the meeting and addressed the Council on behalf of the Steering Committee and the National Association of RMPs.

Future dates were tentatively scheduled for January, February and March 1973 in the event that additional funds will be released. We have decided to cancel the January meeting though, so the next Council session will be on February 12-13 followed by a meeting on March 12-13.

I hope this summary of the meeting will be informative and useful.

Sincerely yours,

Herbert B. Pahl

Herbert B. Pahl, Ph.D.

ENCLOSURE(1)

RESOLUTION BY THE NATIONAL ADVISORY COUNCIL ON REGIONAL MEDICAL PROGRAMS RECOMMENDING ALLOCATION OF ADDITIONAL RMPS FUNDS IN FISCAL YEAR 1974

WHEREAS: RMPS has established a method acceptable to this Council for allocating the funds already made available for Fiscal Year 1974, and

WHEREAS: Substantial additional funds may become available for obligation by RMPS in Fiscal Year 1974,

BE IT RESOLVED THAT: The National Advisory Council recommends that;

1. the Regional Medical Programs Service allocate by established mode the full amount of Fiscal Year 1974 funds made available, up to the maximum amount anticipated under the HEW Continuing Resolution or Appropriation, $81.9 million.

2. up to $10.0 million of any amount over $81.9 million which the Regional Medical Programs Service may be directed to obligate in Fiscal Year 1974, may be distributed in a manner that the Director, Regional Medical Programs Service, finds will make the best possible use of funds in accordance with existing legislation, Council, Department and RMPS policies. All such distributions will be reported to the Council.

3. any other funds in excess of $81.9 million, not awarded pursuant to item 2, above, shall be awarded subject to the Council's recommendation thereon at its next regular or special meeting after such funds shall have become available for obligation.

APPROVED: National Advisory Council on Regional Medical Programs - 11/26/73

DRAFT: 11/26/73

ENCLOSURE(2)

GOVERNING PRINCIPLES AND REQUIREMENTS:
DISCRETIONARY RMP FUNDING AND REBUDGETING AUTHORITY

I. 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.

II. 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, HRA, and RMPS 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, as described in NID of August 30, 1972.

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 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 design 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 re-budgeting authority, the grantee or the Coordinator on its behalf shall communicate with RMPS for advice and guidance.

III. REQUIREMENTS

Because of the changing conditions that have prevailed, the following authorities to act are identical for all RMPs regardless of previous status.

RMPs must obtain prior approval from the Director, RMPS for any proposed program staff 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.)

3. HMO related feasibility studies.

4. End-stage treatment of kidney disease (e.g. dialysis, transplantation and supportive facilities and services).

5. Other specialized activities as identified by RMPS.

IV. 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.

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

ENCLOSURE(3)

RESOLUTION BY THE NATIONAL ADVISORY COUNCIL ON REGIONAL MEDICAL PROGRAMS RECOMMENDING REPORT ON STATUS OF RMPs' COMPLIANCE WITH REVIEW REQUIREMENTS

WHEREAS: Some RMPs still have not complied fully with the the "RMPS Review Process Requirements and Standards" and administrative management requirements, then

BE IT THEREFORE RESOLVED: The National Advisory Council reiterates the necessity for all RMPs to be in compliance with the "RMPS Review Process Requirements and Standards" and administrative management requirements as soon as possible, and therefore, requests the Director, RMPS, to report the status of RMPs' compliance at the next Council meeting.

APPROVED: National Advisory Council on Regional Medical Programs, November 26, 1973

ENCLOSURE(4)

/Excerpt from FEDERAL REGISTER, June 29, 1973
Issue, Pages 17210-17212, Medicare--HEW Interim Regulations on Payment for Treatment of Chronic Renal Disease, Effective July 1, 1973./

Title 20--Employees' Benefits
Chapter III--Social Security Administration, D/HEW
Part 405--Federal Health Insurance for the Aged

Payment for Services in Connection with Kidney Transplant and Renal Dialysis Provided to Entitled Beneficiaries

Section 299I of P.L. 92-603 extends Medicare protection against the cost of chronic renal disease (CRD) to virtually the entire population. The legislation authorizes the Secretary to limit reimbursement to facilities meeting such requirements as he may prescribe by regulation. In view of the new issues that stem from the virtually universal coverage of a very complex service, the absence of prior experience, and possible precedents that the regulations may establish, final decisions on Medicare payment and facility qualification policies will require careful study and reevaluation based upon operating experience. Operations on July 1, 1973, are to be based upon interim regulations.

Section 299I also requires that the regulations to be promulgated include minimum utilization rates, which are associated both with cost of operation and quality of performance, which is generally superior when staff is well-practiced, and a provision for a medical review board to screen the appropriateness of patients for the proposed treatment procedures. The final regulations, when promulgated, will provide for such rates and review boards. In addition, the final requirements for participation in the program will provide that facilities have affiliations which tie them in with the various modalities of treatment so as to support the development of an organized effective system of delivery of treatment of CRD. Authority for participation by a facility on an interim basis should not be construed to imply that it will be approved on a permanent basis for participation in the program. When the selection of qualifying facilities under the final conditions is made, it is expected that those not qualifying will be phased out with a minimum of interruption in the continuity of service. In addition, interim reimbursement levels and mechanisms to be employed should not be contrued to reflect the final policies which will be adopted and which are expected to contain additional features providing incentives for effective and efficient performance. During the interim period, limits will be applied to reimbursement amounts and services covered beyond which payment will be made, i.e., will be considered reasonable and necessary, only if adequate justification is provided. Subject to requirements described below, facilities

which were in operation in the performance of CRD treatment on June 1, 1973, will be reimbursed under the program during the interim period for services which are not increased substantially; additional facilities will be qualified to participate and substantial additions to services will be allowed for reimbursement on an exception basis. Those facilities which have not provided transplatation or chronic maintenance dialysis prior to June 1, 1973, or which have expanded or contemplate substantial expansion of services after June 1, 1973, will in addition be reviewed during the interim period to determine whether their entry into the field is consistent with the criteria described below, which include principles expected to be encompassed in final conditions of participation.

With respect to transplantation, these criteria and principles include the following: (1) The facility is participating in the Medicare program; (2) it can reasonably be expected to perform a sufficient number of transplants per year and otherwise demonstrates a capacity to perform with high quality; (3) it makes a needed contribution to access of care in an area; (4) it contributes to a coordinated system of care by its arrangements for cooperation with other facilities in the area offering the same or other modalities of care for end-stage renal disease patients so that patients should be placed in the appropriate site and receive the appropriate service; (5) its costs of performance are expected to conform with the norms for the services it provides; and (6) its capital expenditures for this service have not been disapproved by a State agency designated in accordance with Section 1122 of Title XI of the Social Security Act. During the period immediately after June 1, 1973, special consideration for participation will be given to a facility that has prior to June 1, 1973, made a substantial investment of time, study, and resources in preparation for provision of the services in question.

Subject to the above caveat transplant hospitals which are currently participating in the Medicare program will continue to be reimbursed in the interim period for renal transplantation until conditions of participation are promulgated and applied.

With respect to chronic maintenance dialysis facilities, the criteria and principles include the following: (1) The facility is expected to meet an acceptable utilization rate and otherwise demonstrates a capacity to perform at high quality; (2) the facility makes a needed contribution to access of care; (3) the facility makes a positive contribution to the total system of care of CRD by working in cooperation with other sites and modalities of care; (4) the facility has arrangements for a patient review mechanism to assure that all patients are screened for the appropriateness of their treatment modality--including suitability for transplant and home dialysis; (5) the cost (or charge) of the service offered by the facility is in conformity

with norms of costs (or charges) for similar services; and (6) its capital expenditures for this service have not been disapproved by a State agency designated in accordance with Section 1122 of Title XI of the Social Security Act. During the period immediately after June 1, 1973, special consideration for participation will be given to a facility that, prior to June 1, 1973, had made a substantial investment of time, study, and resources in preparation for provision of the services in question.

Subject to the above caveat, dialysis facilities which have been in operation before June 1, 1973, will be reimbursed by the program during the interim period until conditions of participation are promulgated, if they meet the following minimal conditions: (1) If hospital-operated, the hospital is participating in the Medicare program; (2) of free-standing, the facility (a) meets State or local licensure requirements, if any, (b) is a facility in which treatment is under the general supervision of a physician (who need not be a full-time supervisor), (c) has an affiliation, e.g., has arrangements for back-up care, etc., with a participating hospital, and (d) agrees that no charge will be made for a covered dialysis service provided by the facility that is in excess of the charge determined to be the reasonable charge of that facility.

In addition to these considerations, regulations are amended hereby to clarify certain aspects of requirements for entitlement to Health Insurance Benefits because of chronic renal disease.

(Catalogue of Federal Domestic Assistance Program Nos. 13,800, Health Insurance for the Aged--Hospital Insurance, and 13,801, Health Insurance for the Aged--Supplementary Medical Insurance).

Dated: June 22, 1973

Arthur E. Hess,
Acting Commissioner of
Social Security.

Approved: June 26, 1973

Caspar W. Weinberger,
Secretary of Health, Education,
and Welfare.

Subparts A, B, D, and E of Regulations No. 5 of the Social Security Administration (20 CFR Part 405) are amended as set forth below.

1. Section 405.104 is added to read as follows:

§405.104 Entitlement to hospital insurance benefits based on chronic kidney failure.

(a) Eligibility--An individual is eligible for hospital insurance benefits based on chronic renal disease if he:

(1) Has not attained age 65; and

(2) Is either--

(i) Fully or currently insured (as such terms are defined in Subpart B of Part 404 of this chapter), or

(ii) Entitled to monthly insurance benefits under Title II of the Act, or

(iii) The spouse or dependent child of a person who meets the requirements of subdivision (i) or (ii) of this subparagraph; and

(3) Is medically determined to have chronic renal disease and continuing renal dialysis or a kidney transplant is essential for treatment of such disease.

(b) Entitlement--(1) When entitlement begins. Effective with respect to services provided after June 1973, an eligible individual, as defined in paragraph (a) of this section, is entitled to hospital insurance benefits beginning with whichever is earlier: (i) The month in which he is hospitalized in preparation for and anticipation of kidney transplant surgery, provided that such transplant surgery occurs in that month or the following month, or (ii) the third calendar month after the month in which he begins a course of dialysis.

(2) When entitlement ends.--An individual's entitlement, established under paragraph (b) (1) of this section ends with the twelfth month after the month in which he received a kidney transplant or such course of dialysis is otherwise terminated, unless before the end of such twelfth month, the individual again requires a course of dialysis or a kidney transplant.

(c) Definitions.--(1) "Child" and"spouse" defined. An individual is the child or spouse of a person, for purposes of paragraph (a) (2) (iii) of this section, if the individual is so related to that person that he meets the relationship requirements set forth in Subpart L of Part 404 of this chapter for entitlement, respectively, (i) to child's insurance benefits, or (ii) to wife's, husband's, widow's, widower's, or mother's insurance benefits under Title II of the Act, on that person's earnings record, whether or not the relationship has continued long enough for such individual to qualify for such benefits.

(2) Dependency of a child.--For purposes of paragraph (a) (2) (iii) of this section, the child of a person is that person's "dependent child" if he meets the dependency requirements set forth in §§404.323-404.327 of this chapter for entitlement to child's insurance benefits on that person's earnings record.

2. Section 405.116 is amended by adding paragraph (g) to read as follows:

§405.116 Inpatient hospital services; defined.

* * * * *

(g) Services in connection with kidney transplantation. With respect to services rendered in connection with kidney transplantation, for an interim period beginning July 1, 1973, for services rendered on and after that date, and until regulations setting forth conditions of participation are promulgated and applied, coverage is limited to services rendered in participating hospitals which on June 1, 1973, have been providing the services and have not substantially increased such services, or which have, in the opinion of the Secretary, demonstrated the need for and appropriateness of their assumption of or increase in the provision of such services, in an effective and economical system of chronic renal disease treatment.

3. Section 405.231 is amended by revising paragraphs (g) and (h) to read as follows:

§405.231 Medical and other health services; included items and services.

Subject to the conditions, limitations, and exclusions set forth in §405.232, the term "medical and other health services" means the following items or services:

* * * * *

(g) Rental or, effective January 1, 1968, the purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, renal dialysis systems, and wheelchairs used in the patient's home. For purposes of this paragraph, the term "home" does not include an insitution which meets the requirements of Section 1861 (e) (1) or 1861 (j) (1) of the Act--see §§405.1001 and 405.1101; with respect to dialysis facilities which render home training and provide equipment, supplies, and back-up services to patients who dialyze in the home, coverage shall be limited to services of those dialysis facilities described in paragraph (h) of this section.

(h) Prosthetic devices (other than dental) which replace all or part of an internal body organ, including replacement of such devices. With respect to renal dialysis facilities, during an interim period beginning July 1, 1973, for facility dialysis services rendered on and after that date and util regulations setting forth conditions of participation for these facilities are promulgated and applied, coverage is limited to the services of those facilities which on June 1, 1973, have been providing the services and which have not substantially increased such services or which have, in the opinion of the Secretary, demonstrated the need for and appropriateness of their assumption of or increase in the provision of such services, in an effective and economical system of chronic renal disease treatment, and which also meet one of the following requirements:

(1) The facility is part of a participating hospital; or

(2) It is a free-standing facility which meets the following conditions--

(i) Meets State or local licensure requirements, if any,

(ii) Is a facility in which treatment is under the general supervision of a physician, who need not be a full-time supervisor.

(iii) Has an affiliation, e.g., has arrangements for back-up care, etc., with a participating hospital, and

(iv) Agrees that no charge will be made for a covered dialysis service provided by the facility that is in excess of the charge determined under the health insurance program to be the reasonable charge of that facility and agrees to bill the program and not the patient for amounts reimbursable under the program.

4. Section 405.402 is amended by adding paragraph (g) to read as follows:

405.402 Cost reimbursement; general.

* * * * *

(g) The Social Security Administration is authorized to issue temporary instructions modifying the provisions of this subpart to the extent it finds appropriate for cost reporting periods ending after June 30, 1973, in order to implement Section 201 (Coverage for Disability Beneficiaries Under Medicare) and 299I (Chronic Renal Disease Considered to Constitute Disability) of P.L. 92-603. In so doing, rules may be developed for establishing limits on costs and services above which reimbursement shall be made only upon appropriate justification.

5. Section 405.502 is amended by adding paragraph (e) to read as follows:

§405.502 Criteria for determining reasonable charges.

* * * * *

(e) Criteria for determination of reasonable charges under the chronic renal disease program--With respect to reimbursement for services in connection with renal dialysis and kidney transplantation, the normal medical market in which customary and prevailing charges can be determined will not be available; most such services will be reimbursed by the health insurance program. With respect to such services, therefore, reasonable charges may be defined in terms related to charges or costs prior to July 1, 1973, the costs and profits that are reasonable when the treatments are provided in an effective and economical manner, and/or charges made for other services, taking into account comparable physicians' time and skill requirements. Definitions may be developed which describe the elements of service included within the scope of a dialysis treatment and limits may be established on charges and services above which reimbursement shall be made only upon appropriate justification.

(FR Doc. 73-13253 Filed 6-28-73; 8:45 a.m.)

MEMORANDUM

PUBLIC HEALTH SERVICE

HEALTH RESOURCES ADMINISTRATION

BUREAU OF HEALTH SERVICES RESEARCH & EVALUATION

TO : Members of the National Advisory Council on Regional Medical Programs

DATE:

ENCLOSURE(5)

FROM : Acting Director, RMP

SUBJECT: Background Information for November 26-27, 1973 Council Meeting

Since we will be having a rather full agenda at the Council meeting next week, I believe it will be helpful to send you the following information in order to bring you up to date on some particulars since the last meeting in July. At the present meeting the Council will be reviewing applications for the first time in a year, and we will need as much time as possible to conduct grant reviews. I will try to keep this report as brief as possible and refer as necessary to the attachments, some of which you have already seen.

I. Status of the National Advisory Council

Dr. Meyer and Dr. McPhedran have resigned from the Council. Dr. Meyer's resignation was due to the pressures of his private practice. Dr. McPhedran has moved to Maine and assumed a position with the Veterans Administration. Since Dr. McPhedran is now a Federal employee, he is precluded by law from continuing to serve on the Council.

The terms of four present Council members, Drs. Cannon, Roth, Watkins and Mr. Milliken, expire on November 30, 1973. Since Dr. Cannon and Dr. Roth have both served more than one term, neither is eligible for reappointment.

After the extension of the program in June, RMPs were requested to propose potential Council nominees, and many names were suggested. RMPS now has submitted a slate of nominees for consideration by the Secretary and, if approved, these will fill the 13 vacancies that will exist after November 30th. Among others, the RMPS nominations include former members of the RMPS Review Committee (which was abolished last June 30), and individuals recommended by the Regions. We have been assured that the processing of the nominations will be expedited.

II. Funds for Grants

The amount made available for RMP grants in Fiscal Year 1974 is $41.236 million. Of this amount $17.1 million was released in September and awarded on October 1. The October 1 awards were intended to maintain the viability of Regions through December 31, 1973. The remaining $24.136 million has just been released to us by the Department and will be awarded by us to RMPs in December. Applications for the remaining funds will be considered at the November Council meeting.

III. Special Projects

Pediatric Pulmonary Centers - In addition to the amounts discussed above, $2 million has been earmarked for continued support of Pediatric Pulmonary Centers through June 30, 1974. Eleven Centers have been funded by RMPS in the past. (see Enclosure 1.) To date awards have been made to eight centers in the amount of $1,340,420. Two centers, California and New Mexico, remain to be funded and the Georgia application has been withdrawn. Administration of the Pediatric Pulmonary Center grants has been transferred to the Bureau of Community Health Services in the Health Services Administration. Any further funds for these projects after June 30, 1974 will come from that agency.

Construction - The Second Supplemental Appropriation Act for Fiscal Year 1973 included $5.0 million under Title IX (the RMP authority) for two specifically designated hospitals, one in Seattle and the other in Newport, Vermont. At the July meeting of the Council it was recommended that funding of these facilities proceed expeditiously in accordance with the Congressional mandate. (see Enclosure 2.) The Seattle project is still in the early planning stage and no application has been received. The Vermont project has been awarded the $0.5 million intended for it. The $4.5 million balance for the Seattle construction project remains available until expended. RMP construction funds have been transferred to the Hill-Burton program for award and administration.

Emergency Medical Services - The Hawaii EMS project was transferred on November 1, 1973 from the Research Corporation of the University of Hawaii to the Hawaii Medical Association. This grant will be administered by the EMS Branch, Bureau of Health Services Research and Evaluation, under an agreement with RMPS. All other EMS projects are still under RMPS. (See Enclosure #3 for listing of active EMS projects.)

Health Service Education Activities - The Mahoning-Shenango Area Health Education Network, Inc. has been funded under a separate

award through October 31, 1974. This project was originally funded through the Northeast Ohio Regional Medical Program, which itself was terminated on July 31, 1973. (See Enslosure 3) for listing of active hs/ea activities.)

Contracts - A summary of RMPS contract activities is presented in Enclosure 4 .

IV. Coordinator Changes

Since July, new Coordinators have been appointed in two Regions, Wisconsin and Greater Delaware Valley. Coordinators in the following Regions have been changed from "acting" to permanent: Alabama, Nassau Suffolk, Northlands, Tennessee/Mid-South, and Texas. (See Enclosure 5 for a complete and current list of RMPs and Coordinators.)

V. Lawsuit

A Class-action Suit against the Government has been filed by the National Association of Regional Medical Programs, et. al. The action seeks release of additional RMPS funds from both the FY 73 and FY 74 appropriations. The suit was filed on September 21, 1973 in the US District Court for the District of Columbia and assigned to Judge Pratt. It has subsequently be reassigned to Judge Flannery. Various affidavits have been submitted to the Court and a hearing before Judge Flannery is scheduled for December 7, 1973.

The suit seeks:

a. release of $90-100 million of FY 73 funds.

b. release of all FY 74 appropriated funds as they become releasable. ($80.453 million for grants and contracts under the Continuing Resolution.)

c. removal of all mission restrictions.

d. removal of all restraints on the time within which funds may be allocated.

In an initial move in the suit, a request by the plaintiffs for a Temporary Restraining Order concerning availability of FY 73 funds was denied by Judge Pratt who ruled that FY 73 funds had lapsed. This was subsequently reversed by the Court of Appeals and the issue of release of FY 73 funds has been restored as part of the suit.

VI. Coordinators' Meeting

The National Steering Committee of RMP Coordinators and later the

full group of 53 RMP Coordinators met in Chicago on October 18th. The following major issues facing RMPS were outlined to both groups.

1. Current restrictions on expenditures of funds by RMPS

2. Commitment to FY 1972 earmarked EMS and HSEA activities which go beyond June 30, 1974 termination date. (See Enclosure 3 .)

3. The effective functioning of the Council in view of the fact that there is nor Review Committee to assist it and that the Council will be reduced seriously in membership if appointments are not made quickly.

4. Approval of the proposed RMPS Spending Plan which is still subject to change until final approval is secured.

5. Size, composition and morale of the RMPS staff.

6. Possible need to distribute substantial additional funds as the result of the litigation.

Dr. Pahl, Mr. Chambliss, Mrs. Silsbee and Mr. Gardell answered questions from the Coordinators. (See Enclosure 6 .)

VII. Status of RMPS

The Division of Professional and Technical Development has been dismantled. The Kidney program staff has been detailed to the Health Services Administration and the remaining DPTD staff has been transferred to the Division of Operations and Development and other office units in RMPS.

Public information about RMPS is the responsibility of the Bureau.

The Planning and Evaluation function has been substantially reduced. P&E now essentially answers inquiries but performs no evaluation functions.

There has been little change in the Office of the Director and, with some personnel changes, the Division of Operations and Development largely remains intact.

Several RMPS staff members will be working part-time over the next few months on task forces concerned with the HRA legislative program.

VIII. Structure of Review

A new, simplified review and award system has been instituted for FY 1974. Instructions containing the new requirements were sent to the Regions on September 7, 1973. (See Enclosure 7 , especially item IC re areas of concentration for review and item II on "Priorities and Options.") The review criteria and rating system used prior to phaseout are no longer germane.

Fiscal Year 74 funds (i.e., the October 1 and forthcoming January 1 awards) are being allocated on the basis of a formula ceiling. Each Region's ceiling is calculated on the basis of its percentage share of the FY 73 annualized funding level for all RMPs. Funds awarded in FY 73 for special projects such as EMS and HS/ea's have not been included in the annualized funding levels used in this calculation. Graphically the formula looks like this:

$$\text{Region's ceiling} = \text{FY 74 funds available} \times \frac{\text{Region's Annualized 73 Funding Level}}{\text{Annualized Funding for all Regions for 73}}$$

Each Region meeting the requirements of the September 7th instructions is entitled to the amount it requests up to the calculated ceiling.

At the Council meeting RMPS staff will explain budgets and provide additional, up-to-date information (from site visits, phone contacts, etc.) on individual Regions, and present on occasion specific issues for Council consideration. Written staff summaries for all 53 active Regions are being mailed to Council members under separate cover.

IX. Miscellaneous

Dr. Margulies is now full-time as Acting Deputy Administrator, HRA. (All key positions in HRA, except Dr. Endicott, the Administrator, are "acting.)

Mr. Daniel Zwick, who was with RMPS a number of years ago, has been appointed Acting Director of the HRA Office of Planning, Evaluation and Legislation. Two former RMPS staff, Mr. Lyman Van Nostrand and Mr. Bob Walkington, have moved into key spots in Mr. Zwick's office.

In August, the Nassau-Suffolk RMP separated from and dissolved the joint program relationship with the Nassau-Suffolk CHP. Neither the RMP's corporate structure nor staff structure have been adversely affected.

The Metro. New York RMP has changed grantee to the New York Academy of Medicine.

The New Jersey RMP changed grantee to the New Jersey Regional Medical Program, Inc.

The Tennessee/Mid-South RMP has reorganized and is now in full compliance with the RMPS policy governing RAG-Grantee-Coordinator relationships.

X. Subjects to be Covered at the Council Meeting

This report does not cover the following items of interest that will be discussed at the Council meeting: (a) new kidney regulations; (b) current status of RMPs; and (c) publications resulting from Section 907 activities. We also expect that Agency and Bureau representatives will cover future plans and legislative developments.

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I hope that the above information will help to bring you up to date on major program developments since the last meeting in July. We recognize that each member has an unusually large number of applications assigned due to the depleted status of the Council. I trust that your reading of the applications will give to you, as it has to our staff, a strong impression of the overall vitality and continued viability of the Regions.

I expect that we will have a very busy and productive meeting, and I would like to thank the entire Council for their time and effort. Further and more detailed staff analyses of the November applications will be available at the meeting.

Herbert B. Pahl, Ph.D.

Enclosures

SOURCES AND STATUS OF RMPS FUNDS ANTICIPATED
TO BE AVAILABLE FOR EXPENDITURE BY RMPs IN FISCAL
YEAR 1974, AS OF NOVEMBER 1, 1973

SOURCE AND CATEGORY OF FUNDS			STATUS AS OF 11/1/73
Fiscal 73 Funds			
FY 73 Balance	$ 6.900 m		. Awarded 6/30/73 But may not be spent by RMPs.
Direct Operations(73 Supplemental)	1.700 m		. Available to RMPS
Congressional Construction Earmark (73 Supplemental Appropriation)	5.000 m		. $.5m awarded to North Country Hosp., Newport, Vt. Remaining $4.5 m earmarked by Congress for Seattle Children's Medical Center.
Total 73 Funds	$13.600 m	$13.600 m	
Fiscal 74 Funds			
RMP Support	$41.236 m		. $17.1 awarded 10/1/73. Remaining $24.136 m apportioned and released for RMP Grants.
HEW Earmark for Pediatric Pulmonary Centers	2.000 m		. Eight centers funded in the amount of $1,340,420. Two centers Calif. and N.M. still to be awarded. Georgia Pediatric Pulmonary application withdrawn.
Direct Operations	2.314 m		. Available to RMPS
Other	1.464 m		. $.338 m set aside for HMO contract extensions through 12/31/73.
Total 74 Funds	$47.014 m	$47.014 m	
TOTAL ANTICIPATED AMOUNT FOR FY 74		$60.614 m	

ENCLOSURE(6)