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212 JU 2-7230

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Dec. 14, 1965

Stuart M. Sessoms, M.D.
Deputy Director
National Institutes of Health
Room 107, NIH Building 1
Bethesda, Maryland 20014

Dear Dr. Sessoms:

We were pleased to have the opportunity of representing the American Nurses' Association at the meeting last Thursday to review and discuss the rules and regulations pertaining to the Heart Disease, Cancer and Stroke Amendments of 1965. Inasmuch as it did not seem appropriate at the time of the meeting to raise the issue as to just what the participating roles of the different professions would be in the implementation of this Act, we would like to suggest that the guidelines which will be used at the local level will include information and instructions on the roles of the individual health disciplines.

The intent of the Heart Disease, Cancer and Stroke Amendments is to make it possible through research, education and service approaches, to provide the best possible care to all patients with these and related diseases. The law provides for an advisory group to the applicant to advise on the formulation and carrying out of the plan for the establishment and operation of such regional medical programs.

We urge that nurses be invited to participate in the planning and implementation of these projects at the local level. As Dr. William Stewart, Surgeon General of the United States Public Health Service, indicated in an article in the December 10 issue of Medical World News, "To make the best care available to all,...will require...the development of better systems, such as team practice and coordinated networks of facilities, so that the best talents can be brought to bear on the needs of all patients."

We recommend that nurses be included among the members of the advisory groups and that they be brought in on the early planning of the centers, physical set-up, operational policies, procedures, and staffing. The ultimate effect of a program, no matter how well planned, depends on the leadership quality of the persons who are going to be administering the programs at the various levels. Therefore, we urge that if qualified personnel are not available, plans should be made to recruit and prepare them to take over when the operation of these health facilities is ready to begin.

We agree with Dr. Stewart that meaningful accountability and evaluation of the contributions made by the different health disciplines can only be brought about by the participation of all involved right from the beginning of these programs. The nursing profession looks forward to the opportunity of contributing to the successful planning and implementation of the Heart Disease, Cancer and Stroke Amendments.

Sincerely,

Julia C. Thompson
Director, Washington Office

Meryle V. Hutchison

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Assistant Director
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JCT/hb

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December 10, 1965

ROBERT C. BERSON, M.D.
EXECUTIVE DIRECTOR
WASHINGTON, D. C.

EVANSTON: AREA CODE 312;328-9505
WASHINGTON: AREA CODE 202;232-5870

Dr. Stuart M. Sessoms, Deputy Director
National Institutes of Health
9000 Wisconsin Avenue
Bethesda, Maryland 20014

Dear Dr. Sessoms:

The purpose of this letter is to summarize a few points concerning the first rough draft of regulations concerning Grants--Regional Medical Programs and the discussion of this topic, which took place on December 9.

Concerning the role of the "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", I think it would be a mistake for the regulations to spell out the function of this Advisory Group any more specifically than the law does. It may be that in some regions the "Advisory Group" will maintain active surveillance of the operation of the program and will have a great deal of authority. This could pose real problems for the institutions which come to have the responsibility for carrying out the program. While it is not difficult to think of examples of organizations or groups operating effectively under administration arrangements that deviate from what is usually considered sound administrative practice, I think it would be a mistake for the National Institutes of Health to write regulations that would go any farther than the law absolutely requires.

In Section 66.8, I think the wording "funds otherwise available for activities under the regional medical programs" is unnecessarily vague. It could be made more specific by altering it to read "funds otherwise available for the same purposes" or by listing more specifically the funds referred to.

Section 66.9 Termination concerns me even more. I do not have alternative wording to suggest. My thought is that the authority for summary termination without prior notice should be tied to malfeasance or defiance of an administrative or fiscal nature and termination because the quality of research, training and related demonstrations of patient care is judged to be unsatisfactory should be handled in a different manner.

I did not make this point in the discussion on December 9, but I wonder if it would not be wise to consider putting in the regulations some provision for termination on the part of the applicant.

Dr. Stuart M. Sessoms December 10, 1965

In Section 66.10, I am concerned by the stipulation that the same policies and methods must be applied to "self-sponsored" research as to that supported by grants or contracts. In every medical school, there is a good bit of activity that could be classified as "research" that is not separately budgeted or planned for. This could be considered self-sponsored research, but since it is not separately budgeted, there is no allocation of expenditures as between direct and indirect cost and I think it would be extremely unwise for the regulations to insist that this be changed. This defect could be corrected by inserting after "the grantee applies to all its" the words separately budgeted.

I am also concerned by the failure of Paragraph (d) in Section 66.10 to make it clear that "third parties", such as Blue Cross and commercial insurance companies, are expected to bear the portion of the cost of caring for these patients that they would if the patients needed and were receiving care in institutions that are not a part of the Regional Medical Program. In addition, I think some real consideration should be given to the patient paying all or part of the cost from his own means. I do not think that patients should be excluded from these programs because they are able to pay for what they need if they would otherwise be eligible, and I would imagine that just about all of them will receive high quality care which their problem warrants.

In the meeting on December 9, Section 66.12 was not discussed. The ten-year commitment of the facility or equipment is spelled out in Paragraph (a) but not in Paragraphs (b), (c), (d) or (e). It seems to me that this is a mistake. If the grantee wishes to put the facility or equipment to some other use after it has served the purpose for which it was constructed or procured for a substantial time, and I think ten years is a reasonable time, I don't think the Surgeon General should, in effect, continue to hold title to that facility or equipment.

It seemed to me that you and the whole Public Health Service team conducted the conference in an exemplary manner and that sound progress toward good regulations is being made.

Best wishes,

Robert C. Berson, M.D.
Executive Director

RCB:sg

Transcribed December 13.
Dictated but not read.