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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
ROCKVILLE, MARYLAND 20852

June 13, 1972

REGIONAL MEDICAL
PROGRAMS SERVICE

It is again time to report to you the highlights of the most recent National Advisory Council meeting which took place on June 5-6. Let me begin with the most intriguing part of the discussion, that relating to the use of RMP funds for organization and development of Health Maintenance Organizations. You will recall that since the inception of the HMO initiative by the Department, we have been discussing the appropriate role of RMP's in this activity both with Coordinators and with the National Advisory Council. You are also aware, I am sure, that RMPS was some time ago given formal responsibility by the Administrator for developing quality of care standards and monitoring procedures for HMO's.

As further background, let me point out that the Department had good reason to believe that authorizing legislation for a special HMO program would be passed during the present session of Congress. In anticipation of this, funds from existing programs have been used, where authority exists for such purposes, to support HMO feasibility and planning studies and some initial organizational activities. These funds have been provided so far through the 314(e) program

and the National Center for Health Services Research and Development, both of which are within HSMHA, and from the 1110 program of the Social and Rehabilitation Service.

The Council knew that \$16.2M of the present RMP appropriation had been earmarked by the Office of Management and Budget for HMO's and was asked to take final action on approval of a portion of these funds. Proposed action of this nature was discussed with the Council in February. The discussion at the current Council meeting was concerned with the allocation of about \$4.3M of the earmarked amount for projects recommended for approval by the Health Maintenance Organization Service.

While RMPS staff has participated in HMO reviews from the beginning of the effort, the Health Maintenance Organization Service has complete responsibility for the review and funding of HMO proposals. Because the present round of HMO grants would require action by the RMP Council, a subcommittee of three Council members, Dr. Cannon, Dr. Watkins and Dr. Komaroff, participated in the final stages of HMO reviews on May 31. We asked them to observe and convey to the Council their impressions of the adequacy of the HMOS review process, which they reported to be satisfactory.

Dr. MacLeod, Director of the HMO Service, presented the HMO applications to the Council and recommended approval of the 29 requests selected for continuing support as the result of HMOS review. At this point, and previously in the meeting, some of the Council members raised questions about the appropriateness of using RMP funds for this purpose. Essentially, the arguments were these: (1) There has been no legislation for HMOs; (2) There is doubt about passage of HMO legislation during the current Congressional session; (3) Grants for HMO's will not advance the goals of RMP; (4) educational functions and quality controls which are a major concern of RMP are not in evidence in a large proportion of the applications; and (5) The Council has endorsed support for quality control and educational activities, not general support for HMOs with RMP funds.

Dr. MacLeod, Mr. Riso, Deputy Administrator for Development, and I advanced the following arguments in support of the Department's position: (1) The General Counsel has determined that RMP funds may be used for planning and development of HMOs; (2) The Secretary has indicated to appropriate Congressional Committees that RMP funds would be used on a one-time basis to get HMO's started; (3) The public benefits when Government uses existing legislative authority to lay the groundwork for new programs; (4) Good programs, including categorical disease control, cannot prosper in a poor delivery system; (5) HMO's will serve as unique settings for testing the interrelationships of manpower, costs and quality, and (6) RMP's professional activities are closely linked to HMO development.

After extensive discussion of the above points, the Council voted by a narrow margin to approve \$4.3M for one year for the 29 HMO proposals recommended by HMOS. In subsequent discussion, it became evident that the Council was not fully comfortable with its readiness to vote on this matter. They therefore decided to set aside their previous action and instead requested that a mail ballot be taken after additional information on HMO's and their relationship to the RMP mission had been provided. The necessary materials are already in the mail.

Dr. Wilson was not available to meet with the Council on the first day when the discussion of HMO's took place. He did however meet with the Council in executive session the following morning.

While I am on the subject of special applications, I am sure that you will all be interested in the actions on requests for EMS and Health Services/Education activities. We received 35 EMS proposals totaling \$33.250M. Of these, 30 were recommended by the Council for approval in the amount of \$11.663M.

Nineteen Regional Medical Programs submitted requests for \$10.230M to support expanded education activities. Fourteen of these were approved for periods ranging from 1 to 3 years for a grand total of \$6.879M. The above figures do not include the requests for planning grants which were received on June 1. These latter requests submitted by 25 Regions and totaling \$1.941M were not reviewed by Council. Instead, Council delegated authority to approve funding of these types of small projects to the Director. A copy of the Council's delegation is attached. (See Appendix 1.)

Now let me turn to other matters that were discussed with the Council, first the RMP budget, I discussed our current budget situation and the prospects for 1973 as outlined in the tables attached as Appendix 2.

Table 1 constitutes an analysis of the '72 budget. You will note that proposed HMO funding will not utilize the full amount of RMP funds originally earmarked for this purpose, and there is a chance of recovering the unused balance for the regular program. In addition, \$7.5M placed in reserve by OMB earlier in the year for funding of Area Health Education Centers may also be released for general and/or high priority HEW/RMP purposes. As of this writing, however, none of the above funds have officially been made available. If they are, we can make full use of the additional resources for approved regular and supplementary activities.

An item that is not shown in the tables, and which I mentioned in Council, is that language in our last appropriation bill urges RMP to maintain a \$1.7M level of expenditure for pulmonary pediatric centers. This amount will be used for new and continued support of existing activities and is now fully committed.

A study of Table 2 will show that all signs point to an increase in the RMP budget for Fiscal 1973. The Administration's request for \$131M far exceeds last year's. The House Subcommittee has reported out \$150M and Senate committee action has not been completed.

Turning to another subject, now, we presented a draft of new Regulations and associated policy documents for discussion and comment by the Council. The current Regulations have not been changed since 1967 and need to be updated to reflect the current Law and the manner in which the Program is currently administered. The bulk of the draft under discussion was prepared by the General Counsel's office on the basis of RMP documents such as the "Mission Statement," "Review Process Requirements and Standards," etc., with which you are all familiar.

Council members made some excellent suggestions for revision of the material in order to insure maximum flexibility in the administration of the program. We agree with these and will work with the General Counsel's Office to incorporate them in the final document.

For your information Departmental procedures require that proposed Regulations be published in the Federal Register and that at least 30 days be provided thereafter for comment. Final Regulation can be issued only after consideration of any comments and publication of the final Regulations again in the Federal Register. As you can see, there will be plenty of opportunity for the Regional Medical Programs to provide advice and suggestions before new Regulations are finalized.

I would now like to call your attention to two policy documents which were considered by the Council copies of which are attached to this letter. The first of these is the RMPS policy concerning "Grantee and Regional Advisory Group Responsibilities and Relationships." (See Appendix 3). We have found through problems which come to our attention from time to time and from the review process verification visits which have now been going on for a period of months that in many instances the responsibilities of the Regional Advisory Group, the Grantee and the Coordinator are ill-defined and need to be spelled out more clearly. The present policy statement is the result of extensive effort and thought on the part of myself and many of our staff. It has been specifically

cleared by the Office of the Administrator. A previous draft has been discussed formally with the Steering Committee and individually with many of you.

In discussing the Grantee-RAG Responsibilities and Relationship Statement with the Council, I pointed out that some structural changes would be required in several Regional Medical Programs. I assured the Council that adequate time would be allowed for regions to effect whatever changes may be necessary. The statement as approved by Council is attached herewith as Appendix 3 for your information. I WOULD SUGGEST THAT THIS POLICY STATEMENT IMMEDIATELY BE CALLED TO THE ATTENTION OF YOUR REGIONAL ADVISORY GROUP AND GRANTEE (WHERE APPLICABLE) IN ORDER TO IDENTIFY WHAT ACTION WILL BE NECESSARY ON YOUR PART WITH RESPECT TO YOUR REGION. In the near future we will advise you regarding deadlines and other matters concerning implementation.

The second policy statement which I alluded to previously is "Governing Principles and Requirements, Discretionary RMP Funding and Rebudgeting" (Appendix 4). This policy statement will, I hope, clear up confusion and misunderstandings concerning what matters require prior RMPS approval under the new decentralized system of operation initiated a year ago. Rather than paraphrasing the Council action, I URGE YOU TO REVIEW IT CAREFULLY WITH THE RAG AND GRANTEE. (See Appendix 4.)

Several other items were presented to the Council by staff. Dr. Hinman reviewed the new kidney disease "Guidelines and Review Procedures Statement" which was distributed to you recently in a NID, dated May 3, 1972. You will recall that these Guidelines require that a technical review of each kidney proposal be carried out by a minimum of three kidney specialists who are selected by the RMP from an RMPS approved list or, if not on the list, may be selected by the RMP subject to RMPS approval. There was extensive discussion of this point during the Review Committee meeting in May. The Review Committee felt strongly that technical reviews should be conducted only by experts selected by RMPS from its national roster. The Council decided to allow the NID to stand as written.

Also in connection with the kidney guidelines, the Council felt that further clarification was needed for the term "full-time transplantation surgeons," as used in item 6B on the second page of the NID. We will get a letter out to you in the near future covering this point in greater detail.

Mr. Chambliss briefly presented a few items to the Council which I am sure you will also find of interest. First, he discussed changes in the composition of the RMPS Review Committee. The terms of Drs. Mayer, Spellman, Besson and White have all expired. Dr. Schmidt will replace Dr. Mayer as Chairman, and, Mrs. Maria Flood of El Paso, Texas, has accepted an appointment to fill one of the vacancies. We are still in the process of appointing individuals to fill the remaining places.

Mr. Chambliss also discussed an opinion which we requested and received from the General Counsel's Office concerning the reproduction and distribution of video tapes and any income therefrom. (Appendix 5)

Before I close, I might mention that Dr. Robert Van Hoek, who has recently moved into the position of Director of the National Center for Health Services Research and Development, spoke briefly about plans for closer coordination with RMPS and RMP's locally. He indicated that the Center is particularly interested in studies relating to quality of care and resource utilization, and manpower with special emphasis on Ambulatory Services.

By now I am sure that I have covered the main points of the meeting; the rumor mills will be buzzing soon with additional details. The next Council meeting will take place on October 16-17, and I will be reporting to you again as soon thereafter as possible.

Sincerely yours,



Harold Margulies M.D.
Director

Enclosures

Enclosures:

- Appendix 1 - Delegation of authority for approval and funding of Community-based educational activities feasibility studies.
- Appendix 2 - Budget tables
- Appendix 3 - Grantee and Regional Advisory Group responsibilities and relationships
- Appendix 4 - Discretionary funding and rebudgeting authority
- Appendix 5 - General Counsel's opinion concerning reproduction rights for videotapes

APPENDIX 1

DELEGATION OF AUTHORITY FOR APPROVAL AND
FUNDING OF COMMUNITY BASED EDUCATIONAL
ACTIVITIES FEASIBILITY STUDIES

The Council, recognizing the need for expeditious action and flexibility in funding feasibility studies that would permit RMPs and local areas to assess the potential and feasibility of developing community based educational activities, delegates to the Director of RMPS authority to award supplemental grants to individual Regional Medical Programs for such purposes. It is understood that (1) no local area shall receive funds for such feasibility study in excess of \$50,000 (total costs), and the duration shall not exceed 12 months; (2) no single RMP shall receive funds in excess of \$250,000 for such feasibility studies in any 12 month period; and (3) approval and funding of such feasibility studies by the Regions will be within such general guidelines as RMPS may establish.

It is further understood that Regions will first utilize "free" Developmental Component funds, where available, and that the general policies and procedures of the individual Regional Medical Programs with respect to review, approval, and funding, including RAG concurrence, will apply.

APPROVED: National Advisory Council on Regional Medical Programs,
June 5, 1972

Table 1
Analysis of 1972 Budget

Appropriation	\$102,771,000	
Carried over from 1971	<u>44,500,000</u>	
Total available	147,271,000	
Transfer of Smoking and Health	<u>-2,189,000</u>	
	145,082,000	
Anticipated increase for pay	<u>83,000</u>	
	145,165,000	
Amount available for grants and contracts (Title IX)	\$135,000,000	
Earmarked for HMO's	-16,200,000	
Earmarked for EMS	- 8,000,000	
OMB reserve (AHEC)	- 7,500,000	
Cancer center	<u>- 5,000,000</u>	
Grants for the RMP's	98,300,000	
Estimated Recovery of HMO Earmark	7,000,000)	?
Release of OMB reserve	<u>7,500,000</u>)	?
Net amount available in FY 72 for grants and contracts (Title IX)	112,800,000	?

Table 2
Analysis of 1973 Budget Request

Total request to Congress	\$131,314,000
Request for grants and contracts	125,100,000
Earmarked for EMS	<u>-15,000,000</u>
Net amount requested in FY 73 for grants and contracts (Title IX)	110,100,000

APPENDIX 3

RMPS POLICY CONCERNING GRANTEE AND REGIONAL ADVISORY GROUP RESPONSIBILITIES AND RELATIONSHIP

May 26, 1972

A. Introduction

There are three major components of the 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 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.

B. Grantee

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 by RMPS. (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.
6. Prescribing fiscal and administrative procedures designed to insure compliance with all Federal requirements and to safeguard the grantee against audit liabilities.
7. Negotiating provisional and/or final indirect cost rates for affiliates.
8. Providing to the RMP all those administrative and supportive services that are included in the grantee's indirect cost rate.

Chief Executive Officer

As an employee of the grantee, the Chief Executive Officer -- the full-time person with day-to-day responsibility for the management of the RMP -- is responsible to it; 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, selecting program staff, and supervising their activities.
4. Insuring both the effectiveness of operational activities and integration of all operational and staff activities into a total program.
5. Monitoring grant-supported activities to insure that all Federal requirements are being complied with.
6. Establishing and maintaining an effective review process in accordance with RMPS requirements.

7. Maintaining appropriate relationships and liaison with RMPS, including Regional Office staff. This shall include the dissemination of Federal program policies and requirements to staff, Regional Advisory Group, and regional provider groups and institutions; site visit preparations; and communication of important developments within the Region and program to RMPS.

C. Regional Advisory Group

The Regional Advisory Group (or 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 staff activities; and evaluating overall program progress and accomplishments.
2. Approving any applications submitted to RMPS.
3. Approving the RMP organizational structure and significant program staff activities.
4. Approving overall budget policy and major budget allocations.
5. Nominating the Chief Executive Officer for selection by the grantee (see B.3 above).
6. Selecting the Chairman for confirmation by the grantee.
7. Subsequent to its establishment (see B.1 above), procedures for selecting its own members; insuring appropriate representation on the Regional Advisory Group in accordance with the Act, RMPS regulations, and guidelines; insuring its continuity; other than the Chairman, selecting its own officers; and establishing an executive committee from its own membership to act on its behalf between RAG meetings.
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.

APPROVED: National Advisory Council on Regional Medical Programs
June 5, 1972

APPENDIX 4

GOVERNING PRINCIPLES AND REQUIREMENTS
DISCRETIONARY RMP FUNDING AND REBUDGETING AUTHORITY

May 26, 1972

- A. Principles - The following principles shall be generally applicable in all situations.
1. No activity shall be undertaken that is contrary to the RMP (P.L. 91-515) and other applicable legislation, regulations, and written Departmental, HSMHA, and RMPS policies.
 2. Any activity undertaken with the Requirements enunciated below shall be subject to the regular review, funding, and rebudgeting requirements and approvals of the particular RMP and its grantee organization and Regional Advisory Group.
 3. Any operational activity or project initiated by an RMP within its discretionary authority must have current RAG approval. That is to say, it must have been approved by the RAG in the budget period during which it is begun or, the immediately preceding one. If not, such an operational activity must be reapproved by the RAG before it can be undertaken.
 4. 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.
- B. Requirements - Prior RMPS approval is required in the following instances.
1. RMPS approved for a triennial period must obtain prior approval for any proposed program or operational activity involving:
 - a. Alterations and renovations in excess of \$25,000 or any new construction. (Present policy generally precludes the latter.)
 - b. Human subjects. (This represents programmatic approval as differentiated from approval of the grantee's system for safeguarding the rights and welfare of human subjects.)
 - c. HMO related feasibility studies.
 - d. End-stage treatment of kidney disease (e.g., dialysis, transplantation) and supportive facilities and services.
 - e. Other specialized activities which may, from time to time, be identified by HSMHA/RMPS.
 2. RMPS not yet approved for a triennial period must obtain prior approval for:
 - a. Any activity enumerated above except that any alterations and renovations regardless of cost must be submitted.

b. Any new operational activity not generally covered by its program as approved by the Council.

C. Notification - New activities may be initiated by an RMP without prior RMPS approval in accordance with the discretionary funding authority stated above and the criteria for rebudgeting contained on page 4 of Instructions for the Financial Data Record. RMPS should be notified in accordance with those instructions at the time the activity is initiated, whether or not there has been a redistribution of funds.

APPROVED: National Advisory Council on Regional Medical Programs
June 5, 1972

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY

TO : Mr. Gerald T. Gardell
Chief, Grants Management Branch
Division of Operations and Development, RMPS

Office of the General Counsel
Date: MAR 15 1972

FROM : Jim Goodman *Jim Goodman*
Public Health Division

SUBJECT: Films produced with Regional Medical Program Funds--Copyright and
Distribution Rights of Grantee--Accountability to the Federal Government

This is in response to your memorandum of January 13, 1972, in which you report that several RMP grantees would like to enter into agreements with private organizations to distribute films and videotapes that were produced with Federal grant funds. Some of the private organizations propose to distribute the films for profit, paying a royalty to the grantee.^{1/} One group wishes to recoup only the costs of producing and distributing the films, turning over any excess fees or profits to the grantee.^{2/} You report that none of the grantees has yet obtained a copyright on any of the films and videotapes and that the National Audio-Visual Center, an operating unit of GSA, has shown an interest in the distribution of these films and videotapes.

You have requested our opinion as to the various rights of the Federal Government, the grantees, the private corporations, and the National Audio-Visual Center with respect to the distribution of these films. We believe that the following general discussion of the issues involved in such a case should answer the questions raised by your memorandum and the various letters and memos attached to it.^{3/}

I. Grant-Supported Films--Publication and Copyright

The regulations for Grants for Regional Medical Programs provide, in regard to publication of materials produced with grant funds,

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- 1/ Videorecord Corp. of America and Univision, Inc.
 - 2/ Winthrop Laboratories.
 - 3/ You also mention that the films were produced in accordance with Chapter 1-450 of the HEW Grants Administration Manual. Due to certain questions regarding the applicability of the Manual, however, discussion of that issue will be found in the final section of this memorandum.

as follows:

"Grantees may publish materials relating to their regional medical program without prior review provided that such publications carry a footnote acknowledging [assistance] from the Public Health Service, and indicating that findings and conclusions do not [necessarily] represent the views of the Service."^{4/}

The films and videotapes produced by the RMP grantees clearly fall within the ambit of this provision. Accordingly, the grantees may produce and distribute their films, or contract for such production and distribution, without prior review by RMPs, provided that they include the required statement in the "credits" or other appropriate portion of the film.

The regulations for Grants for Regional Medical Programs also deal with copyrighting of material produced with grant funds. The applicable provision of the regulations reads as follows:

"Where the grant-supported activity results in copyrightable material, the author is free to copyright, but the Public Health Service reserves a royalty-free, nonexclusive, irrevocable license for use of such material."^{5/}

The films or videotapes involved here are copyrightable material produced with grant funds, and are therefore subject to this provision. Consequently, the grantees may copyright the films and videotapes, subject to the rights reserved by the Public Health Service for the use of such materials.^{6/}

II. Accountability to the Federal Government for Grant-Related Income

In addition to questions involving the copyright and distribution

^{4/} 42 CFR, § 54.412.

^{5/} 42 CFR, § 54.413.

^{6/} This is, of course, subject to any agreements that may have been entered into between the RMP grantees and third parties further limiting the grantee's rights.

rights of RMP grantees, there is the question of accountability to the Public Health Service for grant-related income. The disposition of royalties and other copyright fees paid to grantees for the use of materials produced with grant funds is, we think, controlled by a specific RMP policy that may be found on page 17 of "Guidelines--Regional Medical Programs (Revised May 1968)." That policy reads as follows:

"When the costs of publishing material are provided from Public Health Service grants, any royalties or profits up to the amount charged to the grant for publishing the material shall be refunded to the Public Health Service."

Therefore, the RMP grantees are on notice that all royalties or other fees they receive for the use of films produced with grant funds, up to the amount they charged to the grant for production of the films, must be refunded to the Public Health Service.

III. National Audio-Visual Center

We are unaware of any requirement that grantees awarded Federal grant funds must submit films they produce with those grant funds to the National Audio-Visual Center for distribution. Any such requirement would obviously run counter to HEW's approach, which treats the film essentially as the private property of the grantee, subject to certain specifically retained governmental rights. On the other hand, it is

possible that the Public Health Service, in utilizing those retained rights, might be authorized to distribute a grant-supported film through the National Audio-Visual Center. Should that situation ever be contemplated, we would be willing to give a more fully-researched reply.

IV. Chapter 1-450--HEW Grants Administration Manual

Based upon the information that we have received through informal discussion with members of your staff, it is our understanding that compliance with the HEW Grants Administration Manual by the RMP grantees involved in this case was not an explicit condition to the making of these grant awards, nor is it made so by the regulations or guidelines. We understand, however, that you are presently revising your regulations and guidelines to include considerable reference to the Manual. Assuming that those references will include Chapter 1-450 of the Manual, we offer the following discussion for future reference.

Chapter 1-450 of the Grants Administration Manual for HEW, is entitled "Use of Grant Funds for the Production of Motion Picture Films." It prescribes certain procedures which must be followed in the production of films made with grant money "to introduce safeguards which will insure that the film content does not become a source of embarrassment to the Department or a detriment to the attainment of its objectives."8/

Chapter 1-450: (1) prohibits the use of grant funds for the production of films "required in the conduct of the direct operations of the Department or its agencies;"9/

(2) prohibits the use of grant funds to produce films "for viewing by the general public", unless prior approval by the granting agency has been obtained;10/ and

8/ HEW Grants Administration Manual § 1-450-10.

9/ Id., § 1-450-30-A.

10/ Id., § 1-450-30-C.

(3) allows the use of "grant funds to produce motion picture films intended for viewing by restricted audiences in connection with a program or project conducted by the grantee."^{11/}

According to your memorandum, the films produced by the various RMP grantees were originally intended "for viewing by restricted audiences in connection with" their respective RMP grant projects. They were, therefore, produced without prior approval and would have been produced in accordance with Chapter 1-450, § 1-450-30-B, of the HEW Grants Administration Manual.

As the title of Chapter 1-450 indicates, it deals with the production of films with grant funds. It does not purport to regulate the distribution of films produced with grant funds. Once a film has been produced in accordance with Chapter 1-450, the grantee is not further restricted by that chapter in the distribution of his grant-supported film. Therefore, distribution of the films previously produced by the RMP grantees "for viewing by restricted audiences" would be unaffected by Chapter 1-450.^{12/}

11/ Id., § 1-450-30-B (emphasis added).

12/ The proposed agreements between the RMP grantees and private organizations, however, raise a question as to whether future films would be produced in accordance with Chapter 1-450. It appears that such agreements may provide that all future films produced by these RMP grantees with grant funds will be subject to distribution by the private organizations. If this were the case, then such films would not be "intended for viewing by restricted audiences", and the grantees would need to obtain prior approval by HEW before using future grant funds to produce the films. Once again, however, Chapter 1-450 would not restrict the distribution of these films once they were produced in accordance with that Chapter. Furthermore, if the films were produced with other than grant funds, Chapter 1-450 would not apply.