COUNCIL OF DEANS
ADMINISTRATIVE BOARD

Conference Room, AAMC Headquarters
June 20, 1974
9:00 a.m. - 4:00 p.m.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
MINUTES
ADMINISTRATIVE BOARD OF THE COUNCIL OF DEANS

March 21, 1974
9:00 a.m. - 3:00 p.m.
Conference Room
AAMC Headquarters

PRESENT

(Board Members)

Ivan L. Bennett, M.D.
J. Robert Buchanan, M.D.
Ralph J. Cazort, M.D.
John A. Gronvall, M.D.
Clifford G. Grulee, M.D.
Andrew Hunt, M.D.
William D. Mayer, M.D.
Emmanuel M. Papper, M.D.
Robert L. Van Citters, M.D.

(Staff)

Jane Becker
Prentice Bowsher
John A. D. Cooper, M.D.
Evelyn Harrison
Nan Hayes
William Hilles
Doris Howell, M.D.
Paul Jolly, Ph.D.

(Staff, continued)

Amber B. Jones
James R. Schofield, M.D.
John Sherman, Ph.D.
August Swanson, M.D.
Bart Waldman
Marjorie P. Wilson, M.D.

(Guests)

Mark Cannon
Daniel Clarke-Pearson
Sherman M. Mellinkoff, M.D.

ABSENT

Julian R. Krevans, M.D.
William F. Maloney, M.D.

I. Call to Order

Dr. Papper, Chairman, called the meeting to order shortly after 9:00 a.m.

II. Minutes of the Previous Meeting

The minutes of December 13, 1973 meeting was approved as circulated.

III. Setting of AAMC Priorities

At the December 13, 1973 Administrative Board Meeting, Board members not at the Officers' Retreat registered their dissatisfaction with the AAMC's process for setting annual priorities, noting that being provided a write-up of the retreat conclusions on the day of the Board Meeting

did not permit careful, substantive deliberation. After discussion of this, the Board voted to recommend that the Executive Council place on its March agenda the matter of the retreat and the process by which AAMC priorities for the year are developed, reviewed and approved.

A method of setting of priorities was set forth in the agenda for the March 21, 1974 Executive Council Meeting. There was a consensus that the modifications suggested were entirely appropriate and acceptable. The concern the Council of Deans originally expressed about the limitation of time relative to priority setting at the Executive Council Meeting following the December retreat has been ameliorated by the proposed adjustments in scheduling providing for input during the September meeting of the Board and the annual meeting of the Council in the fall and expanding the meeting of the Executive Council in January to two days. Members of the Board reiterated that there had not been a concern with the priorities themselves, but with the process of setting them.

IV. Appointment of a Task Force to Develop AAMC Position on the GAP Report of the NBME

The Administrative Board believes it is essential that a Task Force be appointed to develop a position on this very important report and that the AAMC Task Force should seek input from both the Group on Medical Education and the Organization of Student Representatives which have already expressed an interest in the matter. Mr. Daniel Clarke-Pearson, Chairperson of the OSR, and Mr. Mark Cannon, Chairperson-Elect of the OSR, were present at the meeting and strongly supported an AAMC-wide Task Force effort on this matter.

V. Appointment of MCAAP Advisory Panel

The Administrative Board discussed the development of the report of the Task Force on the Medical College Admissions Assessment Program study which was provided to the Executive Council as information at the last meeting. Also discussed was the status report on MCAAP projects included in the agenda for this meeting. The comment was made that the AAMC might well concentrate on the first seven areas because of its own unique capability and should certainly take advantage of the ongoing research by other groups on items 8 and 9. (See Executive Council Agenda.) It was the concensus that the substitute proposal to appoint an ad hoc committee to review the Task Force report and evaluate it for the Executive Council was

entirely appropriate. There was some discussion about where the emphasis should come from in terms of a revision of the Medical School Admission Assessment Program. Some individuals felt that the administrators of the medical schools who have responsibilities for undergraduate educational process should have primary input. Others commented on concerns of the public with the quality of the products of the medical education process. No conclusions were reached on these issues. However, it was concluded that there should be a substantial amount of money allocated for these studies to insure an adequate and in-depth methodology and an analysis. It was further suggested that all members appointed to the Task Force understand the time commitment that will be required of them. Action in this area was to support the appointment of the Task Force as stated in the Agenda.

VI. Resolution on Safeguarding Data System

The resolution on Safeguarding Data Systems came from the OSR Annual Meeting. Considerable discussion revolved around the general availability of personal evaluations and the resultant loss of confidentiality. It was concluded that specific policy would be handled at the institutional level. However, in order to emphasize the importance of this issue and to indicate the concern of the Board, it was recommended that the Executive Council approve the following statement: The AAMC urges its member institutions to establish a mechanism for monitoring automated and non-automated personal data systems. There should be no personal data recordkeeping systems whose existence is secret. Note that the Board deleted parts b. through e. as set forth in the Executive Council agenda. It was the concensus that specific policies on this matter would necessarily be developed at the institutional level.

VII. AAMC Response to the IOM Report

Many members of the Administrative Board had not received a copy of the Institute of Medicine Report and voiced some concern about approving a document that they had not seen. It was emphasized that the Board was not being asked to endorse the report, but to help in developing an AAMC response to its general subject matter. Of particular interest to the group was the lack of information on specific methodology from the IOM; such a document is not expected to be released for three to six months. It was agreed that there was similarity on major issues in both the IOM Study and the AAMC Sprague Committee Study and therefore a method of response, supporting the points outlined in the Executive Board Agenda, would be appropriate, namely:

1. The AAMC agrees with the IOM recognition that the federal government has a role in providing ongoing support for health professions education.

2. The AAMC supports the IOM position that the federal role in supporting health professions education may be best administered through first-dollar capitation support, dependent on maintaining the present production of graduates.

3. The level of capitation for medical education recommended by the IOM ($2,450 - 3,900) corresponds to the basic capitation support level recommended by the AAMC Committee on Health Manpower ($3,000).

4. The concept of health professional education as including components of instruction, research, and provision of health services which was utilized by the IOM in allocating costs is similar in principle to the judgments of the AAMC's Sprague Committee.

5. There is remarkable agreement between the IOM cost figures and those determined by the AAMC's Sprague Committee, despite the empirical judgments involved in allocating costs in the highly complex process of educating physicians.

6. The AAMC is attempting to identify the reasons for differences in the costs determined by the two studies by looking at the two methodologies.

VIII. Report of the AAMC Task Force on Foreign Medical Graduates

The Board approved the recommendations as stated in the AAMC Task Force Report on Foreign Medical Graduates as amended by the Council of Teaching Hospitals and the Council of Academic Societies Administrative Board. Recommendation Number 7 "Special Categories" was of concern to the Board members and it was suggested that a remedy would be to delete the phrase "usually required of the house staff" in the Council of Academic Societies' Amendment. This report stimulated more discussion by the Council of Deans Administrative Board than almost any other item. The two primary concerns were (1) undue reliance on the Foreign Medical Graduates for patient services and (2) dual standards for admission to graduate education programs. The matter of greatest concern from the standpoint of the report itself was the requirement that every student, whether U.S. or foreign trained, would be required to take Parts I and II of the National Board in order to be eligible for appointment to approved graduate medical education programs. Concern was also expressed that this limited our capacity for educational diversity. However, the report stipulates the use of

Part I and II only until another examination becomes available. While there is great reluctance to impose inflexible controls, the suggested solution is the only way to come to grips with the problem of FMG training and ultimately with the distribution problems. Concluding that, since the recommendation was not immutable when better methods become available, the Council of Deans Administrative Board moved to accept the report as amended with five in favor, one opposed, and one abstention.

IX. Relationships of AAHC and AAMC

The Board recommended that the Executive Board approve the document "Relationships of the AAHC and the AAMC," noting that the prepared statement has not yet been passed by the AAHC.

X. Coalition for Health Funding

The Board approved the recommendation that the Executive Council endorse the goals and purposes of the Coalition for Health Funding and support the Coalition's recommendations both publicly and in testimony delivered to the Congress.

XI. Modification of the Hill-Burton Program

The Administrative Board endorsed the third option listed in the recommendation in the agenda on the subject of the modification of the Hill-Burton Program. It was recognized that the principles of item three proposed in 1972 AAMC Staff Memo are probably not exclusive of option four and a consistent approach to these two would be appropriate. Options three, four and the recommendation follow:

1. Option three: Extend and modify the program as proposed in a 1972 AAMC staff memorandum: shifting the emphasis from construction of new hospitals to modernization of existing facilities and construction of outpatient facilities; replacing the rural-biased allotment formula with a more equitable formula based on need; increasing the emphasis on assistance for teaching hospitals and outpatient facilities; calling for priority assistance to projects for facilities which will promote the use of innovative and experimental methods of construction and methods of providing hospital and outpatient care.

2. Option four: Convert the program from a formula to a project-grant basis, with or without priorities for urban versus rural hospitals or for certain kinds of

facilities, as proposed in legislation (S2983) introduced February 7, 1974, by Senator Javits, and supported by the Council of Urban Health Providers.

3. Recommendation: The Executive Council select one of the above options or propose an additional option and authorize the AAMC staff to participate appropriately in any legislative process necessary to carry out the designated option.

XII. Modification of the RMP-CHP Programs

After an extended discussion of the relationships of the planning, implementation, and regulatory functions, the Board concluded that the recommendation outlined by the staff for the Executive Council was the most appropriate framework for this issue:

1. Supports the organizational structure of the Kennedy and Rogers' bills relating to health planning and regulation;

2. Reaffirms past Association support of a Presidential panel of health planning and regulatory bodies;

3. Authorizes the Association staff to work with appropriate legislative and Executive agencies and groups in consideration and development of necessary legislative proposals.

Board members coming from medical schools servicing rural areas had experienced difficulties with the definition of a minimum health service area. Rural areas cannot handle the same numbers of people as urban areas, and it was felt that this concern should be recognized and emphasized. A figure of 250,000 to 300,000 participants was recommended as an alternative to the 500,000 serviced in the urban areas.

XIII. Student Participation in NBME

The Administrative Board approved the recommendation that the Executive Council not approve the OSR resolution, but support in principle the concept of adding student representation on the NBME and its committees, and asked the AAMC representatives to the NBME to report this action. In the discussion the OSR people were informed that it would be inappropriate for the AAMC to approve their resolution because the AAMC does not have decision-making authority over the NBME and AAMC representatives serve for the overall

AAMC and do not represent just one element of the constituency. Dr. William Mayer made the statement that he saw no difficulties in adding students to the committee on undergraduate subjects for the NBME and anticipated that student representation would be forthcoming.

XIV. OSR Request for Additional Administrative Board Meetings

The recommendation that the Executive Council approve an increase in the number of OSR Administrative Board Meetings from two (2) to four (4) not including the meetings held at the time of the Annual Meeting was supported. OSR members emphasized their desire to come into sequence with other councils in order to become a more effective part of the AAMC. This action was supported unanimously.

XV. OSR Request for Budget for an OSR Bulletin

Mr. Daniel Clark-Pearson, Chairperson of the OSR, presented the OSR request for a budget for an OSR Bulletin. The Board discussed the OSR's request, which was not on the Executive Council Agenda, and endorsed the goal of incorporating student opinion into existing AAMC publications. Further, the Board emphasized the need to examine all AAMC publications from the standpoint of their continued existence, bearing in mind the importance of their relevance to the student population. The request for a budget for a separate OSR bulletin was not approved. A number of suggestions were made for increasing the visibility of the OSR concerns: editorials and letters to the editor in JME, the use of local institutional publications, and reports in the President's Weekly Activities Report of special student activities.

XVI. Discussion Items

1. The Council of Deans Administrative Board received the report of the OSR Chairperson, Mr. Daniel Clarke-Pearson.

2. Discussion was invited on the AAMC faculty salary survey. Staff solicited suggestions regarding the means by which the accuracy and utility of the survey might be enhanced. Some of the Board felt that the survey was not a useful instrument because figures have not been representative of specific institutional salaries. There was also concern that the data received was not always accurate and that in some geographic areas only a limited number of institutions return the questionnaire. Need for a clarification about the point of origin of salary data and clearer indication of base salary and supplementary income for geographic full-time faculty was emphasized.

In support of the faculty salary study, a wider dissemination of the report was recommended and it was suggested that the report be released earlier in the year. Several Administrative Board members expressed support for the ongoing nature of the salary survey, stating that it is useful for salary review and hiring purposes.

3. The staff also requested guidance on the distribution of confidential reports. Discussion about confidentiality resulted in the following approved motion: Confidential reports will go only to the Dean as has been customary in the past. If other members of the institution require the data, they are to be advised that the Dean's Office has it and that they should either obtain it from the Dean's Office or have the Dean authorize a request for an additional copy. No information goes to any other level of the university without consultation and approval of the Dean.

4. The Annual Council of Deans Meeting Agenda was discussed with the conclusion that the business meeting of the Council of Deans will be shortened and a combined meeting with CAS and COTH will be planned for November.

5. Dr. Marjorie Wilson was asked to present a brief progress report on the Management Advancement Program. Dr. Wilson stated that with the approval of the grant request to the Robert Wood Johnson Foundation for an additional three years, plans for the future of the program are well under way. The first Phase III of this program will be held in June of 1974 with an additional Phase III planned for January 1975. Both of these Phase III seminars have been over-subscribed, and it appears that the demands on the program continue. The Planning Coordinators' group and the Business Officers have expressed an interest in the MAP and are in the process of developing a similar program which will complement COD efforts. The consultants for the Management Advancement Program will be called upon for these new programs. Interface of all these programs will insure a more meaningful management strategy at the institutional level.

6. Concern was voiced about the need to relate to the Veteran's Administration on a formal basis. It was stated that starting in April, eight site visits to the Veteran's Administration supported proposed new medical schools will be undertaken. The Liaison Committee with the Veteran's Administration has not met for about a year but there is no reason that formal communications should not be reintroduced through this vehicle.

XVII. Adjournment

Dr. Papper adjourned the Administrative Board Meeting at 3:00 p.m.

III ACTION ITEMS - A

Review of the 1974 Spring COD Meeting; Planning for the 1975 Spring Meeting

Traditionally the Administrative Board considers the strengths and weaknesses of the Spring Meeting just concluded at its next Board Meeting as a prelude to its determinations regarding the subsequent meeting. Your comments are therefore solicited on the Phoenix meeting program, format and setting. The attached letter has been received from Cheves Smythe in which he provides comments and recommendations.

We need to begin immediately planning for the 1975 meeting. Tentative reservations have been made at teh Broadmoor in Colorado Springs March 26 to 29, 1975 (Wednesday - Saturday). Unfortunately these dates include both Good Friday and Passover. Reservations have also been made at Colonial Williamsburg April 24 to 27 (Thursday - Sunday). The Broadmoor's rates are far more favorable (approximately $22/day single) than Williamsburg ($29-$40/day single or double) Neither includes meals and no American Plan is available.

APPENDIX I

Meetings and Important Holidays in March, April and May Relative to the COD Spring Meeting:

March 26, 1975	LCME
March 27, 1975	Passover
March 27, 1975	Administrative Board *
March 28, 1975	Good Friday
March 28, 1975	Executive Council *
April 7, 1975	CCME *
April 13-16, 1975	MAP Phase II (or III)
May 3 - 6, 1975	AFCR

* Tentative

THE UNIVERSITY OF TEXAS
HEALTH SCIENCE CENTER AT HOUSTON

MEDICAL SCHOOL

John H. Freeman Building
Texas Medical Center

6400 West Cullen Street
Houston, Texas 77025
713/792-2121

May 7, 1974

MAY 13 1974

Marjorie P. Wilson, M.D., Director
Department of Institutional Development
Association of American Medical Colleges
One DuPont Circle, N.W.
Washington, D.C. 20036

Dear Marge:

Without even being asked I am volunteering some reactions to the recently concluded Phoenix COD meeting.

The meeting are important and I believe they should be continued. However, I suggest that we should come to some front end decisions about their objectives. Are the meetings primarily process oriented, that is, to the nature of the dean's job, interpersonal relations, group formation, esprit de corps, formulation of self identifying elite, etc? Are they content oriented, that is, to problem solving experience, increasing the level of knowledge on a particular subject, further formulation of policy of the COD and the AAMC, etc.? I believe that the latter should be the primary objective with the former as the desirable by-product rather than they other way around. Given this choice I would argue that: (1) the meeting format should encourage more of the men present to talk. As hackneyed as it may be the discussion group format does get a larger percentage of the people involved. Even though all deans may be alpha types, some are much more alpha than others; (2) The meetings should be around a central theme rather than a global one. My earnest plea is that the next one center on the financing of graduate medical education; (3) They should be structured so that the dean's learn, but if we are lucky enough to get an action by-product, formal action can be taken and said by-product can be transmitted into the Association's decision making channel.

I believe spouses should be tolerated, but not encouraged to come. Furthermore, there should be an afternoon cocktail hour or reception. It really is valuable in pulling the group together. An after dinner program, especially when dinner has been preceded by alcohol, is lethal for middle aged people. Such a program should be as light as possible, should not feature speakers talking at the audience, but rather should be structured in such a way that there be wide spread participation from the floor.

Please forgive these unsolicited comments. They follow up on our discussion of Sunday morning as we were leaving. I thought the last meeting was great and I am very glad that Polly and I came despite my remark about spouses. With best wishes.

Sincerely yours,

Cheves McC. Smythe, M.D.
Dean

si

III ACTION ITEMS - B

Annual Meeting Program Planning

The staff is currently working on conceptualizing a joint meeting of the COD, the CAS and the COTH to be held on November 13, 1974 at 2:30 p.m. Attached is a draft of our current thinking. We would appreciate your comments and recommendations for speakers.

The COD business meeting is scheduled for November 12, 1974. It is not anticipated that the business agenda will lead to extended debate or deliberations; The meeting is therefore scheduled for only 2 hours.

AGENDA

COD-COTH-CAS JOINT MEETING
NOVEMBER 13, 1974

AAMC ANNUAL MEETING
NOVEMBER 12-16,1974
CHICAGO, ILLINOIS

INSTITUTIONAL RESPONSIBILITY FOR GRADUATE MEDICAL EDUCATION: ISSUES AND ANSWERS?

2:00 - 3:30 Policies for the allocation of medical center resources and facilities for graduate medical education: What is at stake?

- 2:00 - 2:15 The Hospital Administrator Speaks
- 2:15 - 2:30 The Dean Speaks
- 2:30 - 2:45 The Faculty Speaks
- 2:45 - 3:30 Discussion (Moderator and the three speakers lead discussion which is open to the floor.)

This section of the program is designed to lay out the organizational, educational and financing issues from the varying perspectives of those within the medical center who play key roles in graduate medical education and upon whom the success of any move toward institutional responsibility will depend. Questions to be addressed include: How will priorities be set and resources allocated? By whom? Through what organizational framework? Where will the resources be derived? And at what cost?

3:30 - 3:45 COFFEE BREAK

3:45 - 4:30 Qualitative and quantitative assessment: Who calls the shots?

- 3:45 - 4:05 Should the number of residents in each specialty be controlled and by whom?
- 4:05 - 4:25 Who is (or should be) responsible for standards of quality?
- 4:25 - 4:45 Student (Resident)selection- Problems and opportunities.
- 4:45 - 5:30 Discussion (Moderator and the three speakers lead discussion which is open to the floor.)

This section of the program will deal with supra-institutional issues, or those which may involve the operation of national bodies or national level cooperation among the institutions. Questions to be addressed include: Should there be a national system for allocating specialty training positions? If so, is this a governmental or a non-governmental function? What is the appropriate configuration for such a body? On what basis should such decisions be made? What is the role of external assessment procedures, accreditation, PSRO's? Who sets standards of quality and how? Is there any necessity for a national system for facilitating student (Resident) selection? How should it best be operated?

Election of Institutional Members

The following medical schools have received full accreditation by the Liaison Committee on Medical Education, have graduated a class of students and are eligible for full Institutional Membership in the AAMC:

1. University of Massachusetts
   Worcester

2. State University of New York at
   Stony Brook Medical School

3. Texas Tech University
   School of Medicine

4. University of Texas Medical School
   at Houston

The following medical school has received full accreditation by the Liaison Committee on Medical Education (conversion from a two-year to four-year medical school), has graduated a class of students and is eligible for full Institutional Membership in the AAMC.

1. University of North Dakota
   School of Medicine

Recommendation: That the COD Administrative Board recommend that the Executive Council nominate to the Assembly these institutions for election to Institutional Membership in the AAMC, provided that this action is ratified by the full Council of Deans on November 13, 1974.

III ACTION ITEMS - D

Election of Distinguished Service Members

Last year at this time the COD Chairman, at the request of the Administrative Board appointed a committee to propose candidates for the proposed membership category of Distinguished Service Members. At the subsequent COD Meeting the Council nominated the following persons:

Charleton B. Chapman, M.D.
Robert J. Glaser, M.D.
John R. Hogness, M.D.
Robert B. Howard, M.D.
William N. Hubbard, Jr., M.D.
Thomas H. Hunter, M.D.
Robert Marston, M.D.
David Rogers, M.D.
Charles C. Sprague, M.D.
Robert S. Stone, M.D.

The election process requires an affirmative vote of the Assembly upon recommendation of the Executive Council. Executive Council action was completed December 14, 1973. Assembly action is anticipated this fall.

The question before the Board is whether additional nominations should be made by the Council of Deans at the Annual Meeting and whether the Board wishes to take any specific actions in this regard, such as the appointment of a nominating committee.

By the way of background, the following, previously elected Senior Members are now by virtue of the Assembly action in November, Distinguished Service Members.

William G. Anylan, M.D.
Peter P. Bosomworth, M.D.
Kenneth R. Crispell, M.D.
Merlin K. DuVal, M.D.
George T. Harrell, M.D.
Philip R. Lee, M.D.
Manson Meads, M.D.
Richard R. Overman, M.D.
John W. Patterson, M.D.
Robert D. Sparks, M.D.

III ACTION ITEMS - E

Green Book Review

III ACTION ITEMS - F

Review of Executive Council Agenda Items

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
SUITE 301, 1776 MASSACHUSETTS AVENUE, N.W., WASHINGTON, D.C. 20036

May 7, 1974

M E M O R A N D U M
* * * * * * * * * *

TO: Admissions Officers of U.S. Medical Schools
Chief Premedical Advisors of U.S. Undergraduate Colleges

FROM: Davis G. Johnson, Ph.D., Director, Division of Student Studies

SUBJECT: Encouraging Findings of New Study of Early Decision Plan

* *

A new study of experience with the Early Decision Plan (EDP) for the 1974-75 entering class offers considerable encouragement to both admissions officers and preprofessional advisors. Significant findings of this study include the following:

1) almost twice as many EDP applicants (52%) as non-EDP applicants (28%) had been admitted to Medical School as of April, 1974;

2) of those EDP applicants accepted to date, 69% were admitted to their EDP choice schools under Early Decision (i.e., by October, 1973), 18% were admitted to their EDP choice schools as regular candidates (i.e., after October, 1973) and 13% were admitted to schools not participating in EDP. Thus it would appear that candidates not admitted under EDP still have a reasonable chance for admission at a later date;

3) although applicants accepted early by EDP schools have slightly stronger credentials (e.g., grade point averages of 3.6 and Science MCAT of 637) than those accepted by all Medical Schools (GPA of 3.5 and Science MCAT of 610), those admitted later to EDP schools have slightly weaker credentials (3.4 and 604) than those of acceptees in general;

4) since EDP applicants accepted by their EDP choice schools as regular candidates have slightly lower credentials (3.4 and 604) than those accepted to non-EDP schools (3.5 and 624), it appears that admissions committees may be giving some preference to applicants who indicate by participating in EDP that their school is definitely their first choice;

5) over 5,000 needless applications were prevented by the use of EDP. Since the applicants accepted early under

> EDP were a particularly well-qualified group, they would have required even more travelling, advising, interviewing, committee discussion, etc., than the ordinary applicants. Thus the saving in time and money on the part of applicants, advisors and admissions officers was even greater than that represented by 5,000 typical applications.

It is hoped that the above information and the additional details provided in the attached table will be of immediate help in advising applicants about applying to the 58 schools using EDP in the selection of their 1975-76 entering classes.

The growing popularity of EDP is evidenced by 59 schools using EDP in selecting their 1975-76 entering class as compared with 51 schools using it last year. Of the 59 schools using EDP for 1975-76, all but 8 are also participating in AMCAS and are identified in the AMCAS Information Booklet and on the blue AMCAS Designation Form (which also provides for a signed declaration regarding the provisions of EDP). The 8 EDP schools not participating in AMCAS are Baylor, Boston University, Brown, Dartmouth, Johns Hopkins, Kansas, Meharry and New York Medical College. All schools using EDP are identified in their two-page entries in the 1975-76 edition of Medical School Admission Requirements.

Questions and/or comments concerning this study should be directed to the Division of Student Studies. General information about the actual administration of EDP for 1975-76 may be found on page 26 of Medical School Admission Requirements, 1975-76, and on page 2 of the AMCAS Instruction Booklet for 1975-76 Entering Class.

DGJ/bkg 5/7/74
Attachment

CC: Selected AAMC Staff

W# 8363

AAMC DIVISION OF STUDENT STUDIES

Comparison of EDP & Total Applicants for 1974-75 Entering Class

VARIABLE	EDP APPLICANTS TO 43 AMCAS SCHOOLS USING EDP AS OF 4/12/74						TOTAL APPLICANT POOL (as of 4/26/74)	
	Accepted by EDP Schools		Acc. by non-EDP Schools	Total Accepted	Not Accepted	Total Applicants	Applied	Accepted
	Early	Later						
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
a) Applicants	550	142	105	797	747	1,544	39,986	11,245
b) % accepted to date	#	#	#	52%	#	#	#	28%
c) % EDP accepted	69%	18%	13%	100%	#	#	#	#
d) Mean GPA	3.6	3.4	3.5	3.5	3.2	3.4	3.2	3.5
e) MCAT								
Verbal	566	551	558	555	525	554	533	567
Quantitative	630	615	620	626	585	606	576	616
General Info.	567	553	556	563	527	546	535	564
Science	637	604	624	629	561	596	558	610
f) Applications per Applicant	1	6	11	3	6	5*	8*	@

*Since the 1,544 EDP applicants in this study filed an average of 3 fewer applications than did applicants in general, there was a saving of 3 x 1,544 or 4,632 applications for this group alone. Assuming the same experience for the 249 EDP applicants to non-AMCAS schools, there would be an additional saving of 3 x 249 or 747 applications for a total estimated saving of 5,379.

#No figures are entered because they would not be applicable to the given variable.

@The average number of applications per accepted applicant is not known as of this date.

W#8363-T

DGJ/bkg 5/7/74

COD ADMINISTRATIVE BOARD MEETING

ADDITIONAL MATERIALS

DEVELOPING SCHOOLS (Schools progressing from Provisional status to fully developed schools)

	DATE OF SURVEY	YEARS APPROVED
Mayo Medical School	10/10-12/73	Continued provisional approval pending survey visit in Fall, 1975.
College of Medicine & Dentistry of New Jersey Rutgers Medical School	11/26-30/73	LCME voted to delay action until its June meeting at which time a progress report will have been received.

CONVERSION FROM TWO-YEAR TO FOUR-YEAR MEDICAL SCHOOL

University of North Dakota School of Medicine	10/23-26/73	Continued full accreditation for the School of Basic Medical Sciences until 1977. Provisional accreditation as an M.D.-degree-granting institution.

REQUEST FOR LETTER OF REASONABLE ASSURANCE

Texas A & M University/ Baylor College of Medicine	2/4-6/74	The LCME voted against issuing a Letter of Reasonable Assurance and against granting provisional accreditation.

* years from date of survey

ELECTION OF INSTITUTIONAL MEMBERS

The following medical schools have received full accreditation by the Liaison Committee on Medical Education, have graduated a class of students and are eligible for full Institutional Membership in the AAMC:

1. University of Massachusetts
   Worcester

2. State University of New York at
   Stony Brook Medical School

3. Texas Tech University
   School of Medicine

4. University of Texas Medical School
   at Houston

LOUISIANA STATE UNIVERSITY MEDICAL CENTER
P. O. BOX 3932 - SHREVEPORT - LOUISIANA - 71130
School of Medicine in Shreveport

Office of the Dean

June 3, 1974

Marjorie P. Wilson, M.D., Director
Department of Institutional Development
Association of American Medical Colleges
Suite 200, One Dupont Circle, N.W.
Washington, D. C. 20036

Dear Marjorie:

Recently we have been deluged by materials from the United States Department of Health, Education, and Welfare, Office of Education. There are reams of paper and you have to spend quite a bit of time going through it to find out what the real purposes are. When you do, you're not sure you understand them and when, after wasting quite a bit of time, you make inquiry by phone, you find out they were for primary or secondary education and not for medical education. Is there any way that we can prevent receiving all this extraneous material, when indeed this is the case, by having the AAMC monitor it and advise HEW?

A further consideration is that, with modifications, some of these programs could be very helpful to medical education and we are informed that legislative pressures have allowed for the inclusion of new categories of institutions in the past. It might be something to discuss at the Executive Council meeting if you feel it suitable.

Sincerely,

C. G. Grulee, Jr., M.D.
Dean

CCG:bjw

CHAPTER III—SOCIAL SECURITY ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Regulations No. 5, further amended]

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart D—Principles of Reimbursement for Provider Costs and for Services by Hospital-Based Physicians; Appeals by Providers

Subpart F—Agreements, Elections, Contracts, Nominations, and Notices

LIMITATIONS ON COVERAGE OF COSTS UNDER MEDICARE

On March 19, 1974, there was published in the FEDERAL REGISTER (39 FR 10260) a notice of proposed rule making with proposed amendments to Subparts D and F of Regulations No. 5 (20 CFR Part 405), regarding implementation of section 223 of Public Law 92-603 entitled "Limitations on Coverage of Costs Under Medicare." On April 30, 1974, an extension of the comment period was granted (39 FR 15045) giving interested parties until May 18, 1974, to submit written comments or suggestions thereon. Comments and suggestions received with regard to this Notice of Proposed Rules Making, responses thereto and changes in the proposed regulations are summarized below.

1. Many commenters recommended that the proposed regulations be revised to eliminate the necessity for providers to obtain intermediary approval of provider charges to beneficiaries for excess costs and the requirement that similar charges be made to all patients because such provisions are not in accordance with the law. The proposed regulations have been revised to clarify that the intermediary's only role is to validate the computation of the charge. Also, the regulations have been revised to eliminate the requirement that a provider electing to make charges based on excess cost must make such charges to all individuals entitled to benefits under title XVIII. This is not a requirement of the law, and it could result in unjustifiable hardship and difficulty.

2. In response to comments, the regulations have been revised to indicate that public notice required before a provider may impose excess charges on beneficiaries will be published as a notice in a newspaper of general circulation serving the provider's locality and such other notice as the Secretary may require.

3. A recommendation was received and adopted that the definition of "emergency services" in § 405.461(d) be revised to conform to the definition of "emergency services" used for purposes of payment to non-participating hospitals.

4. Comments were received indicating that no limits should be applied to providers. As this is clearly inconsistent with the statute, such suggestions could not be adopted.

5. Comments were received concerning a possible lack of sufficient recognition in the limits of the effect of the cost of teaching programs in a hospital. Our analysis of data indicated that teaching hospitals tended to be concentrated in certain classification groups so that almost always the limits applied to them seem to reflect well the costs of similar hospitals. Nevertheless, the regulations provide that, where a provider can demonstrate that its costs exceed the applicable limit by reason of teaching effort, an exception can be made to the application of the limit to the extent that the added costs flow from approved educational activities and are atypical (although reasonable) for providers in the comparison group. No definition of a teaching hospital that could be reflected in a classification system and could be assumed to improve the effectiveness of the system for setting limits on hospital inpatient general routine service costs has been advanced. As a result, no modifications have been made in response to these comments.

6. A number of comments expressed disagreement with various aspects of the classification system. It is recognized that the presently proposed limits may not be as refined as those which may be developed in the future. However, the initial limits will identify hospitals whose costs are substantially higher than those deemed necessary for efficient delivery of hospital inpatient general routine services. Efforts to develop a more advanced classification system—one that will permit improved identification of hospitals whose costs are excessive—will continue but awaiting the development of such a system is neither desirable nor necessary.

7. A recommendation was received but not adopted for the elimination of the requirement, in § 405.461(a)(2), that a high-cost provider may not impose charges on a beneficiary for emergency services. The basis for this recommendation is the view that charges could not in any event be made for emergency services on the assumption that the cost limits do not apply to such services. However, the language of the law contains no support for the view that the cost limits do not apply to emergency services but states specifically that no charges can be made by the high-cost provider for such services.

8. Recommendations were received, but not adopted, that § 405.461(a) (4) and (5) be modified to eliminate the requirement that the Social Security Administration identify to the public and the high-cost provider identify to the beneficiary the specified charges to meet the costs in excess of costs determined to be necessary in the efficient delivery of health services under title XVIII.

This requirement is contained specifically in section 1866(a) of the Social Security Act as amended by § 223 of P.L. 92-603 and, therefore, this suggestion could not be adopted.

9. A comment was received, but not adopted, that the requirement in section 405.461(a)(3), that the admitting physician have no direct or indirect financial interest in the high-cost provider which is making charges to his patients be modified by the insertion of "significant" before "direct or indirect financial interest." Section 1866(a) of the Social Security Act as amended by § 223 of P.L. 92-603 contains such wording and such a change would be contrary to the statute.

10. Under the provision for recovery by new providers of amounts unreimbursed as a result of application of cost limits published in the Notice of Proposed Rule Making or the lower of cost or charges provision, a new provider's recovery during any year of the new provider base period or recovery period was limited to the lesser of the amount by which the provider's charges exceeded cost or the amount by which the provider's costs were less than the applicable limit. As a result of further study, the Social Security Administration believes that this provision should be liberalized and simplified. Thus, the regulations have been revised to provide that where costs in the current reporting period are below the cost limit, the amount of the recovery of accumulated unreimbursable costs under the lower of cost or charges provision is only limited to the extent aggregate charges applicable to health insurance beneficiaries exceed aggregate costs for services provided to such beneficiaries during such reporting period.

11. A number of editorial changes have also been made in the interest of clarity.

The regulations are issued under the authority contained in sections 1102, 1861(v), 1866(a), and 1871; 49 Stat. 647, as amended; 79 Stat. 313, as amended; 79 Stat. 327, as amended; 79 Stat. 331; 42 U.S.C. 1302, 1395x(v), 1395cc(a), and 1395hh.

Effective date. These regulations will be effective July 1, 1974.

(Catalog of Federal Domestic Assistance Program No. 13.800, Health Insurance for the Aged—Hospital Insurance.)

Dated: May 21, 1974.

J. B. CARDWELL,
Commissioner of Social Security.

Approved: May 30, 1974.

FRANK CARLUCCI,
Acting Secretary of Health, Education, and Welfare.

Part 405 of Chapter III of Title 20 of the Code of Federal Regulations is amended as follows:

Subpart D—Principles of Reimbursement for Provider Costs and for Services by Hospital-based Physicians; Appeals by Providers

1. In § 405.401, paragraph (a) is revised to read as follows:

§ 405.401 Introduction.

(a) Under the health insurance program for the aged and disabled, the amount paid to any provider of services—i.e., hospital, skilled nursing facility, or home health agency—for the covered services furnished to beneficiaries is required by section 1814(b) and section 1833(a)(2) of the Act to be the reasona-

ble cost of such services subject to the provisions of §§ 405.455 and 405.460.

• • • • •

2. In § 405.402, paragraph (a) is revised to read as follows:

§ 405.402 Cost reimbursement: General.

(a) In formulating methods for making fair and equitable reimbursement for services rendered beneficiaries of the program, payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period or a fixed negotiated rate. All necessary and proper expenses of an institution in the production of services, including normal standby costs, are recognized. Furthermore, the share of the total institutional cost that is borne by the program is related to the care furnished beneficiaries so that no part of their cost would need to be borne by other patients. Conversely, costs attributable to other patients of the institution are not to be borne by the program. Thus, the application of this approach, with appropriate accounting support, will result in meeting actual costs of services to beneficiaries as such costs vary from institution to institution. However, payments to providers of services for services rendered health insurance program beneficiaries are subject to the provisions of §§ 405.455 and 405.460.

§ 405.455 [Amended]

3. In § 405.455, paragraph (d)(1) is amended by adding at the end of the material preceding the example the sentence "However, no recovery may be made in any period in which costs are unreimbursed under § 405.460."

4. In § 405.455, paragraph (d)(2) is revised to read as follows:

(2) *New provider*—(i) *General.* A new provider of services may carry forward for five succeeding cost reporting periods costs attributable to program beneficiaries which are unreimbursed under the provisions of this section during a base period, which includes any cost reporting period which begins after December 31, 1973, and ends on or before the last day of its third year of operation. Where beneficiary charges exceed reasonable cost in the five succeeding reporting periods, such previously unreimbursed amounts carried forward shall be reimbursed to the provider to the extent that such previously unreimbursed amounts carried forward, together with costs applicable to program beneficiaries in such subsequent periods, do not exceed customary charges with respect to services to program beneficiaries in such subsequent periods. If such five succeeding cost reporting periods combined include fewer than 60 full calendar months, the provider may carry forward costs unreimbursed under this section for one additional reporting period.

Example. A provider begins its operations on March 5, 1972. However, it begins to participate in the Medicare program as of January 1, 1973, and reports on a calendar year basis. Since it would be subject to the application of the provision for its cost reporting period beginning with January 1, 1974, it would be permitted to accumulate any unreimbursed costs (excess of costs over its charges) incurred during this reporting period. Since this cost reporting period ends before the end of the third year of operation, its carryover period will be the succeeding five cost reporting periods ending with December 31, 1979. Had this provider begun its operation on July 1, 1973, and become a participating provider as of the same date (with a fiscal year ending June 30), it would have been able to accumulate any unreimbursed costs for the two cost reporting periods ending June 30, 1975, and June 30, 1976. Its carryover period would then be the five cost reporting periods ending no later than June 30, 1981, in the case of costs unreimbursed in either of the reporting periods ending June 30, 1975, and June 30, 1976.

(ii) *New provider base period; unreimbursed costs under lower of cost or charges.* Where costs of a new provider are unreimbursed under this section but no costs are unreimbursed under § 405.460 during the new provider base period, such previously unreimbursed amounts which a provider may recover during any cost reporting period in the new provider base period or carry forward period is limited to the amount by which the aggregate customary charges applicable to health insurance beneficiaries during any such period exceed the aggregate costs applicable to such beneficiaries during that period, without regard to the application of the cost limits described in § 405.460(d) during the recovery period; except that no recovery may be made in any period in which costs are unreimbursed under § 405.460.

(iii) *New provider base period; unreimbursed costs under lower of cost or charges and cost limits.* Where costs of a new provider are unreimbursed under both this section and § 405.460 during the base period, such previously unreimbursed amounts carried forward shall be reimbursed to the provider in accordance with § 405.460(g)(3)(ii).

5. Section 405.460 is added to read as follows:

§ 405.460 Limitations on coverage of costs.

(a) *Principle.* In the determination of the allowability of provider costs, costs estimated to be in excess of those necessary in the efficient delivery of needed health services are excluded. Such estimates may be made with respect to direct or indirect overall costs or costs of specific items or services, or groups of items or services and upon publication in the FEDERAL REGISTER will constitute limits on amounts otherwise payable under the program. These limits will be imposed prospectively and may be on a per diem, per visit, or other basis.

(b) *Application.* In determining the limits to be applied, providers may be classified by type of provider (e.g., hospitals, skilled nursing facilities, and home health agencies) and within each provider class by such factors as the Secretary shall find appropriate and practical, such as:

(1) Type of services rendered;

(2) Geographical area where services are rendered, allowing for grouping of noncontiguous areas having similar demographic and economic characteristics;

(3) Size of institution;

(4) Nature and mix of services rendered; or

(5) Type and mix of patients treated.

(c) *Data.* In establishing limits, the estimates of the costs necessary for efficient delivery of health services may be based on cost reports or other data providing indicators of current costs, with current and past period data being adjusted to arrive at estimated costs for the prospective periods to which limits shall be applied.

(d) *Notice of limits to be imposed.* Prior to the onset of a cost period to which a limit shall be applied, a notice shall be published in the Federal Register establishing the limits to be applied to an identified cost and type and class of provider of service.

(e) *Provider rights to review.* A request by a provider for review of the determination of an intermediary concerning classification for, exceptions to, or exemptions from the cost limits imposed under the provisions of this section shall be made to the intermediary under the provisions of §§ 405.490–405.499f.

(f) *Exceptions, exemptions, and adjustments.* The following types of exceptions, exemptions, and classification adjustments may be granted under this section but only upon the provider's demonstration that the conditions indicated are present:

(1) *Reclassification.* A provider shall be entitled to obtain adjustment of its classification by the intermediary for the purpose of cost limits applied under this section on the basis of evidence that such a classification is at variance with the criteria specified in promulgating limits under paragraph (d) of this section.

(2) *Exception of cost of atypical services.* Where the actual cost of items or services furnished by a provider exceeds the applicable limit by reason of the provision of items or services that are atypical in nature and scope as compared to the services generally provided by institutions similarly classified and appropriate reason exists for the provision of such items or services, the limits may be adjusted upward to reflect any added costs flowing from the delivery of such items or services. Such adjustments may only be made where the provider demonstrates: (i) The provision of the atypical items or services were by reason of the special needs of the patients treated and necessary in the efficient delivery of needed health care, or (ii) the added costs flow from approved educational activities (as described in § 405.421) to the extent such costs are atypical (although reasonable) for providers in the comparison group. In addition, such adjustments may be made only to the extent that such justified costs are separately identified by the provider and can be verified by the intermediary.

(3) *Exception because of extraordinary circumstances.* Where a provider's costs exceed the limits due to extraordinary circumstances beyond the control of the provider, the provider may request

an exception from the cost limits to the extent that the provider shows such higher costs result from the extraordinary circumstances. These circumstances may include but are not limited to increased costs attributable to strikes, fire, earthquake, flood, or similar unusual occurrences with substantial cost effects.

(4) *Exemption as sole community provider.* The limitation on costs imposed under this section shall not be applicable where a provider by reason of factors such as isolated location or absence of other providers of the same type, is the sole source of such care reasonably available to beneficiaries.

(g) *New providers; accumulation of unreimbursed costs and carryover to subsequent periods*—(1) *General.* A new provider of services may carry forward for five succeeding cost reporting periods costs attributable to health insurance program beneficiaries which are unreimbursed under this section and not charged to patients during any cost reporting period ending on or before the last day of its third year of operation. Such period is called the new provider base period. If the five succeeding cost reporting periods combined include fewer than 60 full calendar months, the provider may carry forward such unreimbursed costs for one additional reporting period.

Example. A provider begins operation on April 7, 1973. However, it begins to participate in the health insurance program as of January 1, 1974, and reports on a calendar year basis. The provider would be permitted to accumulate any costs unreimbursed under this section which were incurred during reporting periods ending prior to April 7, 1976. Because the calendar year 1975 cost reporting period ends before the end of the third year of operation, its carryover period will be the succeeding five cost reporting periods ending on December 31, 1980. Had this provider begun its operations on July 1, 1973, and become a participating provider as of the same date (with a fiscal year ending June 30), it would have been able to accumulate any such unreimbursed costs for the cost reporting periods ending June 30, 1975, and June 30, 1976 (the limits are not applicable to the year ending June 30, 1974). Its carryover period would then be the five cost reporting periods ending no later than June 30, 1981, in the case of costs unreimbursed in either of the reporting periods ending June 30, 1975, or June 30, 1976.

(2) *New provider defined.* A new provider is an institution that has operated as the type of facility (or the equivalent thereof) for which it is certified in the program under present and previous ownership for less than 3 full years.

(3) *Recovery of unreimbursed excess cost*—(i) *New provider base period; unreimbursed costs under cost limits.* Where costs of a new provider are unreimbursed under this section during the new provider base period, but no costs are unreimbursed under § 405.455 during such base period, such unreimbursed amounts which a provider may recover during any cost reporting period in the new provider base period or carry forward period is limited to the lesser of (A) the amount by which the provider's current cost limit under this section exceeds the provider's reasonable cost for items and services to which such limit is applied during that cost reporting period, or (B) the amount by which the aggregate customary charges applicable to health insurance program beneficiaries during any such period exceeds the aggregate costs for such services which are applicable to such beneficiaries during that period (see § 405.455).

(ii) *New provider base period; unreimbursed costs under lower of cost or charges and cost limits.* Where costs of a new provider are unreimbursed under the provisions of both this section and § 405.455 during the new provider base period, the amount of such unreimbursed costs which a new provider may recover during any cost reporting period in which the cost limit is not exceeded is limited to the extent that such unreimbursed costs plus normally reimbursable costs do not exceed aggregate customary charges with respect to health insurance beneficiaries during that period. In the application of this paragraph, costs previously unreimbursed under this section will be recovered first, in accordance with paragraph (g)(3)(i) of this section, and any remaining unreimbursed costs shall be carried forward to the next succeeding year within the new provider base period or carry forward period. Costs previously unreimbursed under § 405.455 may thereafter be recovered to the extent that aggregate customary charges with respect to health insurance beneficiaries exceed the aggregate reimbursable costs applicable to such beneficiaries plus amounts recovered under paragraph (g)(3)(i) of this section during that period. Any remaining unreimbursed costs under § 405.455 may be carried forward to the next succeeding reporting period within the new provider base period or carry forward period.

6. Section 405.461 is added to read as follows:

§ 405.461 Limitations on coverage of costs; charges to beneficiaries where cost limits are applied to services.

(a) *Principle.* A provider of services that customarily furnishes an individual items or services which are more expensive than the items or services determined to be necessary in the efficient delivery of needed health services described in § 405.460, may charge an individual entitled to benefits under title XVIII for such more expensive items or services even though not requested by the individual. The charge, however, may not exceed the amount by which the cost of (or, if less, the customary charges for) such more expensive items or services furnished by such provider in the second cost reporting period immediately preceding the cost reporting period in which such charges are imposed exceeds the applicable limit imposed under the provisions of § 405.460(d). This charge may be made only if:

(1) The intermediary determines that the charges have been calculated properly in accordance with the provisions of this section; and

(2) The services are not emergency services as defined in paragraph (d) of this section; and

(3) The admitting physician has no direct or indirect financial interest in such provider; and

(4) The Social Security Administration has provided notice to the public through notice in a newspaper of general circulation servicing the provider's locality and such other notice as the Secretary may require, of any charges the provider is authorized to impose on individuals entitled to benefits under title XVIII of the Act on account of costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under such title; and

(5) The provider has, in the manner described in paragraph (e) of this section, identified such charges to such individual or person acting on his behalf as charges to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under title XVIII of the Act.

(b) *Provider request to charge beneficiaries for costs in excess of limits.* (1) Where a provider's actual costs (or, if less, the customary charges) in the second preceding cost period exceed the prospective limits established for such costs, the intermediary shall, at the provider's request, validate in advance the charges which may be made to the beneficiaries for the excess.

(2) Where a provider does not have a second preceding cost period and is a new provider as defined in § 405.460(g), the provider, subject to validation by the intermediary, will estimate the current cost of the service to which a limit is being applied. Such amount shall be adjusted to an amount equivalent to costs in the second preceding year by use of a factor to be developed based on estimates of cost increases during the preceding 2 years and published by the Social Security Administration. The amount thus derived will be used in lieu of the second preceding cost period amount in determining the charge to the beneficiary.

(3) To obtain consideration of such a request, the provider must submit to the intermediary a statement indicating the charge for which it is seeking validation and providing the data and method used to determine the amount. Such statement should include:

(i) Producer's name and number;

(ii) Identity of class and prospective cost limit for the class in which the provider has been included;

(iii) Amount of charge and cost period in which the charge is to be imposed;

(iv) The cost and customary charge for items and services rendered to beneficiaries; and

(v) The cost period ending date of the second reporting period immediately preceding the cost period in which the charge is to be imposed. The intermediary may request such additional information as it finds necessary with respect to the request.

(c) *Provider charges*—(1) *Establishing the charges.* If the actual cost incurred (or, if less, the customary charges) in

the prior period determined under paragraph (a) of this section exceeds the limits applicable to the pertinent period, the provider may charge the beneficiary to the extent costs in the second preceding cost reporting period (or the equivalent when there is no second preceding period) exceed the current cost limits. (Data from the most recently submitted appropriate cost report will be used in determining the actual cost.) For example, if a limit of $58 per day is applied to the cost of general routine services for the provider's cost reporting period starting in calendar year 1975 and if the provider's actual general routine cost in the second preceding reporting period, i.e., the reporting period starting in calendar year 1973, was $60 per day, the provider (after first having obtained intermediary validation and subject to the considerations and requirements specified in paragraph (a) of this section) may charge hospital insurance beneficiaries up to $2 per day for general routine services.

(2) *Adjusting cost.* Program reimbursement for the costs to which limits imposed under § 405.460 are applied in any cost reporting period shall not exceed the lesser of the provider's actual cost or the limits imposed under § 405.460. If program reimbursement for items or services to which such limits are applied plus the charges to beneficiaries for such items or services imposed under this section exceed the provider's actual cost for such items or services, program payment to the provider shall be reduced to the extent program payment plus charges to the beneficiaries exceed actual cost. If the provider's actual cost for general routine services in 1975 was $57,000, the cost limit was $58,000, and billed charges to hospital insurance beneficiaries were $2,000, the provider would receive $55,000 from the program ($57,000 actual cost minus the $2,000 in charges to the beneficiaries).

(d) *Definition of emergency services.* For purposes of paragraph (a) (2) of this section, emergency services are those hospital services which are necessary to prevent the death or serious impairment of the health of the individual, and which, because of the threat to the life or health of the individual, necessitate the use of the most accessible hospital (see § 405.192) available and equipped to furnish such services. Where an individual has been admitted to such hospital as an inpatient because of an emergency, the emergency will be deemed to continue until it is safe from a medical standpoint to move the individual to another hospital or other institution or to discharge him.

(e) *Identification of charges to individual.* For purposes of paragraph (a) (5) of this section, a provider shall give or send to the individual or his representative, a schedule of all items and services which the individual might need and for which the provider imposes charges under this section, and the charge for each. Such schedule shall specify that the charges are necessary to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under title XVIII of the Act and shall include such other information as the Social Security Administration considers necessary to protect the individual's rights under this section. The provider, in arranging for the individual's admission, first service, or start of care, shall give or send this schedule to the individual or his representative when arrangements are being made for such services or if this is not feasible, as soon thereafter as is practicable but no later than at the initiation of services.

Subpart F—Agreements, Elections, Contracts, Nominations, and Notices

7. In § 405.607, paragraph (a) is revised to read as follows:

§ 405.607 Essentials of agreements with providers of services.

Under the terms of the agreement (see § 405.606) the provider agrees:

(a) Not to charge any individual, or other person (except as described in §§ 405.608–405.610 and 405.461):

* * * * *

[FR Doc.74-12867 Filed 6-5-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration

HOSPITAL COSTS UNDER THE HEALTH INSURANCE PROGRAM

Interim Schedule of Limits

On March 19, 1974, there was published in the FEDERAL REGISTER (39 FR 10313) a Notice of Proposed Schedule of Limits on Hospital Costs Under the Medicare program for cost reporting periods beginning on and after the effective date of final regulations implementing section 223 of P.L. 92-603. On April 30, 1974, an extension of the comment period was granted (39 FR 15060) giving interested parties until May 18, 1974, to submit written comments or suggestions thereon. Comments and suggestions received with regard to this Notice of Proposed Schedule of Limits, responses thereto, and changes in the proposed schedule of limits are summarized below:

1. Many commenters suggested that the term "general routine service costs" should be clarified to indicate whether the inpatient routine nursing salary cost differential payment is to be included. This suggestion was adopted and the Notice has been revised to indicate that the limits apply to the total of "hospital inpatient general routine service costs" as defined in § 405.452(d)(2) (also see § 405.452(d)(7)) and the inpatient routine nursing salary cost differential payment defined in § 405.430 and excludes the cost of any inpatient special care units and ancillary services.

2. One of the comments received noted that the District of Columbia was included in both the schedules of limits—within Standard Metropolitan Statistical Area (SMSA) and outside SMSA. The Schedule of Limits applicable to hospitals located outside SMSA's has been revised to delete specific dollar limitations for hospitals located in Washington, D.C. because the entire area of Washington, D.C. is located within an SMSA. The Schedule of Limits for hospitals within SMSA's has been revised to include dollar limitations for hospitals located in a newly designated and defined SMSA in Alaska.

3. The Notice has been revised to reflect a publication (Federal Information Processing Standards Publication—F.I.P.S. Pub. 8-3) in which the definition and list of SMSA's can be found.

4. Some comments were received suggesting that the final published regulations, rather than the Notice of proposed limits, include the detailed methodology employed to establish the limits on general routine service costs for hospitals. The Secretary believes it more appropriate for the Notices to describe the methodology used in determining the published limits and thus make it easier for interested parties to understand the methodology. Moreover, there may be different methods for different types of providers and for different types of services. Therefore, this suggestion has not been adopted.

5. A number of comments were received regarding various aspects of the classification system and their effect on setting limits. While it is recognized that the initial limits may not be as refined as those developed in the future, it is believed the initial limits will identify hospitals whose costs are in excess of those deemed necessary for efficient delivery of hospital inpatient general routine services. Efforts to develop a more advanced classifications system—one that will permit improved identification of hospitals whose costs are excessive—will continue but awaiting development of such a system is neither desirable or necessary. These comments although not adopted at this time, will be taken into account in future efforts to refine the classification system.

6. Various editorial changes have been made in the interest of clarity. The following Notice of Schedule of Limits on Hospital Inpatient General Routine Service Costs has been adopted by the Secretary.

Notice is hereby given that the Schedule of Limits on Hospital Inpatient General Routine Service Costs in the Medicare program has been established by the Commissioner of Social Security, with the approval of the Secretary of Health, Education, and Welfare. This interim schedule is applicable for cost reporting periods beginning on or after July 1, 1974, and before the earlier of July 1, 1975 or the effective date of any revised schedule. The schedule set forth herein will be carefully reviewed by the Commissioner in the coming months with a view toward developing a more refined classification system which better adjusts for such cost factors as patient mix, scope-of-services, and the economic conditions of the local labor market. As revised, a new schedule will be published, with the approval of the Secretary, to be effective for cost reporting periods beginning no later than July 1, 1975.

The Schedule of Limits on Hospital Inpatient General Routine Service Costs set out below will apply to the entire cost reporting period of a provider whose cost reporting period begins during the effective period of this schedule. The schedule, as approved, applies to the total of the cost of routine services as defined in 20 CFR, § 405.452(d)(2) (also see § 405.452(d)(7)) and the inpatient routine nursing salary cost differential payment described in § 405.430. These limits do not apply to the cost of special care units or ancillary services. Section 1861(v)(1) of the Social Security Act as amended by section 223 (Limitations on Coverage of Costs Under Medicare) of P.L. 92-603 (the Social Security Amendments of 1972) permits the Secretary to set prospective limits on overall provider costs or provider costs for specific items or services based on estimates of the costs necessary in the efficient delivery of needed health services. Separate schedules of limits will be issued for skilled nursing facilities and home health agencies prior to the beginning of the cost reporting period to which such limits would be applied.

To provide adequate sized comparison bases and to permit reasonable comparisons between providers within a group a classification system was developed to take into account two principal elements: hospital size and economic environment essentially reflecting urban or nonurban locations by geographic groupings. A provider's location within a Standard Metropolitan Statistical Area is used as a proxy for an urban location while providers not located in a Standard Metropolitan Statistical Area are considered nonurban. (A Standard Metropolitan Statistical Area, as defined by the Office of Management and Budget, is a county or group of contiguous counties which (1) includes at least one city of 50,000 inhabitants, or (2) otherwise meets the basic criteria specified by the Office of Management and Budget for defining such areas. The standard definition and a complete list of Standard Metropolitan Statistical Areas can be found in the Federal Information Processing Standards Publication (F.I.P.S Pub. 8-3), which is available from the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402.)

These two principal elements (size and economic environment) are reflected in five State groupings with the States classified according to per capita income as follows:

STATE GROUP I

Alaska	Nevada
California	New Jersey
Connecticut	New York
Hawaii	Washington, D.C.
Illinois	

STATE GROUP II

Delaware	Ohio
Maryland	Pennsylvania
Massachusetts	Rhode Island
Michigan	Washington

STATE GROUP III

Arizona	Missouri
Colorado	Nebraska
Florida	New Hampshire
Indiana	Oregon
Iowa	Virginia
Kansas	Wisconsin
Minnesota	

STATE GROUP IV

Georgia	South Dakota
Idaho	Texas
Maine	Utah
Montana	Vermont
North Carolina	Wyoming
Oklahoma	

STATE GROUP V

Alabama	North Dakota
Arkansas	Puerto Rico
Kentucky	South Carolina
Louisiana	Tennessee
Mississippi	West Virginia
New Mexico	

Providers in each of the five State groups have been divided between those located in SMSA's and those not in SMSA's. These 10 groups have been further divided into 7 bed-size categories resulting in 70 classes.

The actual limits were developed for each of the 70 groups in the following manner:

1. Inpatient routine service cost data for each participating hospital was obtained from the fiscal intermediaries.

2. The data for hospitals in each class were arrayed in descending order of inpatient routine service cost.

3. The 90th percentile and the median were computed for each class.

4. For each class, an amount equal to

10 percent of the median was added to the 90th percentile amount.

5. This sum was adjusted by a factor at a 10.5 percent annual rate to reflect estimated cost increases.

6. The amounts calculated in step 5 are rounded to the next higher dollar which establishes the limit for each class, subject to adjustment for other than calendar year hospitals.

Under the authority of section 1861(v) of the Social Security Act as amended by P.L. 92-603, the following dollar limitations apply to the total of the hospital inpatient general routine service costs and the inpatient routine nursing salary cost differential (excluding costs incurred for special care units and ancillary services), adjusted upward as provided for below, and are applicable to cost reporting periods beginning on and after July 1, 1974, and before the earlier of July 1, 1975 or the effective date of any revised schedule. Revised schedules of limits will be published on a periodic basis.

Where a hospital has a cost reporting period beginning on or after July 1, 1974, the published limit will be adjusted upward by 9/10th of one percent of the published limit for each elapsed month between January 1, 1974, and the month in which the hospital's reporting period starts. Adjustment must be calculated in dollars and cents.

Example. Hospital A's cost reporting period starting in 1974, begins October 1, 1974, and ends September 30, 1975. The cost factor for Hospital A's group for calendar year 1974 is $83.00.

Computation of adjusted cost limit

Cost factor	$83.00
Plus: Adjustment for 9-mo. period (Jan. 1, 1974 to Sept. 30, 1974, 9 mos. × .9 percent=8.1 percent, 8.1 percent × $83.00	6.72
Adjusted cost limit applicable to hospital A for the Oct. 1, 1974, to Sept. 30, 1975, reporting period	89.72

SCHEDULE OF LIMITS ON HOSPITAL INPATIENT GENERAL ROUTINE SERVICE COSTS

Hospitals located within SMSA's (urban)

State	Bed size						
	Less than 55	55 to 99	100 to 169	170 to 264	265 to 404	405 to 684	685 or more
Alabama	$71	$74	$67	$74	$76	$74	$71
Alaska	113	135	138	139	128	150	167
Arizona	100	86	86	87	82	90	90
Arkansas	71	71	67	71	76	71	71
California	111	108	111	112	102	120	131
Colorado	100	86	86	87	82	90	90
Connecticut	111	108	111	112	102	120	131
Delaware	81	91	88	91	98	99	128
District of Columbia	111	108	111	112	102	120	131
Florida	100	86	86	87	82	90	90
Georgia	71	77	76	78	76	77	77
Hawaii	131	121	127	128	117	138	151
Idaho	71	77	76	78	76	77	77
Illinois	111	108	111	112	102	120	131
Indiana	100	86	86	87	82	90	90
Iowa	100	86	86	87	82	90	90
Kansas	100	86	86	87	82	90	90
Kentucky	71	71	67	71	76	71	71
Louisiana	71	71	67	71	76	71	71
Maine	71	77	76	78	76	77	77
Maryland	81	91	88	91	98	99	128
Massachusetts	81	91	88	91	98	99	128
Michigan	81	91	88	91	98	99	128
Minnesota	100	86	86	87	82	90	90
Mississippi	71	71	67	71	76	71	71
Missouri	100	86	86	87	82	90	90
Montana	71	77	76	78	76	77	77
Nebraska	100	86	86	87	82	90	90
Nevada	111	108	111	112	102	120	131
New Hampshire	100	86	86	87	82	90	90
New Jersey	111	108	111	112	102	120	131
New Mexico	71	71	67	71	76	71	71
New York	111	108	111	112	102	120	131
North Carolina	71	77	76	78	76	77	77
North Dakota	71	74	67	71	76	71	71
Ohio	81	91	88	91	98	99	128
Oklahoma	71	77	76	78	76	77	77
Oregon	100	86	86	87	82	90	90
Pennsylvania	81	91	88	91	98	99	128
Puerto Rico	76	79	72	80	82	89	80
Rhode Island	81	91	88	91	98	99	128
South Carolina	71	71	67	71	76	71	74
South Dakota	71	77	76	78	76	77	77
Tennessee	71	74	67	74	76	71	71
Texas	71	77	76	78	76	77	77
Utah	71	77	76	78	76	77	77
Vermont [1]							
Virginia	100	86	86	87	82	90	90
Washington	81	91	88	91	98	99	128
West Virginia	71	74	67	71	76	71	74
Wisconsin	100	86	86	87	82	90	90
Wyoming [1]							

[1] No Standard Metropolitan Statistical Areas for these States.

SCHEDULE OF LIMITS ON HOSPITAL INPATIENT GENERAL ROUTINE SERVICE COSTS—Continued

Hospitals located outside SMSA's (nonurban)

State	Bed size						
	Less than 55	55 to 99	100 to 169	170 to 264	265 to 404	405 to 684	685 or more
Alabama	$61	$58	$59	$65	$57	$57	$57
Alaska	132	116	125	107	102	102	102
Arizona	69	65	68	65	57	57	57
Arkansas	69	65	68	65	57	57	57
California	69	65	68	65	57	57	57
Colorado	69	65	68	65	57	57	57
Connecticut	69	65	68	65	57	57	57
Delaware	69	65	68	65	57	57	57
Florida	69	65	68	65	57	57	57
Georgia	69	65	68	65	57	57	57
Hawaii	121	105	115	107	102	102	102
Idaho	69	65	68	65	57	57	57
Illinois	69	65	68	65	57	57	57
Indiana	69	65	68	65	57	57	57
Iowa	69	65	68	65	57	57	57
Kansas	69	65	68	65	57	57	57
Kentucky	69	65	68	65	57	57	57
Louisiana	69	65	68	65	57	57	57
Maine	69	65	68	65	57	57	57
Maryland	69	65	68	65	57	57	57
Massachusetts	69	65	68	65	57	57	57
Michigan	69	65	68	65	57	57	57
Minnesota	69	65	68	65	57	57	57
Mississippi	69	65	68	65	57	57	57
Missouri	69	65	68	65	57	57	57
Montana	69	65	68	65	57	57	57
Nebraska	69	65	68	65	57	57	57
Nevada	69	65	68	65	57	57	57
New Hampshire	69	65	68	65	57	57	57
New Jersey	69	65	68	65	57	57	57
New Mexico	69	65	68	65	57	57	57
New York	69	65	68	65	57	57	57
North Carolina	69	65	68	65	57	57	57
North Dakota	69	65	68	65	57	57	57
Ohio	69	65	68	65	57	57	57
Oklahoma	69	65	68	65	57	57	57
Oregon	69	65	68	65	57	57	57
Pennsylvania	69	65	68	65	57	57	57
Puerto Rico	69	65	68	65	57	57	57
Rhode Island	69	65	68	65	57	57	57
South Carolina	69	65	68	65	57	57	57
South Dakota	69	65	68	65	57	57	57
Tennessee	69	65	68	65	57	57	57
Texas	69	65	68	65	57	57	57
Utah	69	65	68	65	57	57	57
Vermont	69	65	68	65	57	57	57
Virginia	69	65	68	65	57	57	57
Washington	69	65	68	65	57	57	57
West Virginia	69	65	68	65	57	57	57
Wisconsin	69	65	68	65	57	57	57
Wyoming	69	65	68	65	57	57	57

(Catalog of Federal Domestic Assistance Program No. 13.800, Health Insurance for the Aged—Hospital Insurance.)

Dated: May 21, 1974.

Approved: May 30, 1974.

FRANK CARLUCCI,
Acting Secretary of Health, Education, and Welfare.

J. B. CARDWELL,
Commissioner of Social Security.

[FR Doc.74-12868 Filed 6-5-74;8:45 am]

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May 17, 1974

Dr. Richard M. Knapp, Director
Department of Teaching Hospitals
Association of American Medical Colleges
One Dupont Circle, N.W., Suite 200
Washington, D. C. 20036

Dear Dr. Knapp:

This concerns the proposed regulations to implement Section 223 of the Social Security Amendments of 1972 (P.L. 92-603) which appear in the March 19, 1974 Federal Register (20 C.F.R. Part 405) (Regulations No. 5). These proposed regulations, which relate to limitation on coverage of hospital costs under the health insurance program, were the subject of a letter of comment from the Association to the Social Security Administration dated April 18, 1974.

This letter of comment contained the Association's contentions that these proposed regulations reflect erroneous interpretations of congressional intent and conflict with the statute they are to ostensibly implement by not screening out only excess costs which flow from inefficiency in the delivery of health care services. On this latter point, the Association expressed its concern that incurred costs of teaching hospitals may be disallowed (i.e. deemed "unnecessary") notwithstanding the fact that such costs are, in every respect, reasonable, in contravention of the intent of Congress.

The comment period with respect to these proposed regulations closes on May 18, 1974, and we understand that they will be signed within seven to ten days thereafter, or toward the end of this month.

Consideration, then, is being given to the possibility of legal action by the Association to forestall the adoption of the proposed regulations in their present form. At the outset, however, it must be noted that there is no avenue of approach here that offers great certainty of success. Moreover, legal action would be premature pending the signing

of these regulations in final form, inasmuch as a court will review an agency's action only when "final" and once all administrative remedies have been exhausted.

The Association could, once the regulations become final, file an action in U.S. District Court, seeking to preliminarily enjoin the promulgation of the regulations and seeking a ruling that the proposed regulations are "arbitrary and capricious" on the ground that they exceed and conflict with the intent of Congress and perhaps that they are constitutionally deficient as well. In this regard, the court will look to see if the regulations have a rational basis in relation to the underlying legislation. (I should note that there does not appear to be any productive basis for attacking the pertinent statutory sections themselves.)

In testing these proposed regulations against the statute and its legislative history to see if they have a rational basis in relation to the statute and the intent of Congress in enacting it, and based upon the following observations, we conclude that the Association (and/or one or more of its member hospitals) has a case that the proposed regulations lack the requisite rational basis and thus should not be implemented (although it is not possible at this time to forecast with any specificity the likelihood of the outcome of such an action):

1. A valid contention can be made that the proposed regulations do not satisfactorily take into account the several factors that influence the variability of reasonable costs across hospitals and, in conflict with statutory requirements and congressional intent, omit certain essential factors.

2. The legislative history of Section 223 supports the view that Congress contemplated the utilization of variables of concern to the Association's membership in ascertaining reasonable costs.

3. A persuasive case can be made that these proposed regulations fail to meet and would in fact impede the ultimate goal of Section 223, which is to limit reimbursement for "unnecessary" costs of health care services. The Senate Finance Committee has stated that Section 223 was designed to initiate "reimbursement mechanisms that limit reimbursement to the costs that would be incurred by a reasonably prudent and cost-conscious management". However, it appears that, at least as applicable to teaching hospitals, the proposed regulations would screen out costs which are attributable to factors other than inefficiency, thereby contravening the expressed intent of Congress.

4. It seems clear that the proposed regulations exceed the scope of the statute they purport to implement, by requiring the intermediary to approve the charge of "excess charges" by the provider.

The question as to when such an action might be instituted depends in part, upon the following factors: (1) whether the comment period can be further extended, (2) when the regulations are signed into final form, and (3) the date the then-final regulations are to become effective.

Preferably, an action would be brought after the regulations become final but prior to the effective date, in an effort to stay the effectiveness of the regulations. The plaintiff in such an action would have to demonstrate, among other things, that such a stay would prevent "irreparable injury" and that requisite standing exists, i.e., that the plaintiff is an "aggreived" party or a party "suffering a legal wrong". As we have discussed, consideration should be given to the possibility of including as plaintiff one or more teaching hospitals, should a decision to file suit be reached.

Once effective, an action could be brought to invalidate the regulations. If for no more than strategic purposes, it would be preferable to initiate such a suit as soon after the effective date as is reasonably possible.

I know that you are thinking of the Association's Board meeting on June 20 in this connection. Assuming no extension of the comment period, these regulations will undoubtedly become final about three weeks in advance of that meeting. As discussed, a suit could be--and probably should be--filed as soon thereafter as possible, if a decision to sue is arrived at. If necessary, however, an action could be initiated in the context of the effective date, although in my opinion the impact on the court in terms of a request for immediate injunctive relief would be less than if the suit were brought right after the regulations became final.

I know the foregoing will prompt additional questions and I will be pleased to discuss them with you at your convenience.

Very truly yours,

Bruce R. Hopkins

cc: Dr. John A. D. Cooper

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
SUITE 200, ONE DUPONT CIRCLE, N.W., WASHINGTON, D.C. 20036

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JOHN A. D. COOPER, M.D., PH.D.
PRESIDENT

June 13, 1974

WASHINGTON: 202: 466-5175

MEMORANDUM

TO: AAMC Executive Council & Administrative Boards

FROM: John A. D. Cooper, M.D.

SUBJECT: Proposed AMA Guidelines for Housestaff Contracts

Enclosed for discussion at the June meetings of the Administrative Boards and Executive Council are proposed AMA Guidelines for Housestaff Contracts. These guidelines have been approved by the AMA Board of Trustees and will be considered by the House of Delegates at their June meeting. The attached correspondence between Henry McIntosh and Jim Sammons provides some background on the subject.

Attachment

May 31, 1974

OFFICE OF THE PRESIDENT
Please Reply To:
The Methodist Hospital
6516 Bertner Boulevard
Houston, Texas 77025

Executive Committee
American College of Cardiology

You will find enclosed a letter from James Sammons of the AMA to me in reply to my letter to him regarding clarification of the rumor that we had heard that the AMA was supporting the collective bargaining of house officers throughout the country in a unified fashion. My first concerns were aroused by the article in the AMA News indicating that this was under study and that the AMA was interested in tying in "compulsory membership" in the AMA with the agreement to support the unionization. (I guess the better term would be collective bargaining). Jim Sammons, surprisingly, seems to favor such a move. If one questions why, it is not difficult to imagine that dues of say $50.00 a year as a house officer member of the AMA for 50,000 people would be $2,500,000 per year, and a large part of the 50,000 might continue their membership for life.

I ask you to read carefully the guidelines that have been prepared for house staff contracts by the AMA and realize that this will be discussed in committee at the AMA meeting in Chicago on June 24th.

I have two concerns about this matter:

1. As the chairman of the department of medicine, I am not certain this is the way to create an environment in which one can train house officers to become compassionate and competent physicians. This may or may not be of concern to the membership of the College.

2. Of even more importance is the fact that as one trains a young person and creates a life style, one can be certain that this will be prepetuated through life. It would seem to me that if it was agreed that the medical profession should be unionized ten years from now, there would be no better way to do this. I believe that

the AMA is being very short sighted in not apparently showing concern over what is the long term implication of collective bargaining on a nationwide basis for physicians in training. Having grown accustomed to this way of living, it hardly seems likely that a doctor, once he completes his training, will give up such a "life style."

I believe that we are looking at a situation which can have a profound effect on the medical profession over the next decade and from then on, and will determine the attitudes of the public to physicians. It is possible that this is what the vast majority of physicians want. If so, I think that we should give careful thought to the matter before instituting it.

Therefore, I think that the College should be concerned about this action. I believe that the College should take a stand that we are aware of the plans. We are aware that some house officers may not have had an ideal type of environment in which to learn and might have had to work extra hours, and so on. We, however, feel that anything with such profound long range implications should be entered into cautiously. I believe that the College should urge a period of thoughtful reflection over a year or so. I would think that the membership of the College would support such a decision.

I have discussed this with Charles Fisch and with Bill Nelligan. Would you please reflect on this matter and give me a call within the next week?

Sincerely,

Henry D. McIntosh, M.D.
President
American College of Cardiology

HDM:hc
Encls.

BAYLOR COLLEGE OF MEDICINE
TEXAS MEDICAL CENTER
HOUSTON, TEXAS 77025

[redacted] INTERNAL MEDICINE
[redacted] 5214051

May 30, 1973

James H. Sammons, M.D.
Executive Vice President Designate
American Medical Association
535 Dearborn Street
Chicago, Illinois 60610

Dear Jim:

Your letter of May 23 with the present status of the Guidelines for House-staff Relationships to Teaching Institutions was received. To say the least I am amazed. I cannot understand how a resolution of this type, if that be what it is called, could have been formulated and approved by the House of Delegates to be referred to the Board of Trustees and its Committee on House Staff Affairs and then get back to the House of Delegates. This [redacted] resolution for all intents and purposes makes a hospital which offers an educational experience and pays salary for it enter into collective bargaining with an organization that cannot police its own ranks, cannot be responsible for recruiting and contributing to the long-term solvency and strength of the institution.

Our House Officers Association has in the past elected its officers with but a handful of members present. We have 540 or more house officers. Even after the House Staff Organization sent out notices (see enclosure), posted notices on bulletin boards, etc., urging wives as well as house officers to come and bring their children to discuss salaries and vacations, with George Jordan and myself mentioned by name as being opposed to the house staff, only about 100 attended the meeting. Yet, this document states on page 2, line 24 and 25, "The representative status of the Housestaff Association should be expressly accepted and recognized in the contract."

The document reads like some of the PSRO and Medicare legislations that you have opposed so violently because they interfere with the internal workings of the physician and his hospital staff. It seems that the AMA is encouraging and in fact propagating such similar restrictive and unnecessary, in many sectors, legislation.

[redacted] The AMA House of Delegates as well as the leadership by this action is deciding that they want American medicine to be unionized ten years from now.

As one trains young people during their formative period of life, so will they function in later years. It is inconceivable that the AMA could expect a house officer to participate actively in collective bargaining on a nationwide basis, albeit salaries, etc. may vary from institution to institution (but not for long), and not expect that these same doctors ten years from now will be negotiating with their hospitals and other agencies through collective bargaining. Maybe this is a part of the grand plan. I urge that serious thought be given to what effect this type of activity will have on the future doctors. It would seem to me that this will deprofessionalize the profession as much as anything I have seen.

Maybe it is thought that the profession should become a union, if so, I think the leadership should speak out to this point. I have no objection to setting up guidelines. But I do think that it is wrong to indicate that these guidelines relate to an organization who is constantly changing and by the mere nature of the activities of the potential members attracts only a relatively small vocal few.

I have been intimately associated with house officers for twenty odd years and have personally visited many programs. I interview countless house officer candidates each year. I do not believe that the "picture" that has apparently been given by the leaders of the Housestaff Association is representative. My concerns are not based only on the experience with programs here at Baylor.

I would like to know when this matter will be brought to the reference committee and how I can arrange to testify.

Sincerely,

Henry D. McIntosh, M.D.
The Bob and Vivian Smith Professor,
and Chief of the Medical Service,
The Methodist Hospital, and
Chairman, Department of Medicine,
Baylor College of Medicine

HDM:sd

REPORT OF THE BOARD OF TRUSTEES

Report: P
(A-74)

Subject: Guidelines for Housestaff Contracts

Presented by: Richard E. Palmer, M. D., Chairman

Referred to: Reference Committee C
(James D. Murphy, M. D., Chairman)

At the 1973 Clinical Convention the House of Delegates referred Resolution 8 to the Board of Trustees and its Committee on Housestaff Affairs, the Intern and Resident Business Session, the Council on Medical Service and the Council on Medical Education. Resolution 8 called for development of principles and guidelines for agreements between housestaff and the institutions in which they serve, and exploration of the development of a model contract.

Attached are guidelines which catalogue options which are appropriate for discussion between housestaff and the respective institution and are submitted for the information of the House of Delegates.

Past House Action: C-73:228

GUIDELINES FOR HOUSESTAFF CONTRACTS

I. Introduction

This is an outline of basic principles to be applied to contracts between Housestaff and the institution at which they serve. There are so many variables present from training institution to training institution that no single form of contract would be helpful. The AMA has therefore developed a set of guidelines for the more important substantive provisions of a Housestaff contract.

The subjects here included are not intended as the only subjects of importance for a contract or appropriate for every contract. Moreover, the definition of the respective responsibilities, rights and obligations of the parties involved can assume various forms: a collective bargaining contract (which is recommended); uniform individual contracts; or as part of the rules of government of the institution. In each instance, it will be necessary for the Housestaff Association to evaluate its needs and the ability of the institution to fulfill them and then establish Housestaff priorities and bargain accordingly with the institution.

II. Proposed Terms and Conditions

A. Parties to the Agreement

The representative status of the Housestaff Association should be expressly accepted and recognized in the contract.

The contract may be between a Housestaff Association with members in several institutions, and a group of related institutions (such as all city hospitals in a certain city), or it may be between a Housestaff Association and a single institution.

Position, salary and all other benefits should remain in effect without regard to rotational assignments, even if they are away from the parent institution.

The agreement should provide coverage for all those performing the duties of interns, residents and fellows. Particular care should be taken to protect against the practice of unpaid "volunteers" performing such duties.

Individual Housestaff Officer contracts should be required to be consistent with the principal contract.

Adequate prior notification of the institution's intention not to renew an individual's contract should be required so that the Housestaff Officer will have sufficient time to obtain another appointment.

B. Obligation of the Institution

The institution should agree to:

provide a training program which meets the standards of the Essentials of Approved Residencies of the AMA;

continuously maintain its staff and its facilities in compliance with all of the standards of the Essentials of Approved Residencies;

proscribe increasing the pyramidal nature of the training program during the tenure of persons already in or accepted to that program.

C. Obligation of Housestaff

Housestaff members should agree to fulfill the educational requirements of the residency program, and to use their efforts to provide safe and effective patient care as assigned or required under the circumstances.

Housestaff Members should comply with the laws, regulations and policies to which the institution is subject.

D. Salary of Housestaff

The salary to be paid to each level of Housestaff, and the day of the payment should be specified. If there are to be progressive increases, the basis for the increase should be specified, together with the time when such increases are to take effect.

In determining the salary level of a Housestaff Officer, credit should be provided for prior training experience where a House Officer has shifted from one program or institution to another.

A specific salary differential should be provided for chief residents or their equivalent.

Specific salary differentials may be provided where appropriate in particular services.

E. Hours of Work

There should be a recognition of the fact that long duty hours extending over an unreasonably long period of time or onerous on-call scheduling are not consistent with the primary objective of education or the efficient delivery of optimum patient care. The institution should commit itself to fair scheduling duty time for all Housestaff members, as well as the provision of adequate and defined off duty hours.

F. Off Duty Activities

This is an appropriate topic for collective bargaining between the Housestaff Association and the institution; and the results of the bargaining on this subject should be clearly set forth in the agreement. The contract could provide that a Housestaff Officer is free to use his off-duty hours as he sees fit, including engaging in outside employment so long as such activity does not interfere with obligations of the Housestaff member to the institution or to the effectiveness of the educational program he is pursuing.

G. Vacations and Leave

The amount of vacation, sick-leave and educational leave to which each Housestaff member is entitled should be specified.

Vacation should be expressed in terms of customary working days as defined by the Institution.

If vacations may be taken only at certain times of the year, this should be expressed. Any requirements for scheduling vacation time also should be stated.

Leave provision may also cover maternity, paternity, bereavement, military duty examinations, preparations therefor, and educational conference purposes. Reimbursements for tuition and expenses incurred at educational conferences should be considered.

The agreement should set forth any progressive increases in the amount of time allowed for vacations, sick leave and educational leave.

Educational leave should not be deducted from vacation time.

H. Insurance Benefits

The insurance benefits which were negotiated should be set forth with particularity and should be tailored to the specific needs of Housestaff Officers.

Some of the more common insurance benefit provisions are (a) hospitalization and basic medical coverage for the Housestaff member and spouse and minor children; (b) Major Medical coverage for Housestaff members and family; and (c) group life insurance, and dismemberment and disability insurance for the Housestaff member only.

It should also be specified whether the institution will pay the full amount of premiums or only a portion of the premiums, the balance to be paid by the Housestaff member. Co-paid benefits should be established, separately from other hospital employee benefits, as a means of maximizing benefits.

In some instances, free care for Housestaff Officers and their families at the training institutions may be provided.

In lieu of insurance benefits, the contract may provide for fixed annual payments to the Housestaff Association for each Housestaff Officer so that the Housestaff Association may determine and provide for insurance or other benefits for Housestaff Officers.

I. Professional Liability Insurance

The contract should specify the amount of Professional Liability Insurance which the institution will provide for each Housestaff member, together with the limits of liability applicable to such coverage.

It might also be appropriate to provide in the contract that the Housestaff members and the institution will fully cooperate with the insurance company in the handling of any professional liability claim.

J. Committee Participation

In so far as possible, the institution should agree to provide for appropriate participation by Housestaff members on the various Committees within the institution. This participation should be on Committees concerning institutional professional and administrative matters. Members should have full voting rights. Housestaff members should be selected by the Housestaff Association members themselves.

K. Grievance Procedures

The contract should provide a grievance procedure. That procedure typically involves the following:

1 – a definition of the term "grievance" (e.g., any dispute or controversy about the interpretation or application of the contract, any rule or regulation, or any policy or practice);

2 – timing and sequence of the grievance steps (initial steps referred to the chief of service, then to the medical board or administrator as a review body);

3 – a right to legal and other representation at each step for the Housestaff Officer;

4 – the right of the Housestaff Association independently to initiate and process a grievance;

5 – a final step – binding arbitration to be initiated only by the Housestaff Association; and

6 – sharing of arbitration costs.

L. Disciplinary Hearings and Procedure

The contract should provide a disciplinary procedure which guarantees "due process" before any disciplinary action is taken against a Housestaff member. Attachment A provides a procedure which may be appropriate or modified for use in a given institution. The procedure adopted should be set forth in full in the contract between the institution and Housestaff Association.

M. Working Conditions and Patient Care Issues

The agreement should provide for adequate, comfortable, safe and sanitary facilities such as on-call rooms, secure storage areas, security personnel, facilities for books, storage of clothing, comfortable sleeping quarters, and limitation of the number of beds per room.

There should be proscription against regular and recurrent performance of duties by Housestaff Officers unrelated to Housestaff Officer training.

Patient care issues, educational training, and salary are compensations for work and are negotiable.

In so far as patient care issues are described in terms of reference to the physician's job description, these frequently fall under contract working conditions.

The quality of patient care services and facilities may be a specified feature of the training program contract, and can include such matters as adequate equipment, bedspace, clinical staffing, and clinical staff structuring.

N. Other Provisions

As indicated, the foregoing provisions are not all-inclusive. Depending upon the institution's size, location and affiliations, if any, and also depending upon the relationship between the institution and the Housestaff Association, other provisions may be included. For example:

payroll deduction of Housestaff dues;

agency dues in those jurisdictions where authorized;

maintenance of existing benefits and practices not otherwise expressly covered;

housing, meals, laundry, uniforms, living out and telephone allowances;

adequate Housestaff Association office space, bulletin boards, secretarial assistance;

Housestaff Association seminars or meetings; and

Housestaff renewal or negotiation of the contract at the end of the term.

III. Legal Assistance

The process of collective bargaining and drafting a contract which will effectively reflect the result of such bargaining will involve many legal considerations. The Housestaff should consider retaining legal counsel to advise and represent them on those matters.

ATTACHMENT A

DISCIPLINARY HEARING AND PROCEDURE

1 - Before any Housestaff member may be reprimanded, suspended, expelled, or suffer a denial of any right or privilege due by virtue of his appointment as a Housestaff member or under any provision of this agreement, said Housestaff member shall be entitled to the benefits of the procedures and appeals provided in this article.

2 - Action seeking to reprimand, suspend, expel, or to deny to any Housestaff member a right or privilege shall be commenced by the preparation of a complaint in writing setting forth the conduct complained of and the requested penalty. This complaint shall be filed with the Disciplinary Committee and a true copy shall be delivered personally to the Housestaff member complained of.

3 - The Disciplinary Committee shall appoint a Hearing Committee consisting of physicians - 40% o f whom are Housestaff Officers to be selected by the Housestaff Association or the Housestaff Officers if there is no Housestaff Association. No member of the Hearing Committee shall be personally involved in the controversy described by the complaint. It shall be the duty of the Hearing Committee to conduct a fair and impartial hearing, pursuant to the provisions of this article and such further rules of procedure as the Committee may adopt for each hearing, which shall not be inconsistent with the provisions of this article.

4 - The Hearing Committee shall set a time and place for a hearing on the complaint, which shall allow the accused Housestaff Officer a reasonable period of time to prepare his defense. The Hearing Committee may extend the time for the hearing by agreement of the parties or as the Hearing Committee may determine.

5 - The accused Housestaff member shall not be required to file a formal written defense to the complaint. The accused Housestaff member may ask the Hearing Committee to order the Complainant to make the complaint more specific by pointing out, in a written request filed with the Hearing Committee and served on the complainant, wherein the complaint is vague or ambiguous. If the Hearing Committee so orders, a more specific complaint must be promptly filed and served on the accused Housestaff member.

6 - Formal rules of evidence shall not prevail at the hearing conducted by the Hearing Committee; however, all evidence offered and considered at the hearing must be reasonably related to the facts and statements contained in the complaint. Both parties may be represented by attorneys or by physicians of their choice at all stages of the procedure. No evidence shall be offered or considered by the Hearing Committee at any time except at a duly convened meeting of the Hearing Committee and while the accused Housestaff member is present.

7 - The accused Housestaff member shall not be obligated to present any evidence by way of defense until the complainant has presented all of the

evidence in support of the complaint. The accused Housestaff member shall not be compelled to be a witness against himself, but shall be given a reasonable opportunity and a sufficient period of time in which to present evidence in support of the defense. Immediately thereafter, the complainant shall be given an opportunity to rebut the Housestaff member's evidence but not to offer new evidence which could have been presented previously.

8 - After hearing all of the evidence, the Hearing Committee shall meet and decide if the evidence offered supports the complaint. If 75% or more of the Hearing Committee shall join in a decision they shall prepare a formal written document entitled "Findings of Fact" in which they state that the allegations of the complaint have or have not been proven and summarize the evidence in support of that finding. This document shall be filed with the Disciplinary Committee and a copy shall be delivered to both parties. If the Hearing Committee finds that the complaint has not been proven, no further action shall be taken on the same facts or occurrence. If the Hearing Committee finds that the complaint has been proven, the Housestaff member shall have the right to appeal as provided below. If the Hearing Committee is unable to reach a decision as aforesaid, they shall so report and no further action shall be taken, but such decision shall not preclude a subsequent complaint on the same charge provided that additional evidence not previously available shall be offered in support of the complaint.

9 - If the Hearing Committee has found the complaint to be proven, the accused Housestaff member shall be entitled to appeal the decision to the full Disciplinary Committee. The accused Housestaff member shall request an appellate hearing in writing and shall serve a copy of the request on the complainant.

10 - A verbatim transcript of the proceedings before the Hearing Committee shall be prepared and filed with the Disciplinary Committee before the appellate hearing shall be convened. Each party also shall have the right to file a written argument with the Disciplinary Committee before the hearing date. A copy of any written argument shall be served on the other party. At the appellate hearing, both parties shall have an equal amount of time for oral argument. No additional evidence shall be offered at the appellate hearing. The Disciplinary Committee shall confine its considerations of the appeal to the records before the Hearing Committee and the appellate argument.

11 - The concurrence of 75% of the members of the Disciplinary Committee shall be required to affirm the decision of the Hearing Committee. Upon such concurrence, the Disciplinary Committee shall report its findings in writing to the Directors of the Institution, together with a recommendation for punishment or penalty to be imposed. A copy of such report shall be delivered to both parties. If the Disciplinary Committee shall not have the concurrence of 75% of its members in any decision, the matter shall be disposed of without further action upon filing the report of the Disciplinary Committee.

12 – Upon receiving the report of affirmance by the Disciplinary Committee and the recommendation of the Committee as to penalty or punishment, the Directors or their delegate(s) may impose punishment or penalty on the Housestaff member, but not in excess of that recommended by the Disciplinary Committee.

13 – No Housestaff member shall be subjected to any disciplinary action or penalty or loss of any compensation until completion of these procedures; provided, however, that a Housestaff member may be suspended, but with pay, pending hearing and appeal where such suspension shall be required by substantial and imminent considerations of patient care.

14 – The contract could provide as a final step in the disciplinary proceedings binding arbitration by a neutral medical expert, mutually selected.

Organization of Student Representatives
Association of American Medical Colleges

--DRAFT--

AAMC STATEMENT ON MOONLIGHTING BY HOUSE OFFICERS

AMENDMENT:

The Association of American Medical Colleges is concerned about the quality of graduate medical education and any activity which might compromise the quality of this experience.

The timely debate regarding house officer "moonlighting" involves a number of considerations which include:

a. The rights of an individual to engage in whatever legal activities he chooses during the time when his services are not required by his primary full-time employer.

b. The dependence that has developed in some sections of the country upon physicians from training programs for the provision of primary and emergency care during their off-duty hours.

c. The financial dependence of some married house officers with children, and other house officers with large previous debts, upon incomes larger than those offered while employed in training status.

d. The broadening educational experience for the house officer who practices some medicine outside the graduate medical education institution.

e. The possible injury to the health of the house officer by working excessive numbers of hours.

f. The possible impairment of the caliber of training opportunities experienced by a house officer whose free time is not available for study and recreation.

g. The relationship of the educational institution that has primary responsibility for recruitment and training of house officers to the larger consumer community when its employees serve in a secondary capacity as a part of a health care system outside the aegis of the primary employer

In creating a statement regarding house officer "moonlighting" the AAMC recognizes that there is no documentation which suggests

that the very occasional time spent pursuing additional work opportunities for income has diverted house officers from their primary responsibilities to their own education and to the patients charged to their care by the training institution.

THEREFORE, as a matter of general principle, the Association of American Medical Colleges urges that institutions of graduate medical education and house officers recognize the importance of the graduate medical education experience both for the individuals' professional development and for the development of the nation's medical resources. Further, the AAMC believes that the house officer, as a medical graduate qualified and accepted by an accredited American graduate medical education program, is a mature individual capable of being responsible for his/her own educational development but urges that the house officer consider the following matters before engaging in additional work opportunities:

a. The capacity of the house officer to fulfill his/her educational objectives while, at the same time, pursuing additional work opportunities for income;

b. The nature of the work opportunity, including its educational value;

c. The needs of the community, and

d. the financial need of the individual.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

SUITE 200, ONE DUPONT CIRCLE, N.W., WASHINGTON, D.C. 20036

June 17, 1974

MEMORANDUM

TO: The COD Administrative Board

FROM: Joseph A. Keyes, Director, Division of Institutional Studies

SUBJECT: 1975 Spring Meeting Facilities

On June 10, I visited Colonial Williamsburg to examine the adequacy of their facilities for our 1975 Spring COD Meeting. The previous tentative arrangements voted in the agenda involved using the Inn and Lodge and the Williamsburg Conference Center. In my judgment these arrangements were inappropriate because of 1) the expense involved, 2) the dispersion of the rooms and range of prices, and 3) the scheduled meeting room was a large auditorium.

Williamsburg has another facility available however; the Motor House and Cascades Meeting Center. I was able to secure a tentative hold on these facilities for the dates April 17-19 (arrival Thursday, departure Sunday) and April 20-22 (arrival Sunday, departure Wednesday). The rooms while not spectacular are quite adequate and are offered at the uniform rate of $27 a day European Plan (no meals). They are set in a wooded area which is quite attractive. The meeting rooms are a short walk away in the Cascades Meeting Center and appear to be well adopted for our needs. Meals at moderate prices are available in a restaurant in the same building, less expensive meals may be had in the cafeteria located nearby.

Recreational opportunities, in addition to visiting the restored area, include: golf, tennis, swimming, bicycling, badminton, croquet, lawn bowling, skeet and trap shooting and horseshoes.

Transportation involves a 20 minute limousine ride from the Patrick Henry International (Newport News) airport. Flights into the airport include daily: 5 from Washington National; 1 from Baltimore; 3 from New York-JFK International; 3 from Boston; 3 from Philadelphia; 2 from Chicago; and 2 from Atlanta. Airlines serving PH International include United, Northwest and Allegheny. Norfork has a similar schedule of flights and is approximately an hour away by cab (fare $25).

While Williamsburg is thus not as accessible as Phoenix, the air service would appear to be nearly adequate.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
SUITE 200, ONE DUPONT CIRCLE, N.W., WASHINGTON, D.C. 20036

June 20, 1974

M E M O R A N D U M

TO: COD, CAS and COTH Administrative Boards

FROM: John A.D. Cooper, M.D.

SUBJECT: Proposed Workshop on the Ethical Aspects of Medical Care

Enclosed please find a preliminary agenda for a proposed workshop jointly sponsored by the AAMC and the National Academy of Sciences which is planned for September 18, 1974. It is proposed to invite the administrative boards of our three Councils, individuals from the Liaison Committee on Medical Education and selected AAMC staff to participate in this one day workshop which will be held at the NAS.

The proposed program is presented to you for comment and an expression of your interest in participating in this program on Wednesday, September 18, the day before the September, 1974 administrative board meetings.

One problem whic should be considered before endorsing the program is that Tuesday, September 17 is Rosh Hashana. Certain of our Jewish colleagues may not be able to participate because of this conflict. The next possible date for the proposed program would be prior to the March, 1975 administrative board meetings.

Attachment

TENTATIVE AGENDA

WORKSHOP ON THE ETHICS OF MEDICAL CARE

National Academy of Sciences

September 18, 1974

Moderator: Bernard Towers, M.B., Ch.B.
Professor of Pediatrics and Anatomy
University of California, Los Angeles

I. Overview of Educational Objectives - 9:30 a.m.

Bernard Towers, M.B., Ch.B.
Professor of Pediatrics and Anatomy
University of California, Los Angeles

This presentation will focus on the educational objectives that are to be achieved in the teaching of ethical issues involving medical care. To accomplish this, the areas of traditional medical ethics -- the value problems that emerge in the individualized physician-patient relationship -- will be discussed with the idea of showing how these issues are related to the broader social justice issues concerning the distribution of medical services.

II. Justice Issues of Resource Allocation in Health Care - 10:50 a.m.

Roger J. Bulger, M.D.
Executive Officer
Institute of Medicine

The justice issues of how money and resources should be allocated in health care is of particular importance now with the potential development of a national health insurance system. This topic will deal with the concept of the preciousness of life from the standpoint of government decision making. It might include an analysis of the implications of the recent passage of the provision

in the Social Security Amendments which cover treatment of end-stage renal disease. In selecting one category of disease, what happens to those who are suffering from other conditions which may also be very expensive and require life-saving technology? How are decisions made regarding government allocation programs and what are the value questions that should be elucidated when such decisions are being made?

12:10-1:30 p.m. LUNCH

III. Ethics and Accountability in Medical Care - 1:30 p.m.

Kerr L White, M.D.
Profes r of Medical Care and Hospitals
The Jc s Hopkins University School
of F lic Health and Hygiene

This topic will ncern itself with the ethical responsibility c those participating in accreditation processes. Hosp al committees such as tissue review and utilization mmittees as well as accreditation bodies at the JC and the Liaison Committee on Medical Educatic are empowered to assess and monitor various functior in the medical system. These committees receive their authority from society and therefore are invested with an ordering of responsibilities, not only to the providers of medical care but also to the consumers in the society in general. With the emergence of large-scale peer review through PSRO's, the issues surrounding the ethical responsibility of such monitoring groups becomes particularly important. The medical students of today are more and more likely to become participants in one way or another on such review committees.

IV. Ethical Assumptions of Various Care Settings - 2:50 p.m.

Rich Magraw, M.D.
President
Norfolk Area Medical Center Authority

The value assumptions of various settings for providing care to patients will be examined. The care settings, which range from the individual proprietorship or

fee-for-service medicine in a highly organized prepaid setting such as health maintenance organizations, affect considerably the way in which care is provided to consumers. Each of these settings creates its own incentives for the provider of care and thereby influences the benefits which are received by the patient. Inevitably some of the ethical considerations surrounding medical settings are related closely to those involved in decisions regarding resource allocation.

V. Existing Teaching Programs in Medical Ethics - 4:10 p.m.

E.A. Vastyan
Associate Professor and Chairman
Department of Humanities
College of Medicine
The Milton S. Hershey Medical Center
of the Pennsylvania State University

This presentation will deal with an overview of some of the existing programs in the teaching of medical ethics. This overview will discuss not only the advantages but also the pitfalls and limitations of various programs.

Summary of Workshop - 5:20 p.m.

We will probably consider someone like Dr. Bernard Towers to chair the entire workshop and to present the summary at the end where he attempts to integrate the beginning statements pulled all together into a conceptual foundation and end with possibly the recommendation for a continuing effort between the Institute of Medicine and the Association of American Medical Colleges.

[CONFERENCE COMMITTEE PRINT]

JUNE 10, 1974

93D CONGRESS, 2d Session } HOUSE OF REPRESENTATIVES { REPORT No. ------

NATIONAL RESEARCH TRAINING AND PROTECTION OF HUMAN RESEARCH SUBJECTS ACT OF 1974

----------Ordered to be printed

Mr. ----------, from the committee of conference, submitted the following

CONFERENCE REPORT

[To accompany H.R. 7724]

The committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 7724) to amend the Public Health Service Act to establish a national program of biomedical research fellowships, traineeships, and training to assure the continued excellence of biomedical research in the United States, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment to the text of the bill insert the following:

Section 1. This Act may be cited as the "National Research Training and Protection of Human Research Subjects Act of 1974".

TITLE I—BIOMEDICAL AND BEHAVIORAL RESEARCH TRAINING

SHORT TITLE

SEC. 101. This title may be cited as the "National Research Service Award Act of 1974".

FINDINGS AND DECLARATION OF PURPOSE

SEC. 102. (a) Congress finds and declares that—

(1) the success and continued viability of the Federal biomedical and behavioral research effort depends on the availability of

excellent scientists and a network of institutions of excellence capable of producing superior research personnel;

(2) direct support of the training of scientists for careers in biomedical and behavioral research is an appropriate and necessary role for the Federal Government; and

(3) graduate research assistance programs should be the key elements in the training programs of the institutes of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration.

(b) It is the purpose of this title to increase the capability of the institutes of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration to carry out their responsibility of maintaining a superior national program of research into the physical and mental diseases and impairments of man.

BIOMEDICAL AND BEHAVIORAL RESEARCH TRAINING

SEC. 103. Part H of title IV of the Public Health Service Act is amended by adding after section 461 the following new sections:

"NATIONAL RESEARCH SERVICE AWARDS

"SEC. 462. (a)(1) The Secretary shall provide National Research Service Awards for—

"(A) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration in matters relating to the cause, diagnosis, prevention, and treatment of the disease (or diseases) or other health problems to which the activities of the Institutes and Administration are directed,

"(B) training at the Institutes and Administration of individuals to undertake such research,

"(C) biomedical and behavioral research at non-Federal public institutions and at nonprofit private institutions, and

"(D) pre- and postdoctoral training at such public and private institutions of individuals to undertake such research.

A reference in this subsection to the National Institutes of Health or the Alcohol, Drug Abuse, and Mental Health Administration shall be considered to include the institutes, divisions, and bureaus included in the Institutes or under the Administration, as the case may be.

"(2) National Research Service Awards may not be used to support residencies.

"(3) Effective July 1, 1975, National Research Service Awards may be made for research or research training in only those subject areas for which, as determined under section 463, there is a need for personnel.

"(b)(1) No National Research Service Award may be made by the Secretary to any individual unless—

"(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

"(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c)(1); and

"(C) *in the case of a National Research Service Award for a purpose described in subsection (a)(1)(C) or (a)(1)(D), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the Award will be conducted.*

An application for an Award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

"(2) *The award of National Research Service Awards by the Secretary under subsection (a) shall be subject to review and approval by the appropriate advisory councils to the entities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration (A) whose activities relate to the research or training under the Awards, or (B) at which such research or training will be conducted.*

"(3) *The period of any National Research Service Award made to any individual under subsection (a) may not exceed three years in the aggregate unless the Secretary for good cause shown waives the application of the three-year limit to such individual.*

"(4) *National Research Service Awards shall provide for such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the recipients of the Awards as the Secretary may deem necessary. A National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.*

"(c)(1)(A) *Each individual who receives a National Research Service Award shall, in accordance with paragraph (3), engage in—*

"(i) *health research or teaching,*

"(ii) *if authorized under subparagraph (B), serve as a member of the National Health Service Corps or serve in his specialty, or*

"(iii) *if authorized under subparagraph (C), serve in a health related activity approved under that subparagraph,*

for a period computed in accordance with paragraph (2).

"(B) *Any individual who received a National Research Service Award and who is a physician, dentist, nurse, or other individual trained to provide health care directly to individual patients may, upon application to the Secretary, be authorized by the Secretary to—*

"(i) *serve as a member of the National Health Service Corps,*

"(ii) *serve in his specialty in private practice in a geographic area designated by the Secretary as requiring that specialty, or*

"(iii) *serve in his specialty as a member of a nonprofit prepaid group practice which may be reimbursed under title XVIII of the Social Security Act,*

in lieu of engaging in health research or teaching if the Secretary determines that there are no suitable health research or teaching positions available to such individual.

"(C) Where appropriate the Secretary may, upon application, authorize a recipient of a National Research Service Award, who is not trained to provide health care directly to individual patients, to engage in a health-related activity in lieu of engaging in health research or teaching if the Secretary determines that there are no suitable health research or teaching positions available to such individual.

"(2) For each year for which an individual receives a National Research Service Award he shall—

"(A) for twelve months engage in health research or teaching or, if so authorized, serve as a member of the National Health Service Corps, or

"(B) if authorized under paragraph (1)(B) or (1)(C), for twenty months serve in his specialty or engage in a health-related activity.

"(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's Award, as the Secretary shall by regulation prescribe. The Secretary shall (A) by regulation prescribe (i) the type of research and teaching which an individual may engage in to comply with such requirement, and (ii) such other requirements respecting such research and teaching and alternative service authorized under paragraphs (1)(B) and (1)(C) as he deems necessary; and (B) to the extent feasible, provide that the members of the National Health Service Corps who are serving in the Corps to meet the requirement of paragraph (1) shall be assigned to patient care and to positions which utilize the clinical training and experience of the members.

"(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirement, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \phi\left(\frac{t - 1/2s}{t}\right)$$

in which 'A' is the amount the United States is entitled to recover; 'ϕ' is the sum of the total amount paid under one or more National Research Service Awards to such individual and the interest on such amount which would be payable if at the time it was paid it was a loan bearing interest at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing at the time each Award to such individual was made; 't' is the total number of months in such individual's service obligation; and 's' is the number of months of such obligation served by him in accordance with paragraphs (1) and (2) of this subsection.

"(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount,

be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any National Research Service Award is paid, there shall accrue to the United States interest on such amount at the same rate as that fixed by the Secretary of the Treasury under subparagraph (A) to determine the amount due the United States.

"(4)(A) Any obligation of any individual under paragraph (3) shall be canceled upon the death of such individual.

"(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve extreme hardship to such individual and if enforcement of such obligation with respect to any individual would be against equity and good conscience.

"(d) There are authorized to be appropriated to make payments under National Research Service Awards $207,947,000 for the fiscal year ending June 30, 1975.

"STUDIES RESPECTING BIOMEDICAL AND BEHAVIORAL RESEARCH PERSONNEL

"SEC. 463. (a) The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

"(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

"(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this Act at or through institutes under the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration, and (B) other current training programs available for the training of such personnel;

"(3) identify the kinds of research positions available to and held by individuals completing such programs;

"(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

"(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

"(b)(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

"(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private

groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).

"(c) A report on the results of such study shall be submitted by the Secretary to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate not later than March 31 of each year."

CONFORMING AMENDMENTS

SEC. 104. (a)(1) Section 301 of the Public Health Service Act is amended (A) by striking out paragraph (c); (B) by striking out in paragraph (d) "or research training" each place it occurs, "and research training programs", and "and research training program"; and (C) by redesignating paragraphs (d), (e), (f), (g), (h), and (i) as paragraphs (c), (d), (e), (f), (g), and (h), respectively.

(2)(A) Section 303(a)(1) of such Act is amended to read as follows:

"(1) to provide clinical training and instruction and to establish and maintain clinical traineeships (with such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary);".

(B) Section 303(b) of such Act is amended by inserting before the first sentence the following: "The Secretary may provide for training, instruction, and traineeships under subsection (a)(1) through grants to public and other nonprofit institutions.".

(3) Section 402(a) of such Act is amended (A) by striking out "training and instruction" in paragraph (3) and inserting in lieu thereof "clinical training and instruction", and (B) by striking out paragraph (4) and by redesignating paragraphs (5), (6), and (7) as paragraphs (4), (5), and (6), respectively.

(4) Section 407(b)(7) of such Act is amended (A) by striking out "and basic research and treatment", and (B) by striking out "where appropriate".

(5) Section 408(b)(3) of such Act is amended by inserting "clinical" before "training" each place it occurs.

(6) Section 412(7) of such Act is amended by striking out "(1) establish and maintain" and all that follows down through and including "maintain traineeships" and inserting in lieu thereof ", provide clinical training and instruction and establish and maintain clinical traineeships".

(7) Section 413(a)(7) is amended by inserting "clinical" before "programs".

(8) Section 415(b) is amended by inserting before the period at the end of the last sentence thereof the following: "; and the term 'training' does not include research training for which fellowship support may be provided under section 462".

(9) Section 422 of such Act is amended (A) by striking out paragraph (c) and by redesignating paragraphs (d), (e), and (f) as paragraphs (c), (d), and (e), respectively, and (B) by striking out

"training and instruction and establish and maintain traineeships" in paragraph (e) (as so redesignated) and inserting in lieu thereof "clinical training and instruction and establish and maintain clinical traineeships".

(10) Section 434(c)(2) of such Act is amended by inserting "(other than research training for which National Research Service Awards may be made under section 462)" after "training" the first time it occurs.

(11) Sections 433(a), 444, and 453 of such Act are each amended by striking out the second sentence thereof.

(12) The heading for part H of title IV of such Act is amended by striking out "ADMINISTRATIVE" and inserting in lieu thereof "GENERAL."

(b) The amendments made by subsection (a) shall not apply with respect to commitments made before the date of the enactment of this Act by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a).

SEX DISCRIMINATION

SEC. 105. Section 799A of the Public Health Service Act is amended by adding at the end thereof the following: "In the case of a school of medicine which—

"(1) on the date of the enactment of this sentence is in the process of changing its status as an institution which admits only female students to that of an institution which admits students without regard to their sex, and

"(2) change is being carried out in accordance with a plan approved by the Secretary,

the provisions of the preceding sentences of this section shall apply only with respect to a grant, contract, loan guarantee, or interest subsidy to, or for the benefit of such a school for a fiscal year beginning after June 30, 1979."

FINANCIAL DISTRESS GRANTS

SEC. 106. Section 773(a) of the Public Health Service Act is amended by striking out "$10,000,000" and inserting in lieu thereof "$15,000,000".

TITLE II—PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

PART A—NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORIAL RESEARCH

ESTABLISHMENT OF COMMISSION

SEC. 201. (a) There is established a Commission to be known as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter in this title referred to as the "Commission").

(b)(1) The Commission shall be composed of eleven members appointed by the Secretary of Health, Education, and Welfare (hereinafter in this title referred to as the "Secretary"). The Secretary shall select members of the Commission from individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs; but five (and not more than five) of the members of the Commission shall be individuals who are or who have been engaged in biomedical or behavorial research involving human subjects. In appointing members of the Commission, the Secretary shall give consideration to recommendations from the National Academy of Sciences and other appropriate entities. Members of the Commission shall be appointed for the life of the Commission. A member of the Commission shall not be eligible for appointment to the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research.

(2)(A) Except as provided in subparagraph (B), members of the Commission shall each be entitled to receive the daily equivalent of the annual rate of the basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of the duties of the Commission.

(B) Members of the Commission who are full-time officers or employees of the United States shall receive no additional pay on account of their service on the Commission.

(C) While away from their homes or regular places of business in the performance of duties of the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703(b) of title 5 of the United States Code.

(c) The chairman of the Commission shall be selected by the members of the Commission from among their number.

(d)(1) The Commission may appoint and fix the pay of such staff personnel as it deems desirable. Such personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(2) The Commission may procure temporary and intermittent services to the same extent as is authorized by section 3109(b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule.

COMMISSION DUTIES

SEC. 202. (a) The Commission shall carry out the following:

(1)(A) The Commission shall (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects, (ii) develop guidelines which should be followed in

such research to assure that it is conducted in accordance with such principles, and (iii) make recommendations to the Secretary (I) for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the Secretary, and (II) concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research.

(B) In carrying out subparagraph (A), the Commission shall consider at least the following:

(i) The boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine.

(ii) The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects.

(iii) Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research.

(iv) The nature and definition of informed consent in various research settings.

(v) Mechanisms for evaluating and monitoring the performance of Institutional Review Boards established in accordance with section 464 of the Public Health Service Act and appropriate enforcement mechanisms for carrying out their decisions.

(C) The Commission shall consider the appropriateness of applying the principles and guidelines identified and developed under subparagraph (A) to the delivery of health services to patients under programs conducted or supported by the Secretary.

(2) The Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by children, prisoners, and the institutionalized mentally infirm. The Commission shall investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary and involving children, prisoners, and the institutionalized mentally infirm to determine the nature of the consent obtained from such persons or their legal representatives before such persons were involved in such research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the competence and the freedom of the persons to make a choice for or against involvement in such research. On the basis of such investigation and study the Commission shall make such recommendations to the Secretary as it determines appropriate to assure that biomedical and behavioral research conducted or supported under programs administered by him meets the requirements respecting informed consent identified by the Commission. For purposes of this paragraph, the term "children" means individuals who have not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which the research is to be conducted; the term "prisoner" means individuals involuntarily confined in penal institutions; and the term "institutionalized mentally infirm" includes individuals who are

mentally ill, mentally retarded, emotionally disturbed, psychotic, or senile, or who have other impairments of a similar nature and who reside as patients in an institution.

(3) The Commission shall conduct an investigation and study to determine the need for a mechanism to assure that human subjects in biomedical and behavioral research not subject to regulation by the Secretary are protected. If the Commission determines that such a mechanism is needed, it shall develop and recommend to the Congress such a mechanism. The Commission may contract for the design of such a mechanism to be included in such recommendations.

(b) The Commission shall conduct an investigation and study of the nature and extent of research involving living fetuses, the purposes for which such research has been undertaken, and alternative means for achieving such purposes. The Commission shall, not later than four months after the month in which the Commission is established, recommend to the Secretary policies defining the circumstances (if any) under which such research may be conducted.

(c) The Commission shall conduct an investigation and study of the use of psychosurgery in the United States during the five-year period ending December 31, 1972. The Commission shall determine the appropriateness of its use, evaluate the need for it, and recommend to the Secretary policies defining the circumstances (if any) under which its use may be appropriate. For purposes of this paragraph, the term "psychosurgery" means brain surgery on (1) normal brain tissue of an individual, who does not suffer from any physical disease, for the purpose of changing or controlling the behavior or emotions of such individual, or (2) diseased brain tissue of an individual, if the sole object of the performance of such surgery is to control, change, or affect any behavioral or emotional disturbance of such individual. Such term does not include brain surgery designed to cure or ameliorate the effects of epilepsy and electric shock treatments.

(d) The Commission shall make recommendations to the Congress respecting the functions and authority of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research to be estabilshed under section 217(f) of the Public Health Service Act.

SPECIAL STUDY

SEC. 203. The Commission shall undertake a comprehensive study of the ethical, social, and legal implications af advances in biomedical and behavioral research and technology. Such study shall include—

(1) an analysis and evaluation of scientific and technological advances in past, present, and projected biomedical and behavioral research and services;

(2) an analysis and evaluation of the implications of such advances, both for individuals and for society;

(3) an analysis and evaluation of laws and moral and ethical principles governing the use of technology in medical practice;

(4) an analysis and evaluation of public understanding of and attitudes toward such implications and laws and principles; and

(5) an analysis and evaluation of implications for public policy of such findings as are made by the Commission with respect to advances in biomedical and behavioral research and technology and public attitudes toward such advances.

ADMINISTRATIVE PROVISIONS

SEC. 204. (a) The Commission may for the purpose of carrying out its duties under sections 202 and 203 hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission deems advisable.

(b) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties. Upon the request of the chairman of the Commission, the head of such department or agency shall furnish such information to the Commission.

(c) The Commission shall not disclose any information reported to or otherwise obtained by it in carrying out its duties which (1) identifies any individual who has been the subject of an activity studied and investigated by the Commission, or (2) which concerns any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code.

(d) Except as provided in subsection (b) of section 202, the Commission shall complete its duties under sections 202 and 203 not later than twenty-four months after the month in which the Commission is established. The Commission shall make periodic reports to the President, the Congress, and the Secretary respecting its activities under sections 202 and 203 and shall, not later than ninety days after the expiration of such twenty-four months, make a final report to the President, the Congress, and the Secretary respecting such activities and including its recommendations for administrative action and legislation.

(e) The Commission shall cease to exist thirty days following the submission of its final report pursuant to subsection (d).

DUTIES OF THE SECRETARY

SEC. 205. Within 60 days of the receipt of any recommendation made by the Commission under section 202, the Secretary shall publish it in the Federal Register and provide opportunity for interested persons to submit written data, views, and arguments with respect to such recommendation. The Secretary shall consider the Commission's recommendation and relevant matter submitted with respect to it and, within 180 days of the date of its publication in the Federal Register, the Secretary shall (1) determine whether the administrative action proposed by such recommendation is appropriate to assure the protection of human subjects of biomedical and behavioral research conducted or supported under programs administered by him, and (2) if he determines that such action is not so appropriate, publish in the Federal Register such determination together with an adequate statement of the reasons for his determination. If the Secretary determines that administrative action recommended by the Commission

should be undertaken by him, he shall undertake such action as expeditiously as is feasible.

PART B—MISCELLANEOUS

NATIONAL ADVISORY COUNCIL FOR THE PROTECTION OF SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

SEC. 211. (a) Section 217 of the Public Health Service Act is amended by adding at the end the following new subsection:

"(f) (1) There shall be established a National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research (hereinafter in this subsection referred to as the 'Council') which shall consist of the Secretary who shall be Chairman and not less than seven nor more than fifteen other members who shall be appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service. The Secretary shall select members of the Council from individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs; but three (and not more than three) of the members of the Council shall be individuals who are or who have been engaged in biomedical or behavioral research involving human subjects. The appointed members of the Council shall have terms of office of four years, except that for the purpose of staggering the expiration of the terms of office of the Council members the Secretary shall, at the time of appointment, designate a term of office of less than four years for members first appointed to the Council.

"(2) The Council shall—

"(A) advise, consult with, and make recommendations to the Secretary concerning all matters pertaining to the protection of human subjects of biomedical and behavioral research;

"(B) review policies, regulations, and other requirements of the Secretary governing such research to determine the extent to which such policies, regulations, and requirements require and are effective in requiring observance in such research of the basic principles which should underlie the conduct of such research and, to the extent such policies, regulations, or requirements do not require or are not effective in requiring observance of such principles, make recommendations to the Secretary respecting appropriate revision of such policies, regulations, or requirements; and

"(C) review periodically changes in the scope, purpose, and types of biomedical and behavioral research being conducted and the impact such changes have on the policies, regulations, and other requirements of the Secretary for the protection of human subjects of such research.

"(3) The Council may disseminate to the public such information, recommendations, and other matters relating to its functions as it deems appropriate.

"(4) Section 14 of the Federal Advisory Committee Act shall not apply with respect to the Council."

(b) The amendment made by subsection (a) shall take effect July 1, 1976.

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 212. (a) Part H of title IV of the Public Health Service Act, as amended by section 103 of this Act, is amended by adding at the end the following new section:

"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

"SEC. 464. (a) The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant or contract assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research.

"(b) The Secretary shall establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately."

(b) The Secretary of Health, Education, and Welfare shall within 240 days of the date of the enactment of this Act promulgate such regulations as may be required to carry out section 464(a) of the Public Health Service Act. Such regulations shall apply with respect to applications for grants and contracts under such Act submitted after promulgation of such regulations.

LIMITATION ON RESEARCH

SEC. 213. Until the Commission has made its recommendations to the Secretary pursuant to section 202(b), the Secretary may not conduct or support research in the United States or abroad on a living human fetus, before or after the induced abortion of such fetus, unless such research is done for the purpose of assuring the survival of such fetus.

INDIVIDUAL RIGHTS

SEC. 214. (a) Subsection (c) of section 401 of the Health Programs Extension Act of 1973 is amended (1) by inserting "(1)" after "(c)", (2) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and (3) by adding at the end the following new paragraph:

"(2) No entity which receives after the date of enactment of this paragraph a grant or contract for biomedical or behavioral research under any program administered by the Secretary of Health, Education, and Welfare may—

"(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

"(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel,

because he performed or assisted in the performance of any lawful health service or research activity, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance or such service or activity would be contrary to his religious beliefs or moral convic-

tions, or because of his religious beliefs or moral convictions respecting any such service or activity."

(b) Section 401 of such Act is amended by adding at the end the following new subsection:

"(d) No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health, Education, and Welfare if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions."

SPECIAL PROJECT GRANTS AND CONTRACTS

SEC. 215. Section 772(a)(7) of the Public Health Service Act is amended by inserting immediately before the semicolon at the end thereof the following: ", or (C) providing increased emphasis on the ethical, social, legal, and moral implications of advances in biomedical research and technology with respect to the effects of such advances on individuals and society".

And the Senate agree to the same.

That the House recede from its disagreement to the amendment of the Senate to the title of the bill and agree to the same.

O

DRAFT QUESTIONNAIRE - INJURIES SUSTAINED DURING RESEARCH

TO: Deans

As a result of the increasing national concern about the ethical aspects of biomedical research, legislators are beginning to raise questions about the number of subjects of biomedical research who have been injured or harmed as a consequence of participation in biomedical research programs. In order to develop information to serve as a data base from which inquiries can be answered, the following brief questionnaire has been developed. We shall treat your response in a confidential manner and, following collation of the data, will not identify responses provided from an individual school.

During the past five years:

1. What is the approximate number of all research projects involving human subjects conducted over the past five years?

   _____

2. What is the approximate average number of persons participating as subjects of biomedical research projects at your institution each year?

   _____

3. What is the approximate age distribution of your research subjects?

   (Check in order as primary, secondary, tertiary or not included)

   Children _____

   Adults _____

   Older Adults _____

4. How many patients/subjects have been seriously injured as a direct result of participation in research projects conducted by your institution?

_____

5. How many of these injuries have resulted in claims against your institution or its staff?

_____

6. How many of these claims have been settled at a cost to your institution or its insurance carrier?

_____

What is your best estimate of these costs?

_____

7. How many possible claims have been "deferred" by institutional delivery of services, care or other considerations?

_____

8. What insurance option does your institution utilize?

Self-insured _____

Insured through Insurance Carrier _____

Insured through State Government _____

9. Does your current insurance program cover the innocent victim of biomedical research?

_____

What is your maximum liability under this program?

_____

10. If your current insurance program does not include coverage for the innocent victims of research, could you briefly indicate the reason?

_____

_____

11. School _____

6/11/74

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
SUITE 200, ONE DUPONT CIRCLE, N.W., WASHINGTON, D.C. 20036

June 20, 1974

M E M O R A N D U M

TO: CAS Administrative Board

FROM: Michael F. Ball, M.D., Director, Division of Biomedical Research

SUBJECT: Scholarly Activities and Medical School Faculty: A Historic Perspective

The attached document entitled "Scholarly Activities and Medical School Faculty: A Historic Perspective" has been prepared by the Biomedical Research Committee for presentation to Executive Council at its fall meeting. We would appreciate receiving your comments and criticisms.

Attachment

MFB:ms

SCHOLARLY ACTIVITIES AND MEDICAL SCHOOL FACULTY

A HISTORIC PERSPECTIVE

At the turn of this century physicians graduating from German universities were publicly acknowledged to be superior to those educated in any other country.[1,2] This excellence of German education reflected a unique characteristic of the German system of medical education which developed during the second half of the 19th century. In Germany a student studied medicine in a university medical school where teaching and investigation were regarded as equal factors in the formulation of medical education. The German university gave comparable emphasis to scientific investigation and to teaching, and eminence in research, as well as ability to teach, became the accepted basis for promotion at the university.

In reviewing the history of the evolution of German medical education, Abraham Flexner noted "How rapidly, once the fundamental importance of successful research to the ambitious teacher was established, the requisite facilities, clinical and laboratory, were obtained, and how rapidly differentiation and specialization took place."[2] Both basic scientists and clinicians aspiring to academic medicine were deliberately trained to be competent investigators. By 1910, German university medical schools had well-equipped and supported laboratories in each of the primary medical disciplines. In contrast, during the same period in the United States, poorly

trained doctors were being produced by proprietary schools unaffiliated with universities. Biomedical research and scholarly pursuit by the faculty were unknown. In his classical monograph on American medical education published in 1910, Abraham Flexner noted "Investigation and practice are thus method and object ... an exacting discipline cannot be imparted except in a keen atmosphere by men who are themselves in training. Of course the business of the medical school is the making of doctors; nine-tenths of its graduates will, as Dr. Osler holds, never be anything else. But practitioners of modern medicine must be alert, systematic, thorough, critically open-minded; they will get no such training from perfunctory teachers. Educationally, then, research is required of the medical faculty because only research will keep the teachers in condition. A non-productive school, conceivably up-to-date today, would be out-of-date tomorrow; its dead atmosphere would soon be careless and unenlightened dogmatism."[1] Flexner viewed medicine as a science in which no distinction can be made between research and practice, rather than as a classical art. In elaborating on this point, Flexner stated, "If medicine is classified as an art, in contradistinction to a science, the practitioner is encouraged to proceed with a clear conscience on superficial or empirical lines; if, on the other hand, he is acutely conscious of the responsibility to the scientific spirit and scientific method, he will almost inevitably endeavor to clarify his conceptions and to proceed more systematically in the accumulation of

data, the framing of hypothesis and the checking-up of results."[1]

It is impossible to over-emphasize the impact of Abraham Flexner on the evolution of the twentieth-century American medical school. At the time of completion of Mr. Flexner's studies, there were 23,927 students enrolled in 148 American medical schools. (Table 1) Over the next 15 years, 68 schools closed and the number of students enrolled decreased by more than 5,000. Medical education became a university discipline with finite educational standards. Teaching in the laboratory and the hospital became a central part of the process of medical education. The costs of these revolutions were high but many voluntary health organizations, philanthropic agencies and industrial firms contributed to help. Schools financed these additional responsibilities from large private gifts. In addition, state revenues began to be used to support medical education. Many schools made increasing efforts to support research and to appoint to their faculties productive scientists. The medical school faculty became our nation's biomedical research scientists and their salaries, equipment and supplies were paid for from the budget of the medical school. In 1932, for the first time, attention was called to the increasing research emphasis in the schools of medical education.[3] Particular concern was expressed about isolating medical research from the education of medical students. By 1941, 17 medical schools had research budgets in excess of $100,000 a year and research expenditures constituted 11% of the budgets of the schools, with 98% of the funds

for sponsored research derived from non-federal grants.[4] Coincident with the increase in university affiliation of the medical schools, there was a progressive trend to employ more medical school faculty on a full-time or a geographic full-time basis, particularly in the clinical departments. Teaching and research had become inseparably intertwined. In many schools the chief consideration in the selection of full-time faculty became proven research ability. By 1950, research expenditures constituted 32% of the expenditures of four-year medical schools.[4] Complaints about the over-emphasis on research became louder. As was indicated by one dean of a privately supported school, "There is over-emphasis on research. It is trite to say this because it has been reiterated ad nauseam, but the fact still remains that we do not place enough emphasis on teaching, nor do we compensate adequately for the capacity to teach. We give lip service constantly to the importance of teaching, but when the chips are down, research always tips the balance."[4] Medical school faculty seemed to have forgotten Abraham Flexner's balanced emphasis; "The truth is that an instructor, devoting part of his day under adequate protection to investigation, can teach even the elements of his subject along rigorously scientific lines. On the other hand, it will never happen that every professor in either the medical school or the university faculty is a generally productive scientist. There is room for men of another type -- the non-productive, assimilative teacher of wide learning, continuous receptivity, critical sense and responsive

interest. Not infrequently, these men, catholic in their sympathies, scholarly in spirit and method, prove the purveyors and distributors through whom new ideas are harmonized and made current. They preserve balance and make connections."[1] Between 1950 and 1965 biomedical research activities of the schools of medical education continued to increase and the federal government assumed a progressively larger responsibility for the support of biomedical research activities of medical schools. In 1961, 73% of the medical school expenditures for sponsored biomedical research derived from federal grants. By 1965, medical research conducted in schools of medical education cost $375 million and constituted 42% of the entire expenditures of the academic medical center.[5]

By early 1960, public outcry against the disappearance of general practitioners, the increasing specialization of physicians, the demand for increased accessibility to health care, caused some medical educators to begin to rethink the university affiliated, research oriented medical school and suggest the development of a new type of medical school, the community-based medical school.

It is appropriate to review German medical education between 1910 and 1925 if we are to place the evolution of the new "community based medical school" in perspective. As noted earlier, by 1910 the university based medical schools in Germany were superior to those in any other country. However, as Germany began to prepare for the

first world war, distinct murmurs began to be heard that biomedical research was not only becoming more and more costly, but the medical research laboratories were less important than the development of a new warship. Money became short; apparatus, supplies, animals and books became unobtainable. The empire attached its own political fortunes to the brains of the universities and the universities became crowded with students. Emphasis in medical education was on training students to practice medicine and to minimize the time devoted to research on the part of the faculty. Research was removed from the universities and scientific institutes isolated from the education of medical students were developed. Between 1910 and 1925 German medical education deteriorated to the point where the education provided to medical students was comparable or even less satisfactory than that accomplished in other countries of the world.[2]

It is interesting to observe that this deterioration in German medical education coincided with the shift from the scientific based medical school to a clinically oriented school designed to turn out large numbers of physicians. This historical precedent is comparable to that in the United States at the turn of the century when the justification for the existence of low quality, high volume, proprietary medical schools was the acute need for more doctors. In commenting on the public cry for more doctors, Flexner indicated "The problem is, of course, practical and not academic. Pending the homogenous filling-up of the whole country, inequalities must be tolerated.

Man has not been inaptly differentiated as the animal with 'the desire to take medicine'. When sick he craves the comfort of a doctor, any doctor rather than none at all, and this he will not be denied. The question is, then, not merely to define the idea of training of a physician; it is just as much, at this particular junction, to strike the solution, that economic and social factors being what they are, will distribute as widely as possible the best type of physicians so distributable." ... "It would appear, then, that over-production on a low basis does not effectively overcome the social or economic obstacles to spontaneous dispersion."[1] In commenting on the shortage of physicians in some localities, Flexner indicated "It would appear, then, that perhaps the salvation of these districts might, under existing circumstances, be better worked out by a different model. A large area would support one good man, whereas separate fragments are unable to support even one poor man. A physician's range, actual and virtual, increases with his competency. A well-qualified doctor may perhaps at a central point set up a small hospital, where the seriously ill of the entire district may receive good care. The region is thus better served by one well-trained man than it could possibly be even if over-production on a low basis ultimately succeeded in forcing an incompetent into every hamlet of 5 and 20 souls."[1]

During the mid-1960s, the increasing American public demand for more readily accessible medical care produced a public out-cry against the scarcity of doctors, the increasing specialization of physicians, the high cost of medical care, the high cost of medical education and

the research oriented medical school. Some medical educators responded to this pressure by developing the concept of a community-based medical school. In these programs, the student receives his basic science education at an academic medical center, or, in other models, at a university science center unaffiliated with a medical school. Physical diagnosis, clinical clerkship and electives are developed at affiliated community hospitals staffed by a small core of full-time faculty. The major portion of clinical teaching is provided by volunteer or part-time practicing physicians. The full-time faculty at these community hospitals are full-time teachers who spend a small portion of their time in the delivery of health care and a negligible portion devoted to scholarly activities, such as biomedical research.

Development of the community-based, 'modern' medical school was not the only response of medical education to the public demand for greater accessibility to high-quality medical care. Many institutions began to increase their involvement in programs directed toward the delivery of health care. As noted earlier, in 1965 medical research conducted in schools of medicine cost $375 million and constituted 42% of the entire expenditures of the academic medical center. By 1971, expenditures for biomedical research were $481 million but this constituted only 28% of the expenditures of the entire academic medical center, which rose from $882 million in 1965-66 to $1.713 billion in 1970-71.[5] Biomedical research had become a

relatively less dominant part of the activities of the academic medical center. Indeed, certain medical educators and state legislators suggested that the United States duplicate the German experience, where biomedical research would be conducted in research institutes and medical schools would devote their entire effort to the education of physicians who would be trained to deliver health care. Some have suggested that physician faculty should put down their test tubes, get out of the ivory towers and participate in the delivery of health care in order to improve our nation's health. This commentary should not be interpreted as a cynical response to the demand of the American public for increased accessibility to health care and a clear cut need to reform our system of health care delivery. Nevertheless, it is clear that the concept of a medical school devoted solely to the instruction of candidates for the M.D. degree would create a non-viable institution. Medical schools must also provide opportunity for advanced study in the various fields of medicine, must develop the specialists and teachers of the next generation and must investigate the problems of health and disease. Thus, scholarly pursuits such as biomedical research are a critically important part of the activities of medical school faculty. Our own history and the German experience tell us that the development of medical schools which place insufficient emphasis on the need for scholarly activity by faculty will ultimately result in a system of medical education which produces poorly trained physicians.

Although participation by the faculty in scholarly pursuits such as biomedical research should be on a voluntary basis, it is important that the medical school encourage among its faculty a zest for the discovery of new knowledge, an eagerness to communicate this knowledge and provide an atmosphere conducive to the development of scholarship. The institutional commitment of the modern American medical school to the academic growth and development of its faculty should include a guarantee that the faculty will have sufficient time to participate in scholarly pursuits as part of its regular academic program. Biomedical research programs are expensive and the faculty should be encouraged to solicit research support through gifts, grants and contracts to provide support for their research programs. Although it is imperative that the investigator's freedom in research, including the direction of the program and communication of results, be preserved, institutional biomedical research policy should ensure that these activities conform to the purposes of the institution and provide an appropriate balance between research, instruction and patient care.

SUMMARY

Modern medicine is concerned with the application of a changing body of knowledge and technology to the problems of health and disease. It is essential that the student of medicine have a direct encounter with the scientific processes involved in the current state

of knowledge in the biomedical sciences. The exponential rate at which medical knowledge has grown in the recent past, and the likelihood that it will continue to expand at the same rate in the future, make it imperative that the physician be able to evaluate for himself the results of scientific investigation and have the ability to discern their usefulness and application. To develop these characteristics in a physician, medical education must encompass the opportunity for the medical student to engage with exemplary faculty in the use of the scientific method for investigative processes directed toward the discovery of new knowledge. This can only be accomplished by a faculty that is involved in adequate measure with the development of knowledge at the frontiers of the health sciences through their own research activities.

REFERENCES

1. Flexner, A. 1910. Medical Education in the United States and Canada: A report to the Carnegie Foundation for the Advancement of Teaching. Bulletin No. 4. New York.

2. Flexner, A. 1925. Medical Education: A Comparative Study, New York: MacMillan

3.

4. Deitrick, J.E., and Berson, R.C. 1953. Medical Schools in the United States at Mid-Century. New York:McGraw-Hill.

5. American Medical Association Council on Medical Education. 1972. Medical Education in the United States, 1971-72, JAMA, 222:990.

AGENDA

COD-COTH-CAS JOINT MEETING
NOVEMBER 13, 1974

AAMC ANNUAL MEETING
NOVEMBER 12-16, 1974
CHICAGO, ILLINOIS

INSTITUTIONAL RESPONSIBILITY FOR GRADUATE MEDICAL EDUCATION: ISSUES AND ANSWERS?

2:00 - 3:30 p.m. Policies for the allocation of medical center resources and facilities for graduate medical education: What is at stake?

2:00 - 2:20	The Hospital Administrator's Perspective
2:20 - 2:40	The Dean's Perspective
2:40 - 3:05	The Faculty's Point of View
3:05 - 3:30	Discussion (Moderator and the three speakers lead discussion which is open to the floor.)

This section of the program is designed to lay out the organizational, educational and financing issues from the varying perspectives of those within the medical center who play key roles in graduate medical education and upon whom the success of any move toward institutional responsibility will depend. Questions to be addressed include: How will priorities be set and resources allocated? By whom? Through what organizational framework? Where will the resources be derived? And at what cost?

3:30 - 3:45 p.m. COFFEE BREAK

3:45 - 4:30 p.m. Qualitative and quantitative assessment: Who calls the shots?

3:45 - 4:05	How should the number of residents in each specialty be controlled and by whom?
4:05 - 4:25	How can genuine educational quality be ensured?
4:25 - 4:45	Student Selection - The issues of quality and continuity in the transition to the graduate phase.
4:45 - 5:05	How should responsibility for financing graduate medical education be assigned?
5:05	Discussion

This section of the program will deal with supra-institutional issues, or those which may involve the operation of national bodies or national level cooperation among the institutions. Questions to be addressed include: Should there be a national system for allocating specialty training positions? If so, is this a governmental or a non-governmental function? What is the appropriate configuration for such a body? On what basis should such decisions be made? What is the role of external assessment procedures, accreditation, PSRO's? Who sets standards of quality and how? Is there any necessity for a national system for facilitating student (resident) selection? How should it best be operated? Should a qualifying exam be instituted at the undergraduate-graduate interface? The financing issue would be approached from the standpoint of national long range policy.

AMERICAN MEDICAL ASSOCIATION
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VES H. SAMMONS, M.D.
Executive Vice President Designate

May 23, 1974

Henry D. McIntosh, M. D.
Chairman, Department of Medicine
Baylor College of Medicine
Texas Medical Center
Houston, Texas 77025

Dear Henry:

I have deliberately not responded to your letter of April 18 until now in order to be able to give you some positive answers to the questions that you raised.

Let me tell you what the present status of the Guidelines for Housestaff Relationships to Teaching Institutions is. First of all, the Board of Trustees, at its meeting in April, approved these Guidelines for transmission to the House of Delegates, at which time, in June, they will be referred to the appropriate reference committee of the House where general discussion and debate, both pro and con, will occur. Following said debate, the reference committee will then make a recommendation to the House to either approve, disapprove, amend or table this document. Frankly, I understand the problems that you present in terms of Baylor's particular situation; however, in all candor, I must also acknowledge that there are teaching institutions in the country in which some form of due process must be instituted if the training programs are to continue to survive because of activities that have occurred over the past several years. Happily, this does not refer to Baylor.

I am aware that all Housestaff situations are different, and particularly in terms of Baylor's relationship with the hospital district, the VA, the Methodist, and St. Luke's, and I also am aware that certainly this committee can "create many problems" but at the same time, I think we must all acknowledge that at the moment, since they are in excess of 50,000 in training programs across the country, that some sort of guidelines for at least reasonable stability is indicated.

I do not know what the response of the AMA House will be; however, I would encourage you to appear before the reference committee here in Chicago during the course of the Annual Convention to present the point of view which you have enunciated in your letter, and also to review the Guidelines that the Board is referring for study. In order to help you with that evaluation, I am enclosing a copy of the Board report which includes a "due process" procedure.

Insofar as your comments relative to the National Society for Medical Research are concerned, I am just now getting into the problem of NSMR and will be in a better position to respond the next time I see you. At the moment, I must confess that I am not very familiar with this organization.

Sorry that I missed you during the course of the Texas Medical Association meeting; however, I am glad that Russ and I had breakfast with Joe Merrill, and felt it was very productive.

Best personal regards,

James H. Sammons, M. D.

Enclosure