

Thursday, April 27

8:30 a.m.- COD BUSINESS

12 Noon MEETING

12 Noon ADJOURNMENT

*Cottonwood
Conference Center*



**Association of American
Medical Colleges
COUNCIL OF DEANS
SPRING MEETING**

PROGRAM

**THE INTERFACE
BETWEEN GOVERNMENT
AND ACADEMIC MEDICINE**

**April 24-27, 1978
Snowbird Village
Snowbird, Utah**

1978 SPRING MEETING
OF THE COUNCIL OF DEANS

April 24-27, 1978
Snowbird, Utah

THE INTERFACE
BETWEEN GOVERNMENT
AND ACADEMIC MEDICINE

PROGRAM

Monday, April 24

1:00 p.m.- ARRIVAL & *Cliff Lodge*
5:30 p.m. REGISTRATION
5:30 p.m.- COD BUSINESS *Cottonwood*
7:00 p.m. MEETING *Conference Center*
Report of the President
7:00 p.m.- RECEPTION *Cottonwood*
8:30 p.m. *Conference Center*

Tuesday, April 25

THE RELATIONSHIP BETWEEN
FEDERAL & STATE POLICY

8:30 a.m.- SESSION I *Cottonwood*
10:10 a.m. *Conference Center*
Moderator: Julius R. Krevans
8:30 a.m. "The Context: A Review of the Forces at Play"
—Lewis Butler
Professor
Health Policy Unit
Univ. of Calif.-San Francisco
9:00 a.m. "The Problem: A National Perspective"
—Henry Foley
Administrator
Health Resources Administration
9:30 a.m.- Discussion
10:10 a.m.
10:10 a.m.- BREAK
10:20 a.m.
10:20 a.m.- SESSION II *Cottonwood*
12 Noon *Conference Center*
10:20 a.m.- "The Problem: The Articulation of Federal
& State Policies"
10:50 a.m. —Peter Petkas
Director, Project Management
President's Reorganization Project
10:50 a.m.- "A Paradigm: The Implementation of the
11:20 a.m. National Health Planning Act"
—Eugene Rubel
Special Asst. to the Administrator
Health Care Financing Administration
DHEW
11:30 a.m.- Discussion
12 Noon
Noon- UNSCHEDULED
6:00 p.m.
6:00 p.m.- SESSION III *Cottonwood*
7:30 p.m. *Conference Center*
6:00 p.m.- "An Association Perspective on National and
6:30 p.m. State Policy Initiatives"
—David M. Kinzer
President
Massachusetts Hospital Assn.
6:30 p.m. Reprise & Discussion
7:30 p.m.

Wednesday, April 26

TOWARD MORE EFFECTIVE RELATIONSHIPS
WITH STATE GOVERNMENT

8:30 a.m.- SESSION IV *Cottonwood*
10:10 a.m. *Conference Center*
Moderator: Christopher C. Fordham
8:30 a.m.- "Medical Education & Health Care: As I See It"
9:00 a.m. —T. H. Bell
Utah Commissioner for Higher
Education
9:00 a.m.- "A Legislator's View of Medical Education and
9:30 a.m. Health Care"
—John Milton
former State Senator from Minnesota
9:30 a.m.- Discussion
10:10 a.m.
10:10 a.m.- BREAK
10:20 a.m.
10:20 a.m.- SESSION V *Cottonwood*
12 Noon *Conference Center*
10:20 a.m.- "The University of Washington Approach"
10:50 a.m. —John N. Lein
Associate Dean
Continuing Education & Development
10:50 a.m.- "The Independent Colleges and Universities of
11:20 a.m. Missouri Approach"
—Charles Gallagher
Executive Director
Independent Colleges & Universities of
Missouri
Robert Blackburn
Director, Governmental Relations
Washington University
11:20 a.m.- Discussion
12 Noon
12 Noon- UNSCHEDULED
6:00 p.m.
6:00 p.m.- SESSION VI *Cottonwood*
7:30 p.m. *Conference Center*
Moderator: Stuart A. Bondurant
6:00 p.m.- "The Voluntary Cost Containment Program"
6:30 p.m. —Gail L. Warden
Executive Vice President
American Hospital Association
6:30 p.m.- Reprise & Discussion
7:30 p.m.



**association of american
medical colleges**

**AGENDA
FOR
COUNCIL OF DEANS**

SPRING BUSINESS MEETING

**SESSION I
MONDAY, APRIL 24, 1978
5:30 P.M. - 7:00 P.M.**

**SESSION II
THURSDAY, APRIL 27, 1978
8:30 A.M. - 12 NOON**

**COTTONWOOD CONFERENCE CENTER
SNOWBIRD VILLAGE
SNOWBIRD, UTAH**

COUNCIL OF DEANS
SPRING BUSINESS MEETING
Cottonwood Conference Center
Snowbird, Utah

AGENDA

Session I
5:30 - 7:00 p.m., Monday
April 24, 1978

Page

- I. Report of the Executive Council Action on Revising the
AAMC Dues Structure... (Separate Distribution)
Robert G. Petersdorf, M.D.
- II. Report of the President
John A.D. Cooper, M.D.

Session II
8:30 - 12 noon, Thursday
April 27, 1978

- I. Call to Order - Quorum Call
- II. Consideration of Minutes 1
- III. Chairman's Report
- IV. Action Item
 - A. Executive Council Action on Revising the AAMC
Dues Structure
- V. Discussion Items
 - A. Report of Task Force on the Support of Medical
Education
Stuart Bondurant, M.D.
 - B. Report of Task Force on Students Financing
Bernard Nelson, M.D.
 - C. AAMC Biomedical and Behavioral Research Policy 4
Thomas Morgan, M.D.
 - D. Industry-Sponsored Research and Consultation:
Responsibilities of the Institution and the
Individual
Thomas J. Kennedy, M.D.
 - E. NIH Division of Research Grants Workload 9
John F. Sherman, Ph.D.

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F. Criteria for Admissions	16
1. Handicapped Regulations: Development of Technical Standards	
2. Participation of Students from unaccredited schools in NBME, Part I James Eckenhoff, M.D.	
3. Acceptance of Students in Advance Standing Steven C. Beering, M.D.	
G. National Institutes of Health Care Research Thomas J. Kennedy, M.D.	26
VI. Information Items	
A. Southern Deans Resolution	32
B. Management Advancement Program Recent Developments Marjorie P. Wilson, M.D.	
C. Continuing Medical Education Report of the Regional Meetings Discussion Emanuel Suter, M.D.	

ASSOCIATION OF AMERICAN MEDICAL COLLEGES
COUNCIL OF DEANS
ANNUAL BUSINESS MEETING

November 7, 1977
Ballroom East
Washington Hilton Hotel
Washington, D.C.

MINUTES

I. Call to Order

The meeting was called to order at 2:00 p.m. by Julius R. Krevans, M.D., Chairman.

II. Quorum Call

Dr. Krevans announced the presence of a quorum.

III. Consideration of Minutes

The minutes of the April 20, 1977 Spring Business Meeting held at the Scottsdale Hilton Hotel were approved as submitted.

IV. Chairman's Report

Dr. Krevans reported on his experiences during the period of his sabbatical leave at the East Maine Medical Center which have led him to conclude that the schools have reason to be proud of their track record in turning out well prepared physicians. He also described his meetings with small groups of deans. While he concluded that the diversity of problems is matched or exceeded by the diversity of perceived solutions, he was heartened to conclude that the AAMC is that congregation where deans can gather without giving up their freedom to pursue other solutions as individuals or acting as individual institutions.

V. President's Report

Dr. Cooper reported on the recent legislative activity on the health manpower bill and described the Senate action in the final hours of the session to eliminate entirely the requirements for accepting U.S. students studying in foreign schools in advance standing as a condition for the receipt of capitation.

VI. Election of Provisional Institutional Members

The Council endorsed the Executive Council recommendation that the following schools be elected to Provisional Institutional Membership by the AAMC Assembly:

Texas A & M University
College of Medicine

East Carolina University
School of Medicine

Northeastern Ohio Universities
College of Medicine

VII. Election of Distinguished Service Member

The Council endorsed the Executive Council recommendation that Andrew D. Hunt, M.D., be elected to Distinguished Service Membership status by the Assembly.

VIII. Report of the Nominating Committee and Election of Officers.

Dr. John Dennis, chairman of the nominating committee, reported the following recommended slate of officers:

Chairman-Elect of the Council of Deans--
Christopher C. Fordham, III, M.D.,
Dean, University of North Carolina
School of Medicine

Member-at-Large of the Council of Deans--
John E. Chapman, M.D., Dean,
Vanderbilt University School of
Medicine

The Council of Deans elected the proposed slate to the positions indicated.

IX. Discussion Items

A. The Officers' Retreat. The date and time of the annual AAMC officers' retreat was announced and members of the Council were invited to submit items for consideration at this meeting.

B. 1978 Spring Meeting of the Council of Deans.

Dr. Fordham, Chairman of the Planning Committee, reported on the progress of the program planning for the Spring Meeting. It is to be held at Snowbird, Utah, and will address a series of issues concerning the relationship of academic medicine to government, particularly state government.

C. Task Force on Student Financing.

Dr. Nelson discussed the interim report of his task force which appeared in the agenda materials.

D. Task Force on Minority Student Opportunities in Medicine.

Dr. Fordham discussed the interim report of this task force which appeared in the agenda materials.

E. Task Force on Graduate Medical Education.

Dr. Clawson, a member of the task force, reported on the initial meetings of the group.

F. Task Force on the Support of Medical Education.

Dr. Bondurant reported on the initial meeting of the task force and described the process it proposed to follow in completing its work.

X. New Business

The Council was asked to discuss the advisability of the AAMC developing a position statement on the ethics of physicians withholding medical care as a means of achieving political, social or personal objectives. Several members urged that the AAMC adopt such a statement.

XI. Adjournment

The Council meeting adjourned at 3:15 p.m.

AAMC BIOMEDICAL AND BEHAVIORAL RESEARCH POLICY

Background

The AAMC Policy on Biomedical Research, last revised in 1974, has been reviewed in anticipation of impending Congressional action on biomedical research authorities. In September a committee consisting of Drs. Theodore Cooper (representing COD), Charles Sanders (COTH) and CAS representatives Phillip Dodge, Harlyn Halvorson, David Skinner, Samuel Thier, Peter Whybrow and Robert Berne (chairman) drafted a policy statement. The policy statement was extensively discussed on January 18, 1978 at a special meeting of CAS and revised according to suggestions received there, at a subsequent Committee meeting, and during the March, 1978, meetings of the Administrative Boards and Executive Council.

A full discussion of the proposed policy will be available on registration at Snowbird; however, the Task Force proposes now that the following goals and recommendations become AAMC policy for biomedical and behavioral research:

GOAL 1: EMPHASIZE THAT ALL LEVELS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, INCLUDING BASIC, APPLIED, AND TARGETED, ARE NECESSARY.

Recommendation 1: The Federal establishment as the principal provider of research funds should recognize the need to assure stability and an appropriate balance among basic, applied and targeted research.

GOAL 2: TRAIN A SUFFICIENT NUMBER AND DIVERSITY OF SKILLED INVESTIGATORS TO CONDUCT BIOMEDICAL AND BEHAVIORAL RESEARCH.

- Recommendation 2:
- a) The Federal government should renew its commitment to both pre- and post-doctoral training of highly qualified research scientists in the biomedical and behavioral sciences.
 - b) The institutional training grants should be recognized as the most appropriate mechanism to provide initial research experiences in either basic or clinical areas.
 - c) Methods should be found to encourage research training and academic careers by physician scientists.
 - d) The possible impact of the payback requirement on reducing the number of clinical science trainees should be monitored and other alternatives sought.

- e) The Medical Scientist Training Program should be continued and expanded cautiously.
- f) The limitation on the length of time an individual can be supported under NRSA should be extended.

GOAL 3: DEVELOP EFFECTIVE PUBLIC INVOLVEMENT IN THE FORMULATION OF RESEARCH POLICY

Recommendation 3: The biomedical and behavioral research community should encourage efforts to increase public understanding and support of biomedical and behavioral research policy. The advisory council apparatus of the NIH and ADAMHA should be strengthened to assist in this objective. Scientists must assume a responsibility to assist the public in setting realistic goals and time tables for research efforts.

GOAL 4: STRENGTHEN THE MECHANISMS OF REVIEWING AND COORDINATING RESEARCH.

- Recommendation 4:
- a) The Public Health Service Act should be modified to permit confidential, closed panel peer review of grant and contract applications so as to obtain high quality reviews of proposals, to prevent invasion of privacy of the applicants, to safeguard clinical trials, and to protect proprietary interests.
 - b) The scientific community through its representatives in the peer review system must assume responsibility for critical evaluation of all research projects particularly those included in multiproject grants or contracts, so that lower quality research is not funded and funds are allocated to the most promising avenues of research.
 - c) The cause and effect of work load increases and other deleterious influences on the peer-review system should be carefully monitored and appropriate corrective action taken.

GOAL 5: IMPROVE THE STRUCTURE AND FUNCTION OF THE INSTITUTIONS WHICH PERFORM RESEARCH AND THOSE WHICH SUPPORT RESEARCH SO AS TO PROMOTE THE ORDERLY TRANSFER OF RESEARCH FINDINGS TO PATIENT CARE.

- Recommendation 5:
- a) Efforts should be made to strengthen the authority of the Director, NIH by creating a special director's fund.
 - b) The programs of the National Cancer Institute should be placed under the authority of the Director of the National Institutes of Health. The research programs of ADAMHA should be carefully monitored with a view to placing them in NIH should they fail to prosper in ADAMHA.
 - c) The NIH and ADAMHA advisory councils should have a greater role in establishing a balance between research and service activities.
 - d) The advisory councils should be protected from political intervention.
 - e) The Director, NIH, assisted by the advisory council should establish criteria for the initiation and evaluation of centers and other broad programs.
 - f) The support of targeted research through the use of selected clinical trials in appropriate areas and interdisciplinary centers is an appropriate mission of NIH.
 - g) NIH or other Federal agencies should be charged with the development of low-profit technology. NIH should develop demonstration and education strategies and should also support the training of the specialists needed for this mission.
 - h) The research mission of NIH should not be compromised by adding the requirement that it serve as the primary agency for technology transfer.

- i) The AAMC urges increased Federal efforts to stabilize research opportunities through the full reimbursement of research costs (including indirect costs and depreciation expenses) and a renewed commitment to the Biomedical Research Support Grant.
- j) The AAMC recommends funding for the construction and renovation of biomedical and behavioral research facilities, and for the purchase and maintenance of research equipment.
- k) The AAMC recommends that more careful attention be given to the costs and unintended effects that administrative requirements and regulations have on the ability of institutions to perform their research mission. The Federal government should strive toward a goal of minimizing the burdens imposed by regulations.
- l) Medical research and education programs should not be subject to review or control by local HSA's.

GOAL 6: ASSURE ADEQUATE SUPPORT FOR ALL ASPECTS OF THE RESEARCH PROCESS.

- Recommendation 6:
- a) To protect their health and improve management of their illnesses the American people should continue their commitment to biomedical and behavioral research supported from diverse sources. Stable funding should be assured and adjusted annually to reflect research needs and costs and to permit exploitation of new research and development opportunities. The Federal government's primary but not exclusive role in this area is affirmed.
 - b) The AAMC strongly endorses the investigator-initiated project grant as the most appropriate mechanism of support of basic and applied research. Consequently, investigator-initiated projects should have priority over centrally directed funding mechanisms which are more appropriate for clinical trials, research/demonstration centers and other targeted activities. Any erosion of support for investigator-initiated activities, regardless of cause should be immediately remedied.

- c) A vigorous program of high quality research applied to clinical problems should be supported by Federal grants, private philanthropy and by industry.
- d) The transfer of research-proven technology to health care should be the mission of a number of Federal agencies, private organizations and industry. A fund for the support of technology transfer activities should be created and related to the health care budget. It should be administered by an agency responsible to the Assistant Secretary of Health assisted by an advisory council.

WORKLOAD PROBLEMS IN THE DIVISION OF RESEARCH GRANTS
OF THE NATIONAL INSTITUTES OF HEALTH

The attached paper, prepared for the Intersociety Council for Biology and Medicine, sets out some of the problems that Dr. Sherman will discuss with the Council.

DISCUSSION OF WORKLOAD PROBLEMS IN
DIVISION OF RESEARCH GRANTS
NATIONAL INSTITUTES OF HEALTH

Prepared For

Representatives of Intersociety Council for Biology and Medicine

THE PROBLEM

Beginning in about 1969 a remarkable increase in the rate of submission of research grant applications by the scientific community occurred. This rate of increase is continuing. The number of applications submitted has now reached more than twice the level it was in 1969. With no appreciable increase in the number of Study Sections or Study Section members over the same period, the integrity of the peer review system is now under serious threat. The overload on Division of Research Grants' (DRG) Study Sections is steadily diminishing the quality of the scientific review. This discussion sets forth for the Intersociety Council information on the magnitude of the problem, provides some insights into factors contributing to it, and describes our attempts at alleviation.

In 1969 the DRG reviewed 8,227 applications; in 1977 the number reviewed was 17,741, or more than twice as many. The number of personnel in the Division decreased from 425 in 1969 to 392 in 1977, however. Over this same time the number of Study Sections increased only from 48 to 50, and the number of Study Section members grew from about 690 to 789. In sum, while the workload more than doubled over the 8 year period, the number of Study Section members to perform reviews increased only about 15 percent, although it must be acknowledged that the Division has increasingly relied on Special ("ad hoc") Study Sections, and "ad hoc" reviewers. (See Attachment.)

Some Study Sections have been more heavily burdened than others. Those in which the number of applications more than doubled include the following: Applied Physiology and Orthopedics; Biochemistry; Cardiovascular and Pulmonary; Cardiovascular and Renal; Developmental Behavioral Sciences; Epidemiology and Disease Control; Experimental Therapeutics; Genetics; General Medicine B; Neurology B; Neurological Sciences; Pathology A; Pathology B; Radiation; Reproductive Biology; Toxicology; and Special Study Sections.

We have examined certain characteristics of the increased workload to attempt to understand it and to develop appropriate means of alleviating the problem. For example,

- there are no discernible marked changes from 1969 to 1977 in the patterns of rates of submission of applications when we examine the top 50 institutions, the states, or the regions;

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- . the number of amended applications per round has remained relatively constant from 1969, ranging from about nine to twelve percent, although in some Study Sections the rate has exceeded 20 percent;
- . neither the average number of competing grant applications submitted per investigator, nor the average number of grants awarded per principal investigator (PI) has changed dramatically in the years we reviewed (early 1970's on);
- . DRG-reviewed applications have more than doubled for the following BID's from 1969 to 1977: National Eye Institute; National Cancer Institute; National Institute of Environmental Health Sciences; National Heart, Lung, and Blood Institute.

The first three findings are not helpful in explaining the increased workload. The last point, however, is significant.

FACTORS CONTRIBUTING TO WORKLOAD AND QUALITY OF REVIEW

Among the factors that contribute directly or indirectly to workload of DRG staff and of Study Section reviewers are new initiatives for accountability (e.g., Sunshine Laws, Human Subjects Regulations), BID programming efforts in response to Congressional mandates, and trends toward increased targeting. Executive Secretaries of Study Sections and initial reviewers must now be concerned with extensive documentation in the applications and perform detailed reviews against applicable guidelines regarding human subjects, animals, and recombinant DNA. About one-third of all NIH applications involve human subjects. The number of applications involving recombinant DNA received for the January 1978 council round was approximately 100.

For the three council rounds in 1977, there were 47 Requests for Applications (RFA's) and Program Announcements generated by Public Health Service research components (principally NIH) that increased the number of applications for which central referral and, in many cases, review resources in DRG were required.

With increased emphasis in 1979 on "basic" research in this "year of the R01," the workload for DRG will not diminish.

Other strains on the peer review system are creating pressures for DRG staff and reviewers. Under DHEW's interpretation of the Privacy Act of 1974, summary statements may be released to PI's prior to council. Between the June 1977 Study Section meetings and the October 1977 council round, approximately 1280 summary statements were released to PI's. This release resulted in some 77 communications to NIH before council rebutting information or requesting amendment to key documents. Current HEW policy on release of summary statements means that often Executive Secretaries are called for information while they are preparing the summary statements, resulting in use of their already limited time and jeopardizing the

confidentiality of outside opinions and the opinions of individual reviewers. More disruptive than the release of the summary statement will be the consideration of the communications that come to NIH from the PI after receipt of the summary statement and prior to the council meetings. We expect these communications to increase just as requests for summary statements increased once PI's knew of their availability.

The NIH has recently announced to the public the NIH Director's decisions on the recommendations of the Grants Peer Review Study Team. Summary statements with priority scores will be sent routinely to the PI after council. With this announcement, and pending development of internal implementing procedures, NIH plans to request PI's to wait for NIH's automatic transmittal of summary statements after council in lieu of making requests while the peer review process is in progress.

The Intersociety Council could be helpful in informing its members of our request. AAMC staff is also working with us in reviewing legislation and legal decisions on which our current Privacy Act policies are based.

IMPACT OF WORKLOAD

The increased number of applications, the increased documentation required, and other strains on the peer review system have lowered morale of both internal staff and reviewers. Although not easily measured, the potential for lowered quality of review and eroded integrity of the system is an effect of the unprecedented workload. We estimate that 3 workweeks (or 120 hours) of unremunerated detailed study and preparation of reports must be given by each reviewer for each round under optimum conditions. At present, some Study Section reviewers have 20 applications per round for which they are responsible as primary or secondary reviewers. The choices are to ask more of our reviewers; to decrease review time for each application; or to continue to maneuver "ad hoc" reviews--the technical legality of which may be open to question.

The workload increase has taken its toll in a measurable way by increasing the resignation rate of Study Section members. In FY 1974 the percentage resignation was 0.6 percent of total membership; in FY 1975 it increased to 2.6 percent; in FY 1977 it was 3.9 percent, a percentage we estimate will be about the same in FY 1978. Reports are that the same professional societies have advised potential Study Section members about the plight of DRG and has questioned the desirability of Study Section appointment under current workload conditions.

ATTEMPTS AT ALLEVIATION

In June 1977 we began systematically considering ways to reverse the DRG workload trend. We discussed most of the alternatives we considered with a group of 12 Study Section chairmen in November 1977. With little or no possibility of increased personnel ceilings, we have attempted to increase manpower by using expert consultant positions loaned from the National Heart, Lung, and Blood Institute. We also have considered loans from the intramural program, intergovernmental personnel agreements (IPA's), and use of "when actually employed" (WAE) and temporary personnel.

Another approach we have considered is the imposition of limits on:

- . the number of pages in an application;
- . the number of applications submitted per investigator per year;
- . the number of different "activity types" of applications per investigator (e.g., Program Project, Research Career Development)
- . the number of revisions of applications; and
- . most dramatically, the number of applications to be reviewed at a single Study Section round, i.e., the establishment of a "queuing" mechanism.

Although we plan to continue considering the possibility of implementing some of the approaches listed above, we recognize that some of these may be unsatisfactory, either because they will have no real impact on workload; will cause more processing or workload problems than would be solved; or would have an inappropriate effect on the principles on which peer review is conducted and meritorious projects selected.

There are several other actions that may be helpful. These include eliminating waivers of receipt dates for new applications; devising a way to prepare less detailed summary statements; working with the National Science Foundation to find more efficient means of dealing with applications submitted to both agencies.

One hopeful event is a discussion Dr. Fredrickson had with representatives of the Office of the Secretary, HEW, about Flexible Study Sections. HEW officials have indicated a willingness to entertain the concept of this type of Study Section. Our proposal is that about half of the existing Study Sections and all future Study Sections be chartered to include two or more subcommittees in the Study Section. Membership would increase from approximately 18 to 36 reviewers. We see many advantages of the Flexible Study Section concept for NIH. Details of the charters for four Study Sections are now under consideration: Genetics, Radiation, Chemical Pathology, and Reproductive Biology.

CONCLUSION

There are conceptually two approaches to dealing with the workload situation. The first would involve expanding the capacity of the review system in terms of DRG resources and the number of Study Section reviewers. A related approach would be to make adaptation of the system at its current capacity; however, if we are to retain valuable features of the system, the options are distinctly limited. The staff of the NIH are working toward relief along both these avenues, i.e., expanding the capacity and improving the efficiency of the system.

Another means of modifying the current pressure will require a moderation in the rate of influx of applications. We would also hope to decrease

demands from the applicant community and the Federal establishment for services from the system that divert its resources from its primary task of performing quality review of the scientific content of the proposed research. It is in this area we seek understanding and cooperation from the scientific community. We would ask, for example, that the research institutions help in developing a reasonable plan of action, including, for example--

- . requesting principal investigators to wait until after council before requesting information about the recommendations on their applications;
- . screening the applications to assure that they are complete and well-presented;
- . exploring ways to limit applications by other means.

February 22, 1978

(\$ in thousands)

FY1978	FY1979	FY1979	FY1980	FY1980	FY1980
APPROPRIATION	AUTHORIZATION	APPROPRIATION	AUTHORIZATION	PRESIDENT'S	CHF
				BUDGET	RECOMMENDATION

V. HEALTH RESOURCES ADMINISTRATION

A. Health Planning and Resource Development

1. Health planning-p.58

a. HSA grants	107,000	EXPIRED	107,000*	EXPIRED	115,400	115,400**
b. States' grants	29,500	EXPIRED	29,500*	EXPIRED	30,000	30,000**
c. Rate regulation (Hospital cost) Moved to HCFA	2,000	6,000	7/	EXPIRED		0**
d. Planning methods/centers	6,500	OPEN	6,500*	OPEN	0	0
e. Modernization and life safety codes (Sec. 1613 and 1625(a))	8/	8/	8/	8/		
f. Resource development	0	0	0	0	0	
g. Special medical facilities	2,750	EXPIRED				
2. Program support	11,383	OPEN	11,882	OPEN	9,132	9,132

B. Health Manpower

1. Health professions, capitation grants-p.59

a. Medicine, osteopathy, & dentistry (MOD)	120,100	186,777	120,100	15/ 196,470	0	120,100
b. MOD, bonus phase-out	---	---	---	---		
c. Veterinary, optometry, pharmacy & podiatry (includes bonus phase-out)	18,000	33,202	18,000	15/ 33,724	0	18,000
d. Public health	5,900	10,462	5,900	15/ 11,060	0	9,800
e. Startup assistance	2,000	5,000	5,000	12/ 5,000	0	5,000
f. Financial distress	3,000	5,000	5,000	12/ 5,000	5,000	5,000

2. Health teaching facilities

a. Construction grants-p.64	6,500	40,000	0	40,000	0	20,000
b. Interest subsidies	2,000	3,000	3,000	4,300	4,300	4,300

3. Health Fac. Financing

a. Conversion/closure	---	---	---	---	30,000	30,000
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4. Health professions, student assistance-p.61

a. Health professions student loans	20,000	27,000	10,000	28,000	0	28,000
b. Loan repayments	1,500	SSAN	1,500	SSAN	0	1,500
c. National Health Service Corps scholarship	60,000	140,000	75,000	200,000	79,500	100,000
d. Health Professions Scholarships		Program Discontinued-----				
e. Exceptional need scholarships	5,000	17,000	7,000	18,000	0	18,000
f. Shortage area scholarships	0	---	---	---	0	

5. Health professions, special educational assistance-p.62

a. Family medicine/general dentistry residencies	45,000	45,000	45,000	50,000	40,500	47,500
b. Family medicine departments	0	15,000	0	20,000	15,000	15,000
c. Primary care residencies and training (Gen. pediatrics/Internal Med.)	15,000	20,000	17,500	25,000	25,000	25,000
d. Interdisciplinary training (Primary care--special projects)	4,000	15,000	7,141	15,000	6,000	10,000
	--	12/	--	12/	(6,000)	(6,000)
e. Physicians assistants	9,100	30,000	9,100	35,000	9,100	9,100
f. Area health education centers	17,000	30,000	20,000	40,000	5,825	30,000

HEW HANDICAPPED REGULATIONS:
THE DEVELOPMENT OF TECHNICAL STANDARDS

In response to the problem described on the following pages, that consideration of handicapped applicants solely on a case by case basis is no longer permissible, the Executive Council authorized the Chairman to appoint a task force to study and recommend for institutions consideration guidelines on technical standards for schools to use in compliance with HEW regulations on the handicapped.

HEW HANDICAPPED REGULATIONS AND
MEDICAL SCHOOL ADMISSIONS

Final Regulations (see following pages) published by DHEW last June implementing Section 504 of the Rehabilitation Act of 1973 have severe implications for medical school admissions. The law states that no "otherwise qualified handicapped individual" may be excluded from participating in any program receiving federal support solely on the basis of the handicap. Handicaps are defined broadly to include any physical, mental, or emotional impairment. Furthermore, schools are effectively prevented from making any pre-admission inquiries directed at these handicaps.

The regulations state that a qualified handicapped person is one who "meets the academic and technical standards requisite to admission or participation in the recipient's education program or activity." Technical standards, a term not defined in the regulations, seem to encompass all those non-academic capabilities which the school can justify as being absolutely essential in each student in order for that student to complete successfully the medical school curriculum.

For example, if the faculty of an institution determined that no medical student could receive the M.D. degree without being able to distinguish organisms under a microscope or read X-rays, a minimal level of eyesight might be a valid technical standard. If dissection or minimal surgical skills were required of every student prior to graduation, some degree of manual dexterity might be a valid technical standard. More difficult is the problem of how to deal with the applicant who presents a severe emotional disturbance, drug addiction, or other handicap which might not preclude success in medical school but could jeopardize the welfare of patients when the student enters independent practice.

The development of technical standards seems to be essential if medical schools are going to make any justifiable discriminations or even to ask any questions related to these capabilities. Staff contacts with GSA members have revealed a sense of helplessness and a desire simply to avoid confrontation. The staff is currently surveying the schools to see how many have attempted to develop technical standards. No formal efforts have as yet surfaced.

Unless we find that this is well underway in the individual institutions, the staff believes that a national effort at developing benchmark technical standards might be of great assistance to the schools. An AAMC task force could develop a set of standards which the individual schools would be free to accept, modify, or reject, but which would have the weight of a carefully conceived recommendation of an expert panel of nationally-selected medical educators. The task force could also review licensing board requirements and experiences which various schools have had with handicapped students in a way that a single institution would find difficult.

RECOMMENDATION

It is recommended that the AAMC Chairman be authorized to appoint a task force to study and recommend for institutional consideration guidelines on technical standards for schools to use in compliance with the HEW regulations on the handicapped.

Adopted 3/23/78

RULES AND REGULATIONS

any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient, but excluding the ultimate beneficiary of the assistance.

(g) "Applicant for assistance" means one who submits an application, request, or plan required to be approved by a Department official or by a recipient as a condition to becoming a recipient.

(h) "Federal financial assistance" means any grant, loan, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the Department provides or otherwise makes available assistance in the form of:

- (1) Funds;
- (2) Services of Federal personnel; or
- (3) Real and personal property or any interest in or use of such property, including:

(i) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(ii) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government.

(i) "Facility" means all or any portion of buildings, structures, equipment, roads, walks, parking lots, or other real or personal property or interest in such property.

(j). "Handicapped person." (1) "Handicapped persons" means any person who (i) has a physical or mental impairment which substantially limits one or more major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment.

(2) As used in paragraph (j) (1) of this section, the phrase:

(i) "Physical or mental impairment" means (A) any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive, digestive; genito-urinary; hemic and lymphatic; skin; and endocrine; or (B) any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

(ii) "Major life activities" means functions such as: caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(iii) "Has a record of such an impairment" means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(iv) "Is regarded as having an impairment" means (A) has a physical or mental impairment that does not substantially limit major life activities but that is treated by a recipient as constituting such a limitation; (B) has a phy-

sical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or (C) has none of the impairments defined in paragraph (j) (2) (i) of this section but is treated by a recipient as having such an impairment.

(k) "Qualified handicapped person" means:

(1) With respect to employment, a handicapped person who, with reasonable accommodation, can perform the essential functions of the job in question;

(2) With respect to public preschool, elementary, secondary, or adult educational services, a handicapped person (i) of an age during which nonhandicapped persons are provided such services, (ii) of any age during which it is mandatory under state law to provide such services to handicapped persons, or (iii) to whom a state is required to provide a free appropriate public education under § 612 of the Education of the Handicapped Act; and

(3) With respect to postsecondary and vocational education services, a handicapped person who meets the academic and technical standards requisite to admission or participation in the recipient's education program or activity;

(4) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

(l) "Handicap" means any condition or characteristic that renders a person a handicapped person as defined in paragraph (j) of this section.

Subpart A—General Provisions

§ 84.1 Purpose.

The purpose of this part is to effectuate section 504 of the Rehabilitation Act of 1973, which is designed to eliminate discrimination on the basis of handicap in any program or activity receiving Federal financial assistance.

§ 84.2 Application.

This part applies to each recipient of Federal financial assistance from the Department of Health, Education, and Welfare and to each program or activity that receives or benefits from such assistance.

§ 84.3 Definitions.

As used in this part, the term:

(a) "The Act" means the Rehabilitation Act of 1973, Pub. L. 93-112, as amended by the Rehabilitation Act Amendments of 1974, Public Law 93-516, 29 U.S.C. 794.

(b) "Section 504" means section 504 of the Act.

(c) "Education of the Handicapped Act" means that statute as amended by the Education for all Handicapped Children Act of 1975, Pub. L. 94-142, 20 U.S.C. 1401 et seq.

(d) "Department" means the Department of Health, Education, and Welfare.

(e) "Director" means the Director of the Office for Civil Rights of the Department.

(f) "Recipient" means any state or its political subdivision, any instrumentality of a state or its political subdivision,

§ 84.4 Discrimination prohibited.

(a) *General.* No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives or benefits from Federal financial assistance.

(b) *Discriminatory actions prohibited.* (1) A recipient, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person

by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipients program;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

(2) For purposes of this part, aids, benefits, and services, to be equally effective, are not required to produce the identical result or level of achievement for handicapped and nonhandicapped persons, but must afford handicapped persons equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement, in the most integrated setting appropriate to the person's needs.

(3) Despite the existence of separate or different programs or activities provided in accordance with this part, a recipient may not deny a qualified handicapped person the opportunity to participate in such programs or activities that are not separate or different.

(4) A recipient may not, directly or through contractual or other arrangements, utilize criteria or methods of administration (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program with respect to handicapped persons, or (iii) that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same State.

(5) In determining the site or location of a facility, an applicant for assistance or a recipient may not make selections (i) that have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives or benefits from Federal financial assistance or (ii) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to handicapped persons.

(6) As used in this section, the aid, benefit, or service provided under a program or activity receiving or benefiting from Federal financial assistance includes any aid, benefit, or service provided in or through a facility that has been constructed, expanded, altered, leased or rented, or otherwise acquired, in whole or in part, with Federal financial assistance.

(c) *Programs limited by Federal law.* The exclusion of nonhandicapped persons from the benefits of a program limited by Federal statute or executive order to handicapped persons or the exclusion of a specific class of handicapped persons

from a program limited by Federal statute or executive order to a different class of handicapped persons is not prohibited by this part.

§ 84.5 Assurances required.

(a) *Assurances.* An applicant for Federal financial assistance for a program or activity to which this part applies shall submit an assurance, on a form specified by the Director, that the program will be operated in compliance with this part. An applicant may incorporate these assurances by reference in subsequent applications to the Department.

(b) *Duration of obligation.* (1) In the case of Federal financial assistance extended in the form of real property or to provide real property or structures on the property, the assurance will obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for the purpose for which Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) In the case of Federal financial assistance extended to provide personal property, the assurance will obligate the recipient for the period during which it retains ownership or possession of the property.

(3) In all other cases the assurance will obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Covenants.* (1) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the instrument effecting or recording this transfer shall contain a covenant running with the land to assure nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) Where no transfer of property is involved but property is purchased or improved with Federal financial assistance, the recipient shall agree to include the covenant described in paragraph (b) (2) of this section in the instrument effecting or recording any subsequent transfer of the property.

(3) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the covenant shall also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant. If a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on the property for the purposes for which the property was transferred, the Director may, upon request of the transferee and if necessary to accomplish such financing and upon such conditions as he or she deems appropriate, agree to

forbear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective.

§ 84.6 Remedial action, voluntary action, and self-evaluation.

(a) *Remedial action.* (1) If the Director finds that a recipient has discriminated against persons on the basis of handicap in violation of section 504 or this part, the recipient shall take such remedial action as the Director deems necessary to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against persons on the basis of handicap in violation of section 504 or this part and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both recipients to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of section 504 or this part, require a recipient to take remedial action (i) with respect to handicapped persons who are no longer participants in the recipient's program but who were participants in the program when such discrimination occurred or (ii) with respect to handicapped persons who would have been participants in the program had the discrimination not occurred.

(b) *Voluntary action.* A recipient may take steps, in addition to any action that is required by this part, to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity by qualified handicapped persons.

(c) *Self-evaluation.* (1) A recipient shall, within one year of the effective date of this part:

(i) Evaluate, with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons, its current policies and practices and the effects thereof that do not or may not meet the requirements of this part;

(ii) Modify, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, any policies and practices that do not meet the requirements of this part; and

(iii) Take, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, appropriate remedial steps to eliminate the effects of any discrimination that resulted from adherence to these policies and practices.

(2) A recipient that employs fifteen or more persons shall, for at least three years following completion of the evaluation required under paragraph (c) (1) of this section, maintain on file, make available for public inspection, and provide to the Director upon request: (i) a list of the interested persons consulted, (ii) a description of areas examined and any problems identified, and (iii) a description of any modifications made and of any remedial steps taken.

§ 84.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A recipient that employs fifteen or more persons shall designate at least one person to coordinate its efforts to comply with this part.

(b) *Adoption of grievance procedures.* A recipient that employs fifteen or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of complaints alleging any action prohibited by this part. Such procedures need not be established with respect to complaints from applicants for employment or from applicants for admission to postsecondary educational institutions.

§ 84.8 Notice.

(a) A recipient that employs fifteen or more persons shall take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of handicap in violation of section 504 and this part. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs and activities. The notification shall also include an identification of the responsible employee designated pursuant to § 84.7(a). A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this part. Methods of initial and continuing notification may include the posting of notices, publication in newspapers and magazines, placement of notices in recipients' publication, and distribution of memoranda or other written communications.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

§ 84.9 Administrative requirements for small recipients.

The Director may require any recipient with fewer than fifteen employees, or any class of such recipients, to comply with §§ 84.7 and 84.8, in whole or in part, when the Director finds a violation of this part or finds that such compliance will not significantly impair the ability of the recipient or class of recipients to provide benefits or services.

§ 84.10 Effect of state or local law or other requirements and effect of employment opportunities.

(a) The obligation to comply with this part is not obviated or alleviated by the existence of any state or local law or other requirement that, on the basis of handicap, imposes prohibitions or limits upon the eligibility of qualified handicapped persons to receive services or to practice any occupation or profession.

(b) The obligation to comply with this part is not obviated or alleviated because employment opportunities in any occupation or profession are or may be more limited for handicapped persons than for nonhandicapped persons.

Subpart B—Employment Practices

§ 84.11 Discrimination prohibited.

(a) *General.* (1) No qualified handicapped person shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity to which this part applies.

(2) A recipient that receives assistance under the Education of the Handicapped Act shall take positive steps to employ and advance in employment qualified handicapped persons in programs assisted under that Act.

(3) A recipient shall make all decisions concerning employment under any program or activity to which this part applies in a manner which ensures that discrimination on the basis of handicap does not occur and may not limit, segregate, or classify applicants or employees in any way that adversely affects their opportunities or status because of handicap.

(4) A recipient may not participate in a contractual or other relationship that has the effect of subjecting qualified handicapped applicants or employees to discrimination prohibited by this subpart. The relationships referred to in this subparagraph include relationships with employment and referral agencies, with labor unions, with organizations providing or administering fringe benefits to employees of the recipient, and with organizations providing training and apprenticeship programs.

(b) *Specific activities.* The provisions of this subpart apply to:

(1) Recruitment, advertising, and the processing of applications for employment;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, lay-off, termination, right of return from lay-off, and rehiring;

(3) Rates of pay or any other form of compensation and changes in compensation;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of progression, and seniority lists;

(5) Leaves of absence, sick leave, or any other leave;

(6) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(8) Employer sponsored activities, including social or recreational programs; and

(9) Any other term, condition, or privilege of employment.

(c) A recipient's obligation to comply with this subpart is not affected by any inconsistent term of any collective bargaining agreement to which it is a party.

§ 84.12 Reasonable accommodation.

(a) A recipient shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program.

(b) Reasonable accommodation may include: (1) making facilities used by employees readily accessible to and usable by handicapped persons, and (2) job restructuring, part-time or modified work schedules, acquisition or modification of equipment or devices, the provision of readers or interpreters, and other similar actions.

(c) In determining pursuant to paragraph (a) of this section whether an accommodation would impose an undue hardship on the operation of a recipient's program, factors to be considered include:

(1) The overall size of the recipient's program with respect to number of employees, number and type of facilities, and size of budget;

(2) The type of the recipient's operation, including the composition and structure of the recipient's workforce; and

(3) The nature and cost of the accommodation needed.

(d) A recipient may not deny any employment opportunity to a qualified handicapped employee or applicant if the basis for the denial is the need to make reasonable accommodation to the physical or mental limitations of the employee or applicant.

§ 84.13 Employment criteria.

(a) A recipient may not make use of any employment test or other selection criterion that screens out or tends to screen out handicapped persons or any class of handicapped persons unless: (1) the test score or other selection criterion, as used by the recipient, is shown to be job-related for the position in question, and (2) alternative job-related tests or criteria that do not screen out or tend to screen out as many handicapped persons are not shown by the Director to be available.

(b) A recipient shall select and administer tests concerning employment so as best to ensure that, when administered to an applicant or employee who has a handicap that impairs sensory, manual, or speaking skills, the test results accu-

ately reflect the applicant's or employee's job skills, aptitude, or whatever other factor the test purports to measure, rather than reflecting the applicant's or employee's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

§ 84.14 Preemployment inquiries.

(a) Except as provided in paragraphs (b) and (c) of this section, a recipient may not conduct a preemployment medical examination or may not make preemployment inquiry of an applicant as to whether the applicant is a handicapped person or as to the nature or severity of a handicap. A recipient may, however, make preemployment inquiry into an applicant's ability to perform job-related functions.

(b) When a recipient is taking remedial action to correct the effects of past discrimination pursuant to § 84.6 (a), when a recipient is taking voluntary action to overcome the effects of conditions that resulted in limited participation in its federally assisted program or activity pursuant to § 84.6 (b), or when a recipient is taking affirmative action pursuant to section 503 of the Act, the recipient may invite applicants for employment to indicate whether and to what extent they are handicapped, *Provided, That:*

(1) The recipient states clearly on any written questionnaire used for this purpose or makes clear orally if no written questionnaire is used that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary or affirmative action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis, that it will be kept confidential as provided in paragraph (d) of this section, that refusal to provide it will not subject the applicant or employee to any adverse treatment, and that it will be used only in accordance with this part.

(c) Nothing in this section shall prohibit a recipient from conditioning an offer of employment on the results of a medical examination conducted prior to the employee's entrance on duty, *Provided, That:* (1) All entering employees are subjected to such an examination regardless of handicap, and (2) the results of such an examination are used only in accordance with the requirements of this part.

(d) Information obtained in accordance with this section as to the medical condition or history of the applicant shall be collected and maintained on separate forms that shall be accorded confidentiality as medical records, except that:

(1) Supervisors and managers may be informed regarding restrictions on the work or duties of handicapped persons and regarding necessary accommodations;

(2) First aid and safety personnel may be informed, where appropriate, if the condition might require emergency treatment; and

(3) Government officials investigating compliance with the Act shall be provided relevant information upon request.

§§ 84.15—84.20 [Reserved]

Subpart C—Program Accessibility

§ 84.21 Discrimination prohibited.

No qualified handicapped person shall, because a recipient's facilities are inaccessible to or unusable by handicapped persons, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity to which this part applies.

§ 84.22 Existing facilities.

(a) *Program accessibility.* A recipient shall operate each program or activity to which this part applies so that the program or activity, when viewed in its entirety, is readily accessible to handicapped persons. This paragraph does not require a recipient to make each of its existing facilities or every part of a facility accessible to and usable by handicapped persons.

(b) *Methods.* A recipient may comply with the requirement of paragraph (a) of this section through such means as redesign of equipment, reassignment of classes or other services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of health, welfare, or other social services at alternate accessible sites, alteration of existing facilities and construction of new facilities in conformance with the requirements of § 84.23, or any other methods that result in making its program or activity accessible to handicapped persons. A recipient is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with paragraph (a) of this section. In choosing among available methods for meeting the requirement of paragraph (a) of this section, a recipient shall give priority to those methods that offer programs and activities to handicapped persons in the most integrated setting appropriate.

(c) *Small health, welfare, or other social service providers.* If a recipient with fewer than fifteen employees that provides health, welfare, or other social services finds, after consultation with a handicapped person seeking its services, that there is no method of complying with paragraph (a) of this section other than making a significant alteration in its existing facilities, the recipient may, as an alternative, refer the handicapped person to other providers of those services that are accessible.

(d) *Time period.* A recipient shall comply with the requirement of paragraph (a) of this section within sixty days of the effective date of this part except that where structural changes in facilities are necessary, such changes shall be made within three years of the effective date of this part, but in any event as expeditiously as possible.

(e) *Transition plan.* In the event that structural changes to facilities are necessary to meet the requirement of paragraph (a) of this section, a recipient

shall develop, within six months of the effective date of this part, a transition plan setting forth the steps necessary to complete such changes. The plan shall be developed with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons. A copy of the transition plan shall be made available for public inspection. The plan shall, at a minimum:

(1) Identify physical obstacles in the recipient's facilities that limit the accessibility of its program or activity to handicapped persons;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve full program accessibility and, if the time period of the transition plan is longer than one year, identify steps that will be taken during each year of the transition period; and

(4) Indicate the person responsible for implementation of the plan.

(f) *Notice.* The recipient shall adopt and implement procedures to ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of services, activities, and facilities that are accessible to and usable by handicapped persons.

§ 84.23 New construction.

(a) *Design and construction.* Each facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such manner that the facility or part of the facility is readily accessible to and usable by handicapped persons, if the construction was commenced after the effective date of this part.

(b) *Alteration.* Each facility or part of a facility which is altered by, on behalf of, or for the use of a recipient after the effective date of this part in a manner that affects or could affect the usability of the facility or part of the facility shall, to the maximum extent feasible, be altered in such manner that the altered portion of the facility is readily accessible to and usable by handicapped persons.

(c) *American National Standards Institute accessibility standards.* Design construction, or alteration of facilities in conformance with the "American National Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped," published by the American National Standards Institute, Inc. (ANSI A117.1-1961 (R1971)),¹ which is incorporated by reference, in this part, shall constitute compliance with paragraphs (a) and (b) of this section. Departures from particular requirements of those standards by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility or part of the facility is thereby provided.

¹ Copies obtainable from American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018.

§§ 84.24-84.30 [Reserved]

Subpart D—Preschool, Elementary, and Secondary Education

§ 84.31 Application of this subpart.

Subpart D applies to preschool, elementary, secondary, and adult education programs and activities that receive or benefit from federal financial assistance and to recipients that operate, or that receive or benefit from federal financial assistance for the operation of, such programs or activities.

§ 84.32 Location and notification.

A recipient that operates a public elementary or secondary education program shall annually:

- (a) Undertake to identify and locate every qualified handicapped person residing in the recipient's jurisdiction who is not receiving a public education; and
- (b) Take appropriate steps to notify handicapped persons and their parents or guardians of the recipient's duty under this subpart.

§ 84.33 Free appropriate public education.

(a) *General.* A recipient that operates a public elementary or secondary education program shall provide a free appropriate public education to each qualified handicapped person who is in the recipient's jurisdiction, regardless of the nature or severity of the person's handicap.

(b) *Appropriate education.* (1) For the purpose of this subpart, the provision of an appropriate education is the provision of regular or special education and related aids and services that (i) are designed to meet individual educational needs of handicapped persons as adequately as the needs of nonhandicapped persons are met and (ii) are based upon adherence to procedures that satisfy the requirements of §§ 84.34, 84.35, and 84.36.

(2) Implementation of an individualized education program developed in accordance with the Education of the Handicapped Act is one means of meeting the standard established in paragraph (b) (1) (i) of this section.

(3) A recipient may place a handicapped person in or refer such person to a program other than the one that it operates as its means of carrying out the requirements of this subpart. If so, the recipient remains responsible for ensuring that the requirements of this subpart are met with respect to any handicapped person so placed or referred.

(c) *Free education.*—(1) *General.* For the purpose of this section, the provision of a free education is the provision of educational and related services without cost to the handicapped person or to his or her parents or guardian, except for those fees that are imposed on nonhandicapped persons or their parents or guardian. It may consist either of the provision of free services or, if a recipient places a handicapped person in or refers such person to a program not operated by the recipient as its means of carrying out the requirements of this subpart, of payment for the costs of the program. Funds available from any pub-

lic or private agency may be used to meet the requirements of this subpart. Nothing in this section shall be construed to relieve an insurer or similar third party from an otherwise valid obligation to provide or pay for services provided to a handicapped person.

(2) *Transportation.* If a recipient places a handicapped person in or refers such person to a program not operated by the recipient as its means of carrying out the requirements of this subpart, the recipient shall ensure that adequate transportation to and from the program is provided at no greater cost than would be incurred by the person or his or her parents or guardian if the person were placed in the program operated by the recipient.

(3) *Residential placement.* If placement in a public or private residential program is necessary to provide a free appropriate public education to a handicapped person because of his or her handicap, the program, including non-medical care and room and board, shall be provided at no cost to the person or his or her parents or guardian.

(4) *Placement of handicapped persons by parents.* If a recipient has made available, in conformance with the requirements of this section and § 84.34, a free appropriate public education to a handicapped person and the person's parents or guardian choose to place the person in a private school, the recipient is not required to pay for the person's education in the private school. Disagreements between a parent or guardian and a recipient regarding whether the recipient has made such a program available or otherwise regarding the question of financial responsibility are subject to the due process procedures of § 84.36.

(d) *Compliance.* A recipient may not exclude any qualified handicapped person from a public elementary or secondary education after the effective date of this part. A recipient that is not, on the effective date of this regulation, in full compliance with the other requirements of the preceding paragraphs of this section shall meet such requirements at the earliest practicable time and in no event later than September 1, 1978.

§ 84.34 Educational setting.

(a) *Academic setting.* A recipient to which this subpart applies shall educate, or shall provide for the education of, each qualified handicapped person in its jurisdiction with persons who are not handicapped to the maximum extent appropriate to the needs of the handicapped person. A recipient shall place a handicapped person in the regular educational environment operated by the recipient unless it is demonstrated by the recipient that the education of the person in the regular environment with the use of supplementary aids and services cannot be achieved satisfactorily. Whenever a recipient places a person in a setting other than the regular educational environment pursuant to this paragraph, it shall take into account the

proximity of the alternate setting to the person's home.

(b) *Nonacademic settings.* In providing or arranging for the provision of nonacademic and extracurricular services and activities, including meals, recess periods, and the services and activities set forth in § 84.37(a) (2), a recipient shall ensure that handicapped persons participate with nonhandicapped persons in such activities and services to the maximum extent appropriate to the needs of the handicapped person in question.

(c) *Comparable facilities.* If a recipient, in compliance with paragraph (a) of this section, operates a facility that is identifiable as being for handicapped persons, the recipient shall ensure that the facility and the services and activities provided therein are comparable to the other facilities, services, and activities of the recipient.

§ 84.35 Evaluation and placement.

(a) *Preplacement evaluation.* A recipient that operates a public elementary or secondary education program shall conduct an evaluation in accordance with the requirements of paragraph (b) of this section of any person who, because of handicap, needs or is believed to need special education or related services before taking any action with respect to the initial placement of the person in a regular or special education program and any subsequent significant change in placement.

(b) *Evaluation procedures.* A recipient to which this subpart applies shall establish standards and procedures for the evaluation and placement of persons who, because of handicap, need or are believed to need special education or related services which ensure that:

(1) Tests and other evaluation materials have been validated for the specific purpose for which they are used and are administered by trained personnel in conformance with the instructions provided by their producer;

(2) Tests and other evaluation materials include those tailored to assess specific areas of educational need and not merely those which are designed to provide a single general intelligence quotient; and

(3) Tests are selected and administered so as best to ensure that, when a test is administered to a student with impaired sensory, manual, or speaking skills, the test results accurately reflect the student's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

(c) *Placement procedures.* In interpreting evaluation data and in making placement decisions, a recipient shall (1) draw upon information from a variety of sources, including aptitude and achievement tests, teacher recommendations, physical condition, social or cultural background, and adaptive behavior, (2) establish procedures to ensure that information obtained from all such

sources is documented and carefully considered, (3) ensure that the placement decision is made by a group of persons, including persons knowledgeable about the child, the meaning of the evaluation data, and the placement options, and (4) ensure that the placement decision is made in conformity with § 84.34.

(d) *Reevaluation.* A recipient to which this section applies shall establish procedures, in accordance with paragraph (b) of this section, for periodic reevaluation of students who have been provided special education and related services. A reevaluation procedure consistent with the Education for the Handicapped Act is one means of meeting this requirement.

§ 84.36 Procedural safeguards.

A recipient that operates a public elementary or secondary education program shall establish and implement, with respect to actions regarding the identification, evaluation, or educational placement of persons who, because of handicap, need or are believed to need special instruction or related services, a system of procedural safeguards that includes notice, an opportunity for the parents or guardian of the person to examine relevant records, an impartial hearing with opportunity for participation by the person's parents or guardian and representation by counsel, and a review procedure. Compliance with the procedural safeguards of section 618 of the Education of the Handicapped Act is one means of meeting this requirement.

§ 84.37 Nonacademic services.

(a) *General.* (1) A recipient to which this subpart applies shall provide non-academic and extracurricular services and activities in such manner as is necessary to afford handicapped students an equal opportunity for participation in such services and activities.

(2) Nonacademic and extracurricular services and activities may include counseling services, physical recreational athletics, transportation, health services, recreational activities, special interest groups or clubs sponsored by the recipient, referrals to agencies which provide assistance to handicapped persons, and employment of students, including both employment by the recipient and assistance in making a available outside employment.

(b) *Counseling services.* A recipient to which this subpart applies that provides personal, academic, or vocational counseling, guidance, or placement services to its students shall provide these services without discrimination on the basis of handicap. The recipient shall ensure that qualified handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students with similar interests and abilities.

(c) *Physical education and athletics.* (1) In providing physical education courses and athletics and similar programs and activities to any of its students, a recipient to which this subpart applies may not discriminate on the basis of handicap. A recipient that offers physical education courses or that operates

or sponsors interscholastic, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation in these activities.

(2) A recipient may offer to handicapped students physical education and athletic activities that are separate or different from those offered to nonhandicapped students only if separation or differentiation is consistent with the requirements of § 84.34 and only if no qualified handicapped student is denied the opportunity to compete for teams or to participate in courses that are not separate or different.

§ 84.38 Preschool and adult education programs.

A recipient to which this subpart applies that operates a preschool education or day care program or activity or an adult education program or activity may not, on the basis of handicap, exclude qualified handicapped persons from the program or activity and shall take into account the needs of such persons in determining the aid, benefits, or services to be provided under the program or activity.

§ 84.39 Private education programs.

(a) A recipient that operates a private elementary or secondary education program may not, on the basis of handicap, exclude a qualified handicapped person from such program if the person can, with minor adjustments, be provided an appropriate education, as defined in § 84.33(b)(1), within the recipient's program.

(b) A recipient to which this section applies may not charge more for the provision of an appropriate education to handicapped persons than to nonhandicapped persons except to the extent that any additional charge is justified by a substantial increase in cost to the recipient.

(c) A recipient to which this section applies that operates special education programs shall operate such programs in accordance with the provisions of §§ 84.35 and 84.36. Each recipient to which this section applies is subject to the provisions of §§ 84.34, 84.37, and 84.38.

§ 84.40 [Reserved]

Subpart E—Postsecondary Education

§ 84.41 Application of this subpart.

Subpart E applies to postsecondary education programs and activities, including postsecondary vocational education programs and activities, that receive or benefit from federal financial assistance and to recipients that operate, or that receive or benefit from federal financial assistance for the operation of, such programs or activities.

§ 84.42 Admissions and recruitment. *

(a) *General.* Qualified handicapped persons may not, on the basis of handicap, be denied admission or be subjected to discrimination in admission or recruitment by a recipient to which this subpart applies. *

(b) *Admissions.* In administering its admission policies, a recipient to which this subpart applies:

(1) May not apply limitations upon the number or proportion of handicapped persons who may be admitted;

(2) May not make use of any test or criterion for admission that has a disproportionate, adverse effect on handicapped persons or any class of handicapped persons unless (i) the test or criterion, as used by the recipient, has been validated as a predictor of success in the education program or activity in question and (ii) alternate tests or criteria that have a less disproportionate, adverse effect are not shown by the Director to be available;

(3) Shall assure itself that (i) admissions tests are selected and administered so as best to ensure that, when a test is administered to an applicant who has a handicap that impairs sensory, manual, or speaking skills, the test results accurately reflect the applicant's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the applicant's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure); (ii) admissions tests that are designed for persons with impaired sensory, manual, or speaking skills are offered as often and in as timely a manner as are other admissions tests; and (iii) admissions tests are administered in facilities that, on the whole, are accessible to handicapped persons; and

(4) Except as provided in paragraph (c) of this section, may not make preadmission inquiry as to whether an applicant for admission is a handicapped person but, after admission, may make inquiries on a confidential basis as to handicaps that may require accommodation. *

(c) *Preadmission inquiry exception.* When a recipient is taking remedial action to correct the effects of past discrimination pursuant to § 84.6(a) or when a recipient is taking voluntary action to overcome the effects of conditions that resulted in limited participation in its federally assisted program or activity pursuant to § 84.6(b), the recipient may invite applicants for admission to indicate whether and to what extent they are handicapped, *Provided, That:*

(1) The recipient states clearly on any written questionnaire used for this purpose or makes clear orally if no written questionnaire is used that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis, that it will be kept confidential, that refusal to provide it will not subject the applicant to any adverse treatment, and that it will be used only in accordance with this part.

(d) *Validity studies.* For the purpose of paragraph (b) (2) of this section, a recipient may base prediction equations on first year grades, but shall conduct peri-

odic validity studies against the criterion of overall success in the education program or activity in question in order to monitor the general validity of the test scores.

§ 84.43 Treatment of students; general.

(a) No qualified handicapped student shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any academic, research, occupational training, housing, health, insurance, counseling, financial aid, physical education, athletics, recreation, transportation, other extra-curricular, or other postsecondary education program or activity to which this subpart applies.

(b) A recipient to which this subpart applies that considers participation by students in education programs or activities not operated wholly by the recipient as part of, or equivalent to, an education program or activity operated by the recipient shall assure itself that the other education program or activity, as a whole, provides an equal opportunity for the participation of qualified handicapped persons.

(c) A recipient to which this subpart applies may not, on the basis of handicap, exclude any qualified handicapped student from any course, course of study, or other part of its education program or activity.

(d) A recipient to which this subpart applies shall operate its programs and activities in the most integrated setting appropriate.

§ 84.44 Academic adjustments.

(a) *Academic requirements.* A recipient to which this subpart applies shall make such modifications to its academic requirements as are necessary to ensure that such requirements do not discriminate or have the effect of discriminating, on the basis of handicap, against a qualified handicapped applicant or student. Academic requirements that the recipient can demonstrate are essential to the program of instruction being pursued by such student or to any directly related licensing requirement will not be regarded as discriminatory within the meaning of this section. Modifications may include changes in the length of time permitted for the completion of degree requirements, substitution of specific courses required for the completion of degree requirements, and adaptation of the manner in which specific courses are conducted.

(b) *Other rules.* A recipient to which this subpart applies may not impose upon handicapped students other rules, such as the prohibition of tape recorders in classrooms or of dog guides in campus buildings, that have the effect of limiting the participation of handicapped students in the recipient's education program or activity.

(c) *Course examinations.* In its course examinations or other procedures for evaluating students' academic achievement in its program, a recipient to which this subpart applies shall provide such methods for evaluating the achievement of students who have a handicap that

impairs sensory, manual, or speaking skills as will best ensure that the results of the evaluation represents the student's achievement in the course, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where such skills are the factors that the test purports to measure).

(d) *Auxiliary aids.* (1) A recipient to which this subpart applies shall take such steps as are necessary to ensure that no handicapped student is denied the benefits of, excluded from participation in, or otherwise subjected to discrimination under the education program or activity operated by the recipient because of the absence of educational auxiliary aids for students with impaired sensory, manual, or speaking skills.

(2) Auxiliary aids may include taped texts, interpreters or other effective methods of making orally delivered materials available to students with hearing impairments, readers in libraries for students with visual impairments, classroom equipment adapted for use by students with manual impairments, and other similar services and actions. Recipients need not provide attendants, individually prescribed devices, readers for personal use or study, or other devices or services of a personal nature.

§ 84.45 Housing.

(a) *Housing provided by the recipient.* A recipient that provides housing to its nonhandicapped students shall provide comparable, convenient, and accessible housing to handicapped students at the same cost as to others. At the end of the transition period provided for in Subpart C, such housing shall be available in sufficient quantity and variety so that the scope of handicapped students' choice of living accommodations is, as a whole, comparable to that of nonhandicapped students.

(b) *Other housing.* A recipient that assists any agency, organization, or person in making housing available to any of its students shall take such action as may be necessary to assure itself that such housing is, as a whole, made available in a manner that does not result in discrimination on the basis of handicap.

§ 84.46 Financial and employment assistance to students.

(a) *Provision of financial assistance.*

(1) In providing financial assistance to qualified handicapped persons, a recipient to which this subpart applies may not (i), on the basis of handicap, provide less assistance than is provided to nonhandicapped persons, limit eligibility for assistance, or otherwise discriminate or (ii) assist any entity or person that provides assistance to any of the recipient's students in a manner that discriminates against qualified handicapped persons on the basis of handicap.

(2) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established under wills, trusts, bequests, or similar legal instruments that require awards to be made on the basis of factors that discriminate or have the effect of discriminating on the basis of handicap only if the overall

effect of the award of scholarships, fellowships, and other forms of financial assistance is not discriminatory on the basis of handicap.

(b) *Assistance in making available outside employment.* A recipient that assists any agency, organization, or person in providing employment opportunities to any of its students shall assure itself that such employment opportunities, as a whole, are made available in a manner that would not violate Subpart B if they were provided by the recipient.

(c) *Employment of students by recipients.* A recipient that employs any of its students may not do so in a manner that violates Subpart B.

§ 84.47 Nonacademic services.

(a) *Physical education and athletics.*

(1) In providing physical education courses and athletics and similar programs and activities to any of its students, a recipient to which this subpart applies may not discriminate on the basis of handicap. A recipient that offers physical education courses or that operates or sponsors intercollegiate, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation in these activities.

(2) A recipient may offer to handicapped students physical education and athletic activities that are separate or different only if separation or differentiation is consistent with the requirements of § 84.43(d) and only if no qualified handicapped student is denied the opportunity to compete for teams or to participate in courses that are not separate or different.

(b) *Counseling and placement services.*

A recipient to which this subpart applies that provides personal, academic, or vocational counseling, guidance, or placement services to its students shall provide these services without discrimination on the basis of handicap. The recipient shall ensure that qualified handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students with similar interests and abilities. This requirement does not preclude a recipient from providing factual information about licensing and certification requirements that may present obstacles to handicapped persons in their pursuit of particular careers.

(c) *Social organizations.* A recipient that provides significant assistance to fraternities, sororities, or similar organizations shall assure itself that the membership practices of such organizations do not permit discrimination otherwise prohibited by this subpart.

§§ 84.48—84.50. [Reserved]

Subpart F—Health, Welfare, and Social Services

§ 84.51 Application of this subpart.

Subpart F applies to health, welfare, and other social service programs and activities that receive or benefit from federal financial assistance and to recipients that operate, or that receive or benefit from federal financial assistance for the operation of, such programs or activities.

§ 84.52 Health, welfare, and other social services.

(a) *General.* In providing health, welfare, or other social services or benefits, a recipient may not, on the basis of handicap:

- (1) Deny a qualified handicapped person these benefits or services;
- (2) Afford a qualified handicapped person an opportunity to receive benefits or services that is not equal to that offered nonhandicapped persons;
- (3) Provide a qualified handicapped person with benefits or services that are not as effective (as defined in § 84.4(b)) as the benefits or services provided to others;
- (4) Provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified handicapped persons; or
- (5) Provide different or separate benefits or services to handicapped persons except where necessary to provide qualified handicapped persons with benefits and services that are as effective as those provided to others.

(b) *Notice.* A recipient that provides notice concerning benefits or services or written material concerning waivers of rights or consent to treatment shall take such steps as are necessary to ensure that qualified handicapped persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their handicap.

(c) *Emergency treatment for the hearing impaired.* A recipient hospital that provides health services or benefits shall establish a procedure for effective communication with persons with impaired hearing for the purpose of providing emergency health care.

(d) *Auxiliary aids.* (1) A recipient to which this subpart applies that employs fifteen or more persons shall provide appropriate auxiliary aids to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(2) The Director may require recipients with fewer than fifteen employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services.

(3) For the purpose of this paragraph, auxiliary aids may include brailled and taped material, interpreters, and other aids for persons with impaired hearing or vision.

§ 84.53 Drug and alcohol addicts.

A recipient to which this subpart applies that operates a general hospital or outpatient facility may not discriminate in admission or treatment against a drug or alcohol abuser or alcoholic who is suffering from a medical condition, because of the person's drug or alcohol abuse or alcoholism.

§ 84.51 Education of institutionalized persons.

A recipient to which this subpart applies and that operates or supervises a program or activity for persons who are

institutionalized because of handicap shall ensure that each qualified handicapped person, as defined in § 84.3(k)(2), in its program or activity is provided an appropriate education, as defined in § 84.33(b). Nothing in this section shall be interpreted as altering in any way the obligations of recipients under Subpart D.

§§ 84.55-84.60 [Reserved]

Subpart G—Procedures

§ 84.61 Procedures.

Norm: Incorporation by reference provisions approved by the Director of the Federal Register, May 27, 1976. Incorporated documents are on file at the Office of the Federal Register.

The procedural provisions applicable to title VI of the Civil Rights Act of 1964 apply to this part. These procedures are found in §§ 80.6-80.10 and Part 81 of this Title.

§§ 84.62-84.99 [Reserved]

**APPENDIX A—ANALYSIS OF FINAL REGULATION
SUBPART A—GENERAL PROVISIONS**

Definitions—1. "Recipient". Section 84.23 contains definitions used throughout the regulation. Most of the comments concerning § 84.3(f), which contains the definition of "recipient," commended the inclusion of recipients whose sole source of federal financial assistance is Medicaid. The Secretary believes that such Medicaid providers should be regarded as recipients under the statute and the regulation and should be held individually responsible for administering services in a nondiscriminatory fashion. Accordingly, § 84.3(f) has not been changed. Small Medicaid providers, however, are exempt from some of the regulation's administrative provisions (those that apply to recipients with fifteen or more employees). And such recipients will be permitted to refer patients to accessible facilities in certain limited circumstances under revised § 84.22(b). The Secretary recognizes the difficulties involved in federal enforcement of this regulation with respect to thousands of individual Medicaid providers. As in the case of title VI of the Civil Rights Act of 1964, the Office for Civil Rights will concentrate its compliance efforts on the state Medicaid agencies and will look primarily to them to ensure compliance by individual providers.

One other comment requested that the regulation specify that nonpublic elementary and secondary schools that are not otherwise recipients do not become recipients by virtue of the fact their students participate in certain federally funded programs. The Secretary believes it unnecessary to amend the regulation in this regard, because almost identical language in the Department's regulations implementing title VI and title IX of the Education Amendments of 1972 has consistently been interpreted so as not to render such schools recipients. These schools, however, are indirectly subject to the substantive requirements of this regulation through the application of § 84.4(b)(iv), which prohibits recipients from assisting agencies that discriminate on the basis of handicap in providing services to beneficiaries of the recipients' programs.

2. "Federal financial assistance". In § 84.3(h), defining federal financial assistance, a clarifying change has been made: procurement contracts are specifically excluded. They are covered, however, by the Department of Labor's regulation under section 503. The Department has never considered such contracts to be contracts of assistance; the

explicit exemption has been added only to avoid possible confusion.

The proposed regulation's exemption of contracts of insurance or guaranty has been retained. A number of comments argued for its deletion on the ground that section 504, unlike title VI and title IX, contains no statutory exemption for such contracts. There is no indication, however, in the legislative history of the Rehabilitation Act of 1973 or of the amendments to that Act in 1974, that Congress intended section 504 to have a broader application, in terms of federal financial assistance, than other civil rights statutes. Indeed, Congress directed that section 504 be implemented in the same manner as titles VI and IX. In view of the long established exemption of contracts of insurance or guaranty under title VI, we think it unlikely that Congress intended section 504 to apply to such contracts.

In its May 1976 Notice of Intent, the Department suggested that the arrangement under which individual practitioners, hospitals, and other facilities receive reimbursement for providing services to beneficiaries under Part B of title XVIII of the Social Security Act (Medicare) constitutes a contract of insurance or guaranty and thus falls within the exemption from the regulation. This explanation oversimplified the Department's view of whether Medicare Part B constitutes Federal financial assistance. The Department's position has consistently been that, whether or not Medicare Part B arrangements involve a contract of insurance or guaranty, no Federal financial assistance flows from the Department to the doctor or other practitioner under the program, since Medicare Part B—like other social security programs—is basically a program of payments to direct beneficiaries.

3. "Handicapped person". Section 84.3(j), which defines the class of persons protected under the regulation, has not been substantially changed. The definition of handicapped person in paragraph (j)(1) conforms to the statutory definition of handicapped person that is applicable to section 504, as set forth in section 111(a) of the Rehabilitation Act Amendments of 1974, Pub. L. 93-516.

The first of the three parts of the statutory and regulatory definition includes any person who has a physical or mental impairment that substantially limits one or more major life activities. Paragraph (j)(2)(i) further defines physical or mental impairments. The definition does not set forth a list of specific diseases and conditions that constitute physical or mental impairments because of the difficulty of ensuring the comprehensiveness of any such list. The term includes, however, such diseases and conditions as orthopedic, visual, speech, and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, and, as discussed below, drug addiction and alcoholism.

It should be emphasized that a physical or mental impairment does not constitute a handicap for purposes of section 504 unless its severity is such that it results in a substantial limitation of one or more major life activities. Several comments observed the lack of any definition in the proposed regulation of the phrase "substantially limits." The Department does not believe that a definition of this term is possible at this time.

A related issue raised by several comments is whether the definition of handicapped person is unreasonably broad. Comments suggested narrowing the definition in various ways. The most common recommendation was that only "traditional" handicaps be covered. The Department continues to believe, however, that it has no flexibility within the statutory definition to limit the term to persons who have those severe, permanent,

NATIONAL INSTITUTES OF HEALTH CARE
RESEARCH ACT OF 1978

A Preliminary Statement of the Position of the
Association of American Medical Colleges

I. Introduction

On January 31, 1978, Senator Edward Kennedy (D.-Mass.) introduced S. 2466, the National Institutes of Health Care Research Act of 1978. This bill would add to the Public Health Service a new agency devoted primarily to health care services delivery research, within which would be three separate institutes: National Institute for Health Policy Research; National Institute for Health Statistics and Epidemiology; and National Center for the Evaluation of Medical Technology. On February 28, 1978, following staff analysis of the legislation and Executive Committee review of staff papers, the Association sent a letter to Senator Kennedy both supporting the legislation and recommending modifications.

Following is a summary of the legislation, a rationale for the Association's positions and a listing of the suggested modifications submitted to Mr. Kennedy.

II. Summary of the Major Provisions of S. 2466 National Institutes of Health Care Research

This bill would create the National Institutes of Health Care Research (NIHCR) as a co-equal research entity to the National Institutes of Health, in the Department of Health, Education and Welfare. The Director of the National Institutes of Health Care Research would be appointed by the President, with the advice and consent of the Senate. The Institutes would conduct research into health care delivery and statistics much as the National Institutes of Health conduct basic scientific research. The Institutes would be charged with the duty of conducting and supporting research, demonstrations, evaluations, statistical studies and epidemiological activities designed to improve health care delivery in the United States. Special emphasis for the NIHCR is to be directed towards research regarding: (1) the accessibility, acceptability, planning, organization, distribution, utilization and financing of systems of health care; (2) alternate methods for measuring and evaluating the quality of systems for the delivery of health care; (3) the collection, analysis and dissemination of health related statistics; (4) alternate methods to improve and promote health statistical and epidemiological activities; (5) the safety, efficacy, cost of effectiveness, and social, economic and ethical impacts of medical technologies; (6) alternate methods of disseminating knowledge concerning health and health related activities.

As noted earlier, three institutes would be established under the National Institute of Health Care Research. They are as follows:

• National Institute for Health Policy Research: To replace the existing National Center for Health Services Research (NCHSR), the bill would establish within NIHCR a National Institute for Health Policy Research. The functions of the new Institute would remain basically the same as those now delegated to

NCHSR, although a new mandate to undertake and support activities relating to the uses of computer science in health services delivery and medical information systems would be added. Moreover, the Institute would be required to undertake the research and demonstration activities in its assigned areas rather than authorized to undertake them as is the present law.

- National Institute for Health Statistics and Epidemiology: The National Center for Health Statistics would be replaced by a National Institute for Health Statistics and Epidemiology, located within the National Institutes of Health Care Research. Its activities also would become mandatory. Added as a new activity would be the conduct and support of epidemiological research, demonstrations, and evaluations in areas in which the National Center for Health Statistics now gathers data. These include information on the extent and nature of illness and disability in the U.S., on the impact of illness and disability on the economy, on the determinants of health, on health resources, and on utilization of health care.

- National Center for Evaluation of Medical Technology (NCEMT): A new National Center for the Evaluation of Medical Technology would be established in the National Institutes of Health Care Research. Acting through this Center, the Secretary would establish priorities for research, demonstrations and evaluations of medical technology. Emphasis in establishing these priorities would be placed on the actual or potential risks and the actual or potential benefits to patients associated with the use of the medical technology, cost of the technology, the rate of utilization, and the stage of development of the technology.

To carry out a major portion of such research, the National Center would be authorized to fund the development and operation of "Centers" in academic institutions, and to conduct research in the field of medical technology. The Centers are to be established by the end of 1981. The statute authorizes a National Council for the Evaluation of Medical Technologies within the NCEMT.

Appropriation authorizations for the National Institutes of Health Care Research and the National Institute of Health Statistics and Epidemiology are: FY 1979 - \$34 million; FY 1980 - \$40 million; FY 1981 - \$45 million. Those for health statistical and epidemiological research are: FY 1979 - \$60 million; FY 1980 - \$65 million; FY 1981 - \$70 million. Appropriation authorizations for research and review of medical technologies are: FY 1979 - \$25 million; FY 1980 - \$35 million; FY 1981 - \$50 million.

III. Rationale for AAMC Position

In the spring of 1976, the Report of the President's Biomedical Research Panel was released and on June 25, 1976 the Association issued a formal response to the Report. Although the issue of Technology Transfer was only briefly addressed in the Panel Report it was a recurrent theme of witnesses appearing before the panel and thus the AAMC in formulating its response considered the issue thoroughly and in its broadest context.

Included in the Panel Report was an articulation of the NIH mission which was stated as follows:

1. Discovery, through research, of new knowledge and the relating of new knowledge to the existing base;
2. Translation of new knowledge, through applied research, into new technology and strategy for movement of discovery into health care;
3. Validation of new technology through clinical trials;
4. (a) Determination of the safety and efficacy of new technology,
(b) for widespread dissemination through demonstration projects".

In its response, the AAMC agreed with the President's Panel that the mission of NIH is primarily research but stated that the research mission did not encompass "widespread dissemination through demonstration projects" or total responsibility for technology transfer. More specifically the AAMC view was the following:

"NIH activities should include the initial 'determination of the safety and efficacy of new technology (4a)' but the further adjudication of claims of safety and efficacy is not properly an NIH function. The 'widespread dissemination (of new technology) through demonstration projects' (4b) is a health service, not a biomedical research, agency function. To add such service requirements to a research agency would be an error because widespread demonstration projects and health care delivery impose almost insatiable demands on the energies and resources of the agency. The experience of the National Institute of Mental Health is instructive in this regard. As the Overview Cluster pointed out: 'It is unfortunate that the ADAMHA has already become committed to large-scale service programs, and it is clear that the research programs have suffered because of this'.

"Biomedical technology transfer increasingly arouses concern and attracts attention among those interested in health research. The AAMC holds that this transfer is so multi-faceted and necessary that responsibility for it should be shared by the biomedical research community, by private agencies, by public agencies (including but not limited to the NIH) and by industry. The transfer of research advances to clinical care is the area which is the most complex, poorly understood, and demands most resources. The uncoordinated nature of current activities in this area would appear to require new approaches, but the number and complexity of activities and the interrelationships between research, testing, demonstration and practice are such that no single government agency should be expected to assume the entire burden of whatever the Federal role is finally determined to be. Primary responsibility for technology transfer should not be assigned to the NIH simply because NIH has performed its research mission so well. A more rational responsibility for NIH would be to act as a broker in the initiation and promotion of technology transfer".

It was the AAMC's recommendation, therefore, that responsibility for

technology transfer should be shared by a number of federal agencies working together with private industry. To put the total burden of technology transfer on the NIH in the AAMC's view would compromise the research mission of NIH.

The preliminary position of the AAMC regarding S. 2466 is consistent with the AAMC position of two years ago. More precisely S. 2466 embodies many of the principles encompassed in the AAMC's response to the President's Panel Report, and which the Association still holds to be true today. Moreover, the Association recognized other strengths in the legislation as well:

- The proposed legislation recognizes the critical need for initiatives in the areas assigned to the proposed National Institutes of Health Care Research. While elements of these activities are presently undertaken in both the public and private sectors, there is presently no overall framework or institution to relate these functions to one another and no comprehensive managerial strategy for their conduct and support.
- The proposal is timely. Examination of the various studies conducted in this area in recent years and the evidence developed in various Congressional hearings, suggest that now is an appropriate time to modify the programmatic nature, the organizational location and the magnitude of effort for the National Centers for Health Statistics and for Health Services Research.
- S. 2466 enumerates for the first time in understandable, reasonable and badly needed fashion some of the specific components which comprise the important but amorphous and poorly understood spectrum of activities encompassed by the term, "technology transfer".
- The bill offers a potentially effective and appropriate counterpart in the health care area to the National Institutes of Health, and its important and productive programs in biomedical research and related areas.
- The designation of separate authorizations for these activities should provide a necessary identifiable focus for assuring that each can gain at least minimal allocation of the essential financial resources for expanded programs in each area.
- The inclusion of an overarching organization, similar to the Office of the Director, NIH, provides the basis for both intra- and inter-agency cooperation and coordination required for its success.
- While advancing health care research and technology transfer through separately identified functions, the NIH and other agencies can conduct or support, within reasonable limitations, epidemiological research and clinical trials which are especially pertinent to their categorical missions.

- The programs of the NIHCR will complement the programs of the NIH and should increase the total funding of research in the areas of biomedical, behavioral and health care research. The inherent appeal of the categorical foci of the NIH will remain a potent magnet for funds as in the past.

IV. AAMC Recommendations

In conveying its endorsement of the legislation the AAMC recommended that consideration be given to modifying the legislation in the following ways:

- The appointment of an Advisory Council should be mandated for each of the three components, rather than just for the National Center for Evaluation of Medical Technology as presently proposed, since the activities proposed for each component are quite different. Furthermore, in Report language an Advisory Committee to the Director of the entire organization, similar to the administratively established Director's Advisory Committee at NIH, should be recommended.
- The Advisory Councils, like their counterparts at NIH, should have public representatives and should otherwise be appropriately constituted so as to reflect the specific responsibilities of each component. For example, eminent statisticians, epidemiologists and clinicians should be members of the Advisory Council for the National Institute for Health Statistics and Epidemiology. Similarly, on the Advisory Council for the National Institute for Health Policy Research there should be prominent clinicians and other provider representatives, economists, and behavioral and social scientists.
- Peer review of grants and contracts should be mandated for each component so as to assure the highest possible quality in the awards and the subsequent research.
- The authorization ceilings for the three components should total at least 0.5 percent of Federal health care expenditures. This would represent at the present time approximately \$200 million. There are two reasons behind this proposal. First, this provision would provide a reasonable and definite level of financial underpinning for these activities. Second, in very explicit fashion it would tie support for these types of research to the health care function and the Federal component of its funding. It seems only proper to set out in highly visible fashion the necessity of an investment for the future through research so as to assure continued improvements in the quality, quantity and cost effectiveness associated with the health care delivery system.
- Report language should reaffirm the propriety that agencies outside NIHCR, including NIH, conduct and/or support to a reasonable degree epidemiological studies and clinical trials related to the appropriate categorical mission.

V. Current Status

S. 2466 was marked-up by the Senate Subcommittee on Health and Scientific Research on April 3, 1978, and passed on to the full committee essentially unchanged. No mark-up has as yet been scheduled by the full committee. Although a comparable bill has been introduced in the House, H.R. 10839, hearings will not be held until April 25 and 26. A list of witnesses is not yet available.

SOUTHERN DEANS RESOLUTION RE AFFIRMATIVE ACTION

The medical school deans of the Southern Region at their October 7-9 meeting in New Orleans discussed the potential implications of the Bakke case, now before the Supreme Court. They were concerned that the decision, which may well be determined on the basis of fairly narrow legal arguments, not be construed in a way which would erode the gains of well-conceived affirmative action programs. In order that their own position on the matter be clearly stated, the deans adopted the following resolution:

"The Southern Regional Council of Deans reaffirms its continuing commitment to affirmative action programs for recruitment and retention of qualified disadvantaged students, including minority students, to the medical schools of the South represented in this Council."

adopted unanimously
October 8, 1977