MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF HEALTH

ATK
NJL

PATENT BRANCH, OGC
DHEW

TO : B/I/D Directors
OD Staff
PPE Directors

DATE: August 17, 1978

AUG 18 1978

FROM : Director
Division of Legislative Analysis

SUBJECT: Side-by-Side Analysis of Health Services, Health Statistics, and Health Technology Legislation

Attached, for your information, is a side-by-side analysis of H.R. 12584 and S. 2466. The Senate bill, originally defeated as the National Institutes of Health Care Research Act of 1978, was extensively revised, submitted for reconsideration, and passed by a vote of 74 to 19 on August 9, 1978. The House bill has been granted a rule for consideration, and floor action is anticipated within the week.

G. Raymond Womeldorf

Attachment

cc:
Mr. Hill, NICHD
Dr. Kalberer, NCI
Mr. Latker, GC
Ms. Fox, DPA/OD
Dr. Whitescarver, NIAID

COMPARISON BY SUBJECT AREA OF H.R. 12584 AND S. 2466

	Title	H.R. 12584 Health Services Research, Health Statistics, and Health Care Technology Act of 1978	S. 2466 1 Health Services Research, Health Statistics, and Medical Technology Act of 1978
	Sponsors	Rogers, Preyer, Scheuer, Waxman, Florio, Maguire, Markey, Ottinger, Walgren, Carter	Kennedy, Schweiker, Williams, Javits
	Purpose	To amend the Public Health Service Act to revise and extend the authorities under that Act relating to health services research and health statistics and to establish a National Center for Health Care Technology, and for other purposes.	To amend the Public Health Service Act to extend and revise the assistance programs for health services research and health statistics, to establish the Office of Health Technology, and for other purposes.
Subject	Existing Authority	H.R. 12584	S. 2466
Authorities General	Sec. 304 authorizes NCHSR and NCHS to undertake and support health services research and statistical activities.	Would amend general authority to place emphasis on collection of health care cost data and analyzing the reasons for increases.	Would amend Sec. 304(a)(1) to include the Office of Health Technology in the general authority, and emphasize data collection related to the impacts of medical technologies.
	No existing authority	New Sec. 304(d) would require the Secretary to conduct a very broad study "of the present and projected future costs of diseases and conditions which are environmentally related."	New Sec. 110(a) would require the Secretary to develop a plan of statistical and epidemiological data collection of the effects of the environmental health.
NCHSR	No existing authority	Would add new subsection to Sec. 305 to require that HCFA and NCHSR review all health services research grants and contracts. It also reiterates that the Secretary is required to coordinate all health services research.	No comparable provision.

Subject	Existing Authority	H.R. 12584	S. 2466
Authorities NCHSR	Sec. 305(b). The Secretary acting through the Center may undertake and support research, evaluation, and demonstration projects.	No amendment to this authority.	New subsection would place emphasis on computer science in health systems delivery and medical information systems.
NCHS	Sec. 306(b). The Secretary Acting through the Center may collect statistics on . nature of illness and disability in the population . impact of illness and disability on the economy . environmental, social, health hazards . resources . utilization . health care costs and financing	Would amend Sec. 306(b) to require the Secretary to collect statistics with particular emphasis on standardized health statistical data collections. It would also establish the Cooperative Health Statistical System to do the following: . coordinate Federal agencies . assist local agencies financially to aid in compliance with the system . review DHEW statistical collections for consistency.	Would add new subsection to Sec. 306 requiring the Secretary to coordinate health statistical and epidemiological activities and in consultation with the National Committee on Vital and Health Statistics establish, regulate, and review all health statistical, and epidemiological data.
	No existing authority.	Designates NCHS as lead statistical collection and information agency in DHEW, with authority to require compliance to NCHS-developed guidelines.	No comparable provision.
Evaluation of Medical Technologies	No existing authority.	Amend Sec. 309 to establish the National Center for Health Care Technology (NCHCT) with a Director supervised by the Assistant Secretary for Health or designee of the Secretary. All authorities require the Secretary to act through the Center.	Add new Sec. 306A to establish the Office of Health Technology (OHT) with a Director supervised by the Assistant Secretary for Health or designee of the Secretary. All authorities require the Secretary to act through the Center.

Subject	Existing Authority	H.R. 12584	S. 2466
Evaluation of Medical Technologies	No existing authority.	Sec. 309(b)(1)(A) would require the Secretary to undertake or support by grant or contract comprehensive assessments of health care technology, including safety, effectiveness, cost effectiveness, social, ethical, and economic impact.	Sec. 306A(b)(1) would require the Secretary to establish in consultation with the Council for the Evaluation of Medical Technology, priorities for research, demonstrations, and evaluations of medical technologies, emphasizing risk, benefit, cost, utilization, and stage of development.
	No existing authority.	It would further allow that in determining if such assessments should be given priority, emphasis should be placed on risks and benefits, cost, rate of use, state of development of the technology.	
	No existing authority.	New Sec. 309(b)(2) would require the Secretary to undertake and support by grant or contract research on and demonstrations and evaluations of: . factors affecting use of technologies . dissemination of information to health professionals.	New Sec. 306A(b)(2) would require the Secretary to undertake and support by grant, contract, or both, research, demonstrations, and evaluations concerning safety, efficacy, effectiveness, cost effectiveness, social, ethical, and economic impacts as well as: . factors affecting use . dissemination of information to health professionals . quality assurance of health services. The Secretary is required to consult with NIH and other interested Federal agencies.

Subject	Existing Authority	H.R. 12584	S. 2466
Evaluation of Medical Technologies	No existing authority.	New section would allow the Secretary to grant assistance to nonprofit entities in planning, establishing, and operating centers to assess health care technologies.	New section would provide for the establishment of three centers by 1981 for multi-disciplinary research similar to the requirements for OHT.
Advisory Body	No existing authority.	Would establish a Health Care Technology Advisory Committee to advise the Secretary concerning priorities for assessments to be undertaken as well as review grants and contracts for such assessments.	Would establish within OHT a National Council for the Evaluation of Medical Technology to advise and consult with the Secretary, and develop when appropriate and to the extent practicable exemplary standards, norms, and criteria and through NLM disseminate such.
	No existing authority.	Ex officio members include the Director, NIH.	Ex officio members include the Director, NIH.
	No existing authority.	No comparable provision.	New Sec. 477 would require the Director, NIH, to report emerging technologies once a year to OHT.
Authorization Levels (in millions of dollars)	NCHSR / NCHS FY 75: 65.2 / 30 FY 76: 80 / 30 FY 78: 28.6 / 33.6	NCHSR / NCHS / NCHCT FY 79: 36 / 60 / 15 FY 80: 44 / 75 / 25 FY 81: 49 / 80 / 35	NCHSR / NCHS / OHT FY 79: 32.6 / 43.4 / 15 FY 80: 35 / 47 / 25 FY 81: 40 / 50 / 30
Experts or Consultants	No existing authority.	208(g) positions allowed: 10 for NCHSR 12 for NCHS 7 for NCHCT	Would amend Sec. 304(b)(3) to authorize expert or consultant positions: 15 for NCHSR 15 for NCHS No similar positions for OHT.

Subject	Existing Authority	H.R. 12584	S. 2466
Training (in millions of dollars)	No existing funds authorized.	FY 79 80 81 Health Services Research Training 2 4 4 Epidemiology and Biostatistics Training 1 2 2	Under Sec. 472 (NRSA's), NCHSR, NCHS, and OHT are authorized to do training, but no new funding is supplied.
National Eye Institute	Sec. 453 is the main authority for NEI.	Would amend Sec. 453 to grant construction authority to NEI or public and nonprofit vision research facilities.	No comparable provision.
Patent Policy	No existing authority in the PHS Act.	No comparable provision.	Would amend PHS Act to transfer all administrative responsibilities of patent administration relating to patent inventions by DHEW employees, grantees, and contractors to OHT with the Office of General Counsel retaining only the legal services.
Commissioned Study	NCHSR is authorized to to undertake or support health services research.	No comparable provision.	Would require NCHSR to conduct a study on the utilization of health services by the United Mine Workers and their dependents as a result of the copayment provision in the March '78 collective bargaining agreement.

COMPARISON OF HEALTH SERVICES RESEARCH LEGISLATION

Bill Number	S. 2466	H.R. 12584
Sponsors	Kennedy, Schweiker, Williams, Javits	Rogers, Preyer, Scheuer, Waxman, Florio, Maguire, Markey, Ottinger, Walgren, and Carter
Purpose of Bill	To amend the PHS Act to establish the National Institutes of Health Care Research; to extend and revise the assistance programs for health services research and health statistics; to establish the National Center for the Evaluation of Medical Technology.	To amend the PHS Act to revise and extend the authorities relating to health services research and health statistics and to establish a National Center for Health Care Technology.
Technology Transfer and Assessment	Section 306 of the PHS Act would be amended to establish within NIHCR a National Center for the Evaluation of Medical Technology (NCEMT) which shall: o Establish priorities for research, demonstrations, and evaluation of medical technologies. o Consult and cooperate with NIH, VA, and other Federal agencies. o Undertake and support the above by grant, contract, or both, and establish 3 new centers for multidisciplinary research, evaluation, and demonstration by Sept. 1, 1981. o Establish within the NCEMT a Council which would consult with and make recommendations to the Secretary, Director of NIHCR, and Director of the NCEMT. A new Section 477 would be added to the PHS Act to require the Director of NIH to submit annual report to NCEMT and the Council on effective technologies under development which may be used in practice in the near future. Such information shall be disseminated by the NLM to PSRO's, health system agencies, and VA health facilities.	Adds a new Section 309 to the PHS Act to establish a National Center for Health Care Technology which shall: o Undertake and support by grant or contract (1) comprehensive assessments of health care technology, taking into account safety effectiveness, cost effectiveness, social, ethical, and economic impact. In determining if a particular technology should be given priority, emphasis shall be placed on risks/benefits, costs rate of use, and stage of development; (2) research in, demonstration, and evaluations of factors that affect use of health technologies, and methods for disseminating information on health care technologies to health professionals. o Recommend to the Secretary on health technology issues. o Assist public and private nonprofit entities to plan, establish, and operate health care technology centers.

	S. 2466	H.R. 12584
		° Report to the Congress within one year and report to the House and Senate Health Committees on additional authority or or organizational changes neede to accomplish tasks; progress; recommendations for technology assessments and action taken.
	The Center shall be within the NIHCR headed by a Director supervised by the Director of NIHCR.	The Center shall be within HEW under the direction of a Director supervised by the Assistant Secretary for Health.
Advisory Mechanism	A National Council for the Evaluation of Medical Technologies composed of Surgeon General, Director of NIH, Chief Medical Officer of the VA, Chairman of PSRO, three other members of DHEW appointed by Secretary, and ex officio members. Sixteen members appointed by the Secretary: 7 medical or scientific authorities 2 lay public in economics 2 lay public in law 5 general public The Council would: (A) advise and make recommendations to Secretary, Director of NIHCR and NCMET, (B) advise on impact of technologies (C) develop standards concerning utilization of medical technologies, (D) disseminate through NLM and VA, PSRO, all health systems agencies, (E) review and approve grants over $35,000.	A National Health Care Technology Advisory Committee composed of Director, NIH; Chairman of the PSRO; Chief Medical Officer of VA DoD; Chairman of the National Council on Health Planning and Development; Director, OSTP; Commissioner, FDA; Director, CDC; and head of HCFA. Sixteen member appointed by the Secretary: 7 from medical engineering or science fields (2 must be physicians) 2 hospital administrators 2 economists 2 from field of law 1 ethicist 2 general public The Committee shall advise the Secretary and the Director of the Center on establishment of priorities for assessing technologies; review and approve grants and contracts over $35,000.
Authorization	$25 million for 1979 $35 million for 1980 $50 million for 1981	$15 million for 1979 $25 million for 1980 $35 million for 1981