Calendar No. 770

95TH CONGRESS, 2d Session | SENATE | REPORT No. 95-839

THE NATIONAL INSTITUTES OF HEALTH CARE RESEARCH ACT OF 1978

MAY 15 (legislative day APRIL 24), 1978.—Ordered to be printed

Mr. KENNEDY, from the Committee on Human Resources, submitted the following

REPORT

[To accompany S. 2466]

The Committee on Human Resources, to which was referred the bill (S. 2466) to amend the Public Health Service 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, and for other purposes, having considered the same, report favorably thereon with an amendment in the nature of a substitute and recommend that the bill as amended do pass.

I. SUMMARY OF LEGISLATION

As approved by the committee, S. 2466 would—

(1) Establish in the Department of Health, Education and Welfare, a National Institutes of Health Care Research. The Institutes would be charged with the responsibility of conducting and supporting research, demonstrations, evaluations and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the Nation. It would be headed by a Director appointed by the President, by and with the advice and consent of the Senate.

(2) Expand, redirect, and rename the National Center for Health Services Research. This agency would become the National Institute for Health Policy Research and would be a component part of the National Institutes of Health Care Research.

(3) Expand, redirect, and rename the National Center for Health Statistics. This agency would become the National Institute for Health Statistics and Epidemiology and would be a component part of the National Institutes of Health Care Research.

least six independent health services research centers to address both local and national health services research and information needs. The new law resulted from the recognition of the need for a better understanding of the behavior and performance of the health industry as a prerequisite for improving its performance. In order to acquire this better understanding, Congress legislated a more directed, coordinated research effort.

In a very real sense, the National Center has been a service organization which, on the one hand, has had the responsibility for identifying the information that is needed by various kinds of decision-makers, and on the other, the responsibility for stimulating and supporting the production of that information. Other governmental agencies also support health services research, but their research priorities are usually defined and constrained by the immediate information needs of the operating program of which they are a part. The National Center by contrast has been responsible for ensuring thst comprehensive and systematic efforts are made to develop new options for health services delivery and health policy, test the assumptions on which current policies and delivery practices are based, and develop the means for monitoring the performance of the health care system.

Since the enactment of Public Law 93–353, the National Center's principal activities have included managing intramural and extramural health services research programs. The National Center has formulated a research agenda comprised of the following eight issues: (1) Cost containment; (2) health insurance; (3) planning and regulation; (4) quality of care; (5) long-term care; (6) health manpower; (7) ambulatory care; and emergency medical services; and (8) health care and the disadvantaged. The research agenda has been a critical determinant in the allocation of National Center resources in support of its intramural and extramural research, evaluation, and demonstration activities. The priority issues have been published in an annually revised program statement and in soliditations inviting proposals that address particularly timely issues. The National Center has made significant progress in implementing a program of intramural research. The data and findings growing out of an intramural study of medical care expenditures will be of material assistance in the analysis of national health insurance proposals. Another intramural study which examines the efficacy of alternative approaches to quality assurance will be of substantial value to those concerned with various aspects and activities of the PSRO program.

In addition, the National Center has supported five general and two special emphasis (technology and management) health services research centers. In 1976, Congress added a center for health services policy analysis to the list of special emphasis centers.

The National Center has begun to make progress in the coordination and dissemination of information, notably with respect to dissemination. Emphasis has been placed on preparing and distributing research syntheses and digests and conference reports which make the findings of Center-supported activities widely available. Findings generated by Center-supported activities are included in the report on the Nation's health, prepared by the National Center for Health Services Research and the National Center for Health Statistics.

the National Center for Health Statistics and provided the Center with extensive authority for the collection, analysis, and publication of health statistics.

Statistical activities authorized under sections 304, 306, and 307 of the Public Health Service Act and conducted by the National Center for Health Statistics are the major Public Health Service efforts in the collection, analysis, and dissemination of a wide range of general purpose health statistics that shed light on current and projected health problems of the Nation, the resources available to address those problems, the types of health services provided, and the quality and costs of those services.

Through the household interview survey and the health and nutrition examination survey, data is collected using personal interview and direct physical examinations, clinical and laboratory tests, and other measurement procedures to provide national estimates on prevalance and incidence of specific diseases and health conditions, injuries, disability, nutritional status and distributions of the total population for physical characteristics such as height, weight, blood pressure levels, visual acuity.

The vital statistics program and the complementary family growth survey provide information on natality, mortality, marriages, divorces, fertility rates, family planning practices, and infant and maternal health.

A master facility inventory is maintained by the Center and provides census-type data on the Nation's health facilities. Sample surveys of these facilities and of health care providers develop information on the medical, dental, nursing, and other services received by the people. These surveys include the hospital discharge survey which obtains data on persons treated, diagnoses, and services received in hospitals; the national ambulatory medical care survey which is the first survey to produce data on the hundreds of thousands of patient-physician contacts that take place in physician offices, including the volume and content of ambulatory medical practices, the reasons people visit a physician, physician diagnoses for those problems, and the treatments or services provided; the national nursing home survey which provides comprehensive information on the nursing home industry and the residents in those homes; and the national reporting system for Family Planning Services which produces estimates of services available and provided by family planning clinics.

In collaboration with the National Center for Health Services Research, the Center has conducted a national medical care expenditure survey which provides comprehensive information on the health care expenditures of subgroups of the Nation's population and the financing of these expenditures.

The increased demand by Federal programs for State and local area data for planning and evaluation, as opposed to national totals and rates, has led to the development of the cooperative health statistics system. Through this system, data is collected and processed only once and then used by any number of agencies at all levels of government with a resulting increase in efficiency and decrease in duplication of effort, overall costs, and respondent reporting burden. The system, in effect, provides an economical and effective method of establishing and maintaining a data base to guide decisionmaking at national, State, and local levels regarding health care in the United

HEALTH SERVICES RESEARCH—APPROPRIATION HISTORY; FISCAL YEARS 1970–79

[In millions]

	Authorization [1]	Appropriation (Adjusted)
Fiscal year:		
1970	$60.0	$40.7
1971	71.0	51.6
1972 (includes supplemental)	82.0	56.2
1973	94.0	[2] 58.0
1974	42.6	37.9
1975	65.2	[3] 35.9
1976	80.0	26.0
1977	80.0	24.0
1978	28.6	26.1
1979	Proposed	[4] 23.8

[1] Authorization levels reflect those amounts identified under sec. 304 (1970–74) and sec. 308 (1975–79). Through 1974, the National Center also conducted activities under the indefinite authority of sec. 301, PHS Act.
[2] $12,800,000 impounded. Released for obligation in 1974–75.
[3] $8,000,000 intramural funds re-programed within other DHEW accounts.
[4] President's budget.

Note: Excludes program management.

III. History of Legislation

S. 2466 was introduced on January 31 (legislative day, January 30), 1978 by Senators Kennedy, Schweiker, Williams, and Javits and was referred to the Committee on Human Resources. On February 7, 1978, the Subcommittee on Health and Scientific Research held a hearing on the legislation. Testimony was received from:

(1) the Department of Health, Education, and Welfare; Dr. Julius B. Richmond, Assistant Secretary for Health, Surgeon General of the Public Health Service;

(2) Dr. David Hamburg, President, Institute of Medicine, National Academy of Sciences;

(3) Dr. Philip Lee, Professor of Social Medicine and Director, Health Policy Program, University of California, San Francisco; and

(4) Dr. Richard Remington, Dean, School of Public Health, University of Michigan.

In addition, statements were supplied for the record by: Dr. Kerr L. White, M.D., director, institute for health care studies, United Hospital Fund of New York; Dr. S. David Pomrinse, M.D., M.P.H., chairman, New York State Study for Unified Hospital Data System, Inc., and president, Greater New York Hospital Association; Eugene W. Fowinkle, M.D., commissioner, Tennessee Department of Public Health and past president of the Association of State and Territorial Health Officials; American Hospital Association; Association of Schools of Public Health; American Nurses' Association, Inc.; Association of American Medical Colleges; American Public Health Association.

Related hearings were held by the subcommittee during 1977 on an examination of the development and spread of new medical technologies and research in disease prevention. Witnesses at these hearings included:

(4) Establish within the National Institutes of Health Care Research a National Center for the Evaluation of Medical Technology. Its major purpose would be to assess the cost and effectiveness of medical practices and procedures.

NATIONAL INSTITUTES OF HEALTH CARE RESEARCH (NIHCR)

As the committee has surveyed Federal efforts in the area of health research and development, it has become increasingly aware of some glaring program imbalances. The Federal Government has over the years lavishly supported research in the biological sciences. It has provided these research activities with a sound institutional home in the form of the National Institutes of Health, and it has funded these health science programs at levels currently approaching $3 billion.

The committee is pleased with this record of support for the biological sciences, and it notes the gratifying dividends which this research investment has yielded. At the same time, however, the committee notes that there are a number of date gathering and research disciplines whose potential remains substantially untapped. These activities include—

(1) Health services research and development: The study of the organization and functioning of our health delivery system for the purpose of perfecting its performance.

(2) Health statistics: The gathering of information on the health of the Nation's population. This data points up the strengths and weaknesses of the country's health care system as revealed by the health status of Americans.

(3) Epidemiology: The collection and analysis of health data which might provide information relevant to the prevention and treatment of illness and disease.

(4) Technology evaluation: The study of the usefulness, cost, and economic and social impact of medical practices and procedures.

These research activities have made major contributions to our understanding of health care trends in the Nation. They have provided a factual backdrop for many important decisions in the health field in the areas of cost containment, quality of care, the distribution of health services, and the control of toxic substances. They have done so despite inadequate funding. In addition, where funds are available for such research activities, they are often fragmented haphazardly among uncoordinated and competitive programs. As a result, valuable opportunities to effect improvements in the Nation's health care system and the health of Americans have been lost.

The committee believes that we cannot expect research investments to pay off unless we provide the disciplines involved with the necessary support. The committee feels that the research activities described above need better funding. But just as much as more money, they need a defined institutional home and a more hospitable organizational climate.

Since they are related but distinct disciplines, these research activities need to be coordinated, but at the same time given enough room to follow separate leads. They must have public accountability. They

with the administration's expressed commitment to ending the prevailing fragmentation of programs in these areas, the committee remains convinced, nevertheless, that this legislation is necessary.

The committee continues to hold this view for a number of reasons. First of all, it notes that the Congress has in the past received repeated assurances that the required coordination of programs could be achieved through administrative means. These administrative efforts, however, have been repeatedly frustrated—primarily by the nature of the bureaucracy itself.

Second, the committee cannot help noting that the Department relies heavily on the personal ties between key administrators in the Public Health Service and the Health Care Financing Administration in making the case for an administrative solution to existing organizational problems. Important as these relationships may be, the committees finds them a fragile foundation for a long-term solution to ingrained institutional rivalries and fragmentation.

Third, the committee continues to see evidence of destructive competition and poor coordination in the areas of health services research and health statistics. These persist despite administration arguments that substantial progress has been made in working out agreements between various Department subunits in the Public Health Service and the Health Care Financing Administration.

Fourth, the committee feels that placing the two existing Centers in the proposed National Institutes of Health Care Research will promote the long-term development of these two Centers and of their related research and data-gathering functions. Under a recent reorganization, the National Center for Health Services Research and the National Center for Health Statistics were placed in the immediate office of the Assistant Secretary for Health. The committee is concerned that this move will constrain the long-term growth of health services research and health statistics in the Federal Government. Placed in an administrative office, the two Centers may not receive the personnel or the appropriations which their programmatic functions justify. What is more, their visibility is decreased. Finally, their current location increases the chances that their activities may be subject to political manipulation in a way which undermines their credibility as objective, research agencies. It is the committee's views that many of these real and potential difficulties could be circumvented by placing the two existing Centers in the proposed National Institutes of Health Care Research.

Finally, the committee notes that, should the proposed National Center for the Evaluation of Medical Technologies become law without the creation of the NICHR, this new center might also be placed in the office of the Assistant Secretary. This would create a situation in which the Assistant Secretary was directly administering programs with authorizations totalling over $100 million and with personnel levels approaching 1,000. This is clearly an inappropriate role for the Assistant Secretary, and creates a bureaucratic environment which cannot promote the long-term interests of the research and development functions involved.

The committee is aware of the concerns expressed in some quarters that the strong coordinating mandate of the proposed NIHCR will interfere with the ability of various programs in the Department to perform their missions effectively. The committee recognizes that

The new National Institute for Health Policy Research would be required specifically to undertake and support research, evaluation, and/or demonstration projects which examine—

(1) The accessibility, acceptability, planning, organization, distribution, utilization, quality, and financing of health services and systems;

(2) The supply and distribution, education and training, quality, utilization, organization, and costs of health manpower;

(3) The design, construction, utilization, organization, and cost of facilities and equipment; and

(4) The use of computer science in health services delivery and medical information systems.

This last directive grows out of a comprehensive Office of Technology Assessment study which illustrated the pressing need for work on medical information systems, particularly as they employ computer technologies.

The committee believes that despite the many accomplishments of the National Center for Health Services Research since 1974, the need for reform in the National Center's mandate and functioning is clear. The National Center has had a number of problems during these years of accomplishment, but it is not clear that these problems reflect exclusively a failing of the Center. And in no way do these difficulties imply that health services research is anything less than vital and indispensable. The committee believes that the creation of a National Institute for Health Policy Research would lay the necessary institutional groundwork for a revitalized and strengthened health services research facility.

The history of the National Center has demonstrated that a continuing research effort is required. Its work has contributed directly to major legislative initiatives. Research and development work at the National Center laid the groundwork for the professional standards review organization. It has provided much of the support for the pioneering work in the development of nurse practitioners and physician assistants and their reimbursement under the Rural Health Clinic Services Act of 1977. The National Center provided critically needed information to the Congress on foreign medical graduates during its deliberations on the Health Professions Educational Assistance Act of 1976. Finally, work funded by the Center was instrumental in justifying the National Consumer Health Information and Health Promotion Act of 1976. These achievements were accomplished despite steadily declining budgetary support and despite continued reorganizations, changes in leadership, and the consequent demoralization of agency leadership.

By transforming the National Center for Health Services Research into the National Institute for Health Policy Research, the committee has been guided by the following objectives and intentions:

First, health services research must be regarded as a research discipline, not simply a short-term aid to policy formation.

Second, health services research must be protected to the extent possible from political pressures so that excellent research may be conducted and so that talented personnel may be recruited.

Third, health services research must remain relevant to policy needs—thus the *Institute* for "Health Policy Research"—but the time frame for its accomplishments must be reasonable.

The committee has placed responsibility for research in the use of computer science in health services delivery and medical information systems with the National Institute for Health Policy Research. In so doing, it is the desire of the committee that the new institute establish, as one of its priorities, a research program with respect to small data management systems. This is in no way intended to detract from research currently underway.

The committee has also provided for the Institute to conduct a special study of the effects on United Mineworkers and their dependents of the introduction of copayments and/or deductibles for health services as a result of their collective bargaining agreement. Some experts have maintained that patient cost-sharing, such as that required under the UMW contract settlement of March 1978, will have a favorable impact on health care costs and reduce utilization without adversely affecting health status. Hard data for this position is somewhat lacking, however, and the committee believes that a major new study is warranted. For more than 20 years, the UMW health benefits package required no cost-sharing, and the committee is convinced that the changes mandated in the new collective bargaining agreement afford an excellent opportunity to test hypotheses about the effect of cost-sharing in a large population sample, an opportunity which should not be missed. The study should emphasize the impact of copayments and deductibles on the utilization of health services by mineworkers and upon their health status and that of their dependents.

NATIONAL INSTITUTE FOR HEALTH STATISTICS AND EPIDEMIOLOGY

The committee proposes to establish as a component part of the National Institutes of Health Care Research a National Institute for Health Statistics and Epidemiology which would incorporate the mission of the National Center for Health Statistics and add two crucial new functions to the Center's activities. The new National Institute will continue the Center's excellent and widely respected health surveys and monitoring activities which have provided detailed information on such crucial matters as the prevalence and incidence of various diseases in the Nation, infant mortality rates, the frequency of visits to physician offices, utilization of hospital beds, and the levels of expenditures for various health services.

The committee has mandated for the new National Institute two additional functions which the Center never fully addressed or implemented. First, it will become by law the Secretary's instrument for coordinating health data collection in the Department of Health, Education, and Welfare and for eliminating overlap, duplication and lack of standardization in data gathering. Second, the National Institute will assume major new responsibilities intended by the Committee to strengthen the Nation's capability to perform epidemiological work.

The need for improved coordination of the Department's health statistical activities has long been recognized by both the administration and the Congress. The Center, under its mandate to establish the cooperative health statistical system, has made progress recently in achieving coordination of data gathering activities within the Public Health Service. However, progress has been slow and the com-

> * * * while the Department [HEW] is extensively involved with technology as a developer, an evaluator, a purchaser, and a regulator, it has no comprehensive strategy to link systematically stages in the life cycle of technology development, evaluation, transfer, diffusion, utilization, and phaseout.

The Nation has witnessed in recent years an unprecedented explosion in out understanding of biology and of disease. The research community is often criticized for failing to transfer this new knowledge rapidly enough from bench to bedside, from laboratory abstraction to practical application. This is a problem of "technology transfer" with which the Congress and this committee has been especially concerned recently.

This alleged lag in the translation of knowledge from bench to bedside is one part of the technology transfer problem. There is another side to the problem, a dimension which also has its roots in the productivity of the research establishment. While some new medical technologies lag in their translation brom bench to bedside, others are applied too quickly. With the quickening pace of biomedical research, there has been a proliferation in the number and kinds of health practices and procedures to which patients are subjected. Some of these new technologies and practices have found their way into widespread use before their efficacy and safety have been established by thorough scientific testing. In addition, the Nation's medical care system contains forces which encourage the rapid spread and use of medical technology. As Steven Schroeder and Jonathan Showstack point out in their study, The Dynamics of Medical Technology Use: Analysis and Policy Options, these forces include:

> Concerns for high quality and efficient care, as well as financial gain and competition. The educational system in which physicians are trained, the structure of the reimbursement system by which physicians and hospitals are paid, and the demand by consumers for increased use of technological procedures encourage relatively uncritical use of medical technologies.

Dr. Charles Sanders, General Director of Massachusetts General Hospital, elaborated upon several of these points when, at subcommittee hearings on July 19, 1977, he discussed those forces which influence the adoption of medical technologies despite the limited quantitative information developed "concerning technology's costs, its impact on health, the mechanism of introduction, or its place within the vast array of technology currently available." He enumerated these forces as follows:

(1) The public itself, who equate new technology with improvement in health care.

(2) The Federal Government, whose policies in biomedical research have led to technological innovation and adoption.

(3) The Federal Government and other third party carriers employing a cost reimbursement methodology to pay for health services. This mechanism facilitates adoption of technology through the ability to pass through costs to the insurance carrier without examining critically the place of that technology in the system as a whole.

DHEW appointed by the Secretary. Though they cannot be referred to in law for technical reasons, the committee feels strongly that the additional HEW personnel sitting on the Council should be the following: The Commissioner of the Food and Drug Administration; the Director of the Bureau of Health Planning in the Public Health Service; and the Administrator of the Health Care Financing Administration. Eighteen other members would be appointed by the Secretary: Six selected from among leading medical or scientific authorities; two practicing hospital administrators, two practicing physicians, two leader in the field of economics, two leaders in the field of law, and four members of the general public.

In addition to advising the National Center, the National Council would be assigned the function of issuing, where appropriate, exemplary or model standards for the use of medical technologies.

The committee is aware of the concerns expressed by certain groups that the Center for the Evaluation of Medical Technology may become a regulatory agency which, by formulating model standards, will attempt, on behalf of the Federal Government, to dictate acceptable medical techniques or technologies. The committee does not intend for the standards developed by the Center to be regulatory in nature or to be binding in any fashion on the private practice of medicine, or on administration decisionmaking concerning reimbursement under titles XIX or XVIII of the Social Security Act, health planning guidelines, or drug and device regulation.

The committee strongly believes that the Council will perform a valuable function simply in formulating model standards based on the most up-to-date information on the safety, costs and efficiency of new and existing medical practices and procedures. These guidelines, the committee feels, could have an important impact on the health care system through better informing physician decisionmaking and through providing background for Federal, State and local decisionmakers. In order to maximize the usefulness of this new information, the Center would be instructed to disseminate its model norms and standards as widely as possible.

The committee is aware that multiple other agencies are currently involved in studying medical "technologies" as these are defined under the proposed law. The Food and Drug Administration examines safety and efficacy data submitted by manufacturers of drugs and devices. The Center for Disease Control evaluates new vaccines. The National Institutes of Health do over $100 million worth of clinical trials on various devices, practices and procedures.

The committee expects and hopes that these agencies will continue to perform evaluations of particular technologies, practices and procedures as these fall within their legislative or substantive jurisdiction. The mission of the new National Center is, the committee believes, complementary to these on-going activities.

The committee sees a number of special roles for the National Center which are not and cannot be fulfilled by other agencies. First, the committee hopes the Center and its Council will provide valuable assistance to the Department in setting priorities for the study of medical practice and procedures. This priority setting process must take into account multiple views and perspectives, including those of clinicians, scientists, Federal regulatory decisionmakers, hospital administrators and others. The proposed membership of the Council

tics and Epidemiology (NIHSE), which would replace the National Center for Health Statistics; and a National Center for the Evaluation of Medical Technology (NCEMT). The Institutes would conduct and support research, demonstrations, evaluations, and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services.

This bill would repeal part K of title III of the Public Health Service Act, which authorizes funds for quality assurance activities.

5. Cost estimate:

[In millions of dollars]

	Fiscal year				
	1979	1980	1981	1982	1983
Authorization levels:					
308(i)(1) (NIHPR)	40.0	45.0	50.0		
308(i)(2) (NIHSE)	60.0	65.0	70.0		
308(i)(3) (NCEMT)	25.0	35.0	50.0		
Total, authorization levels	125.0	145.0	170.0		

	1979	1980	1981	1982	1983
Projected costs:					
NIHPR	14.4	36.2	46.1	31.3	7.0
NIHSE	43.8	54.7	64.9	17.9	10.2
NCEMT	4.5	28.6	40.0	29.9	7.0
Total, projected costs	62.7	119.5	151.0	79.1	24.2

The costs of this bill fall within budget function 550.

6. Basis of estimate: These estimates are based on the following assumptions: (1) authorized amounts are fully appropriated at the beginning of each year; (2) the NIHPR and the NIHSE are fully operational in fiscal year 1979; (3) outlays by the NCEMT are 50 percent of normal in the first year, reflecting lags due to starting a new program; and (4) spending by the NIHSE will resemble that by the National Center for Health Statistics and, similarly, spending by both the NIHPR and the NCEMT will resemble that by the National Center for Health Services Research. Accordingly, outlays were estimated using spendout rates computed by CBO on the basis of the appropriate recent program data.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Malcolm J. Curtis.

10. Estimate approved by: James L. Blum, *Assistant Director for Budget Analysis.*

The amount of additional paperwork that will result from the regulations would be relatively small and would include applications by individuals seeking support for health services research training and applications of academic institutions seeking program support for conducting such training.

The regulations required by S. 2466 with respect to health statistics would not increase the numbers of individuals or businesses who would be regulated. The bill specifies that the Secretary of DHEW acting through the National Center for Health Statistics shall coordinate statistical activities of DHEW by providing through regulation, minimum sets of data and quality control procedures to be followed by DHEW components in their data collection, analysis, and dissemination activities.

The intent of these provisions of the bill is in support of the spirit of Section 602 of Senate Resolution 4. It is anticipated that the provisions of S. 2466 related to health statistics will increase the usefulness of data collected by DHEW and possibly reduce the total respondent burden through better coordination and sharing of data by the DHEW agencies.

Insofar as the medical technology evaluation provisions are concerned, there will be no direct regulatory impact on individuals, businesses, or the public generally. The provisions of the bill establishing the National Center for the Evaluation of Medical Technology relate to internal program policy and implementation of research programs. While issuance of regulations is neither mandated in the bill nor necessary for carrying out the provisions of the bill, it is the intent of the legislation that research findings and advice of the Center will be taken into account by the Secretary of HEW in the development of policy and regulations related to utilization of particular medical technologies.

VIII. Section-by-Section Analysis—S. 2466

Short title; reference to act

Section 1.—Names the act (S. 2466) the "National Institutes of Health Care Research Act of 1978." Specifies that an amendment or repeal proposed by this act shall refer to the Public Health Service Act.

Section 101.—Amends section 304 of the PHS act to read as follows:

National institutes of health care research

New section 304(a).—Requires the Secretary of HEW, to establish in the Department of Health, Education, and Welfare, the National Institutes of Health Care Research (hereinafter referred to as the "Institutes"). Requires the Institutes to be headed by a Director appointed by the President, by and with the advice and consent of the Senate. Specifies that the Director, with the approval of the Secretary, may appoint a Deputy Director and may employ and prescribe the functions of such officers and employees as are necessary to administer the activities to be carried out through the Institute.

New section 304(b)(1).—Requires the Secretary, acting through the Institutes, to conduct and support research, demonstrations, evalua-

experts or consultants who have appropriate scientific or professional qualifications; and

(3) acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District.

New section 304(d).—Requires the Secretary to coordinate, through the Institutes, the above-mentioned research, evaluation, demonstration, and statistical and epidemiological activities undertaken and supported through units of DHEW.

New section 304(e).—Requires the Director of the Institutes to submit not later than October 30 of each year to the Secretary for simultaneous transmittal to the President and to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives a report setting forth the program accomplishments of the Institutes in the preceding fiscal year and the objectives and priorities for the current fiscal year.

Section 102.—Revises section 305 of the PHS Act, National Center for Health Services Research, with a series of substantive and conforming technical amendments. Redesignates this section as the National Institute for Health Policy Research.

New section 305(a).—Establishes in the National Institutes of Health Care Research, the National Institute for Health Policy Research (hereinafter in this section referred to as the "Institute"). Requires that this Institute be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.

New section 305(b).—Revises the Secretary's current law authority to undertake and support research evaluation, and demonstration projects to establish such authority for the National Institute for Health Policy Research. Requires the Secretary, acting through the Institute, to undertake and support research, evaluation, and/or demonstration projects (which may include and shall be appropriately coordinated with experiments and demonstration activities authorized by the Social Security Act and the Social Security Amendments of 1967) which examine—

(1) the accessibility, acceptability, planning, organization, distribution, utilization, quality, and financing of health services and systems;

(2) the supply and distribution, education and training, quality, utilization, organization, and costs of health manpower;

(3) the design, construction, utilization, organization, and cost of facilities and equipment; and

(4) the uses of computer science in health services delivery and medical information systems.

New section 305(c).—Makes a conforming technical amendment. Requires the Secretary to afford appropriate consideration to requests of—

(1) State, regional, and local health planning and health agencies,

health care services, and Federal, State, and local governmental expenditures for health care services; and

(H) family formation, growth, and dissolution;

(2) undertake and support (by grant or contract or both) research, demonstrations, and/or evaluations respecting new or improved methods for obtaining current data on the matters referred to in paragraph (1) above; and

(3) undertake and support (by grant or contract or both) epidemiological research, demonstrations, and evaluations on the matters referred to above in paragraph (1).

New section 306(c).—Requires the Institute to furnish such special statistical and epidemiological compilations and surveys as the Committee on Human Resources and the Committee on Appropriations of the Senate and the Committee on Interstate and Foreign Commerce and the Committee on Appropriations of the House of Representatives may request. Specifies that such statistical and epidemiological compilations and surveys shall not be made subject to the payment of the actual or estimated cost of the preparation of such compilations and surveys.

New section 306(d).—Requires the Secretary, through the Institute, to provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data so as to insure the comparability and reliability of health statistics.

New section 306(e).—Requires the Secretary, through the Institute, to (1) assist State and local health agencies, and Federal agencies involved in matters relating to health, in the design and implementation of a cooperative system for producing comparable and uniform health information and statistics at the Federal, State, and local levels, to be known as the Cooperative Health Statistics System; (2) coordinate the activities of such Federal agencies respecting the design and implementation of such System; (3) undertake and support (by grant or contract or both) research, development, demonstrations, and evaluations respecting such System; (4) provide the Federal share of the data collection costs under such System; and (5) review statistical activities of DHEW to assure that they are consistent with such cooperative System.

New section 306(f).—Requires the Secretary, through the Institute, to cooperate and consult with the Departments of Commerce and Labor and any other interested Federal departments or agencies and with State and local health departments and agencies, so as to assist in carrying out this section. Specifies that for this purpose, the Secretary shall utilize, insofar as possible, the services or facilities of any agency of the Federal Government and, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5), of any appropriate State or other public agency, and may, without regard to such section, utilize the services or facilities of any private agency, organization, group, or individual, in accordance with written agreements between the head of such agency, organization, or group and the Secretary or between such individual and the Secretary. Specifies that payment, if any, for such services or facilities shall be made on such amounts as may be provided by the agreement.

Further requires the Secretary, in carrying out the health statistical activities of this part to consult with and seek the advice of the Committee and other appropriate professional advisory groups.

New section 306(j).—Requires the Secretary, acting through the Institute, to coordinate health statistical and epidemiological activities of DHEW in carrying out the requirements of sections 304(d) and 305(e)(2) by—

(1) developing in consultation with the National Committee on Vital and Health Statistics, promulgating by regulation, and maintaining the minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b)(1).

(2) after consultation with the National Committee on Vital and Health Statistics, establishing, by regulation, standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis,

(3) reviewing periodically all existing health statistical data collections of the Department that were previously approved pursuant to the Federal Reports Act of 1942 to determine whether such collections conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If any such collections are found not to be in conformance, the Secretary shall take the necessary action to assure that any future collections (effective ninety days after the review) are in conformance.

(4) reviewing all proposed health statistical data collections of the Department that require approval pursuant to the Federal Reports Act of 1942 to determine whether such proposed collections conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If any such proposed collections are found not to be in conformance, the Secretary shall take the necessary action to bring them into conformance before such proposed collections are initiated.

Section 104.—Amends title III of the PHS by adding the following new section:

NATIONAL CENTER FOR THE EVALUATION OF MEDICAL TECHNOLOGY

New section 306A(a).—Establishes in the National Institutes of Health Care Research the National Center for the Evaluation of Medical Technology (hereinafter in this section referred to as the "Center"). Specifies that the Center shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institute of Health Care Research.

New Section 306A(b).—Requires the Secretary acting through the Center, to—

(1) establish, in consultation with the Council for the Evaluation of Medical Technology, priorities for research, demonstrations, and evaluations of medical technologies as prescribed below in paragraph (2). Requires that in establishing such priorities, particular emphasis be placed on—

(A) the actual or potential risk and the actual or potential benefits to patients associated with the use of the medical technology,

Specifies terms of office of these members and their compensation. Requires the Council to meet at the call of the Chairman, but not less often than four times a year. Authorizes the Council to—

(A) advise, consult with, and make recommendations to the Secretary, the Director of the National Institutes of Health Care Research, and the Director of the Center with respect to carrying out the provisions of this section;

(B) after consultation with appropriate public and private entities, advise the Secretary concerning the safety, efficacy, effectiveness, cost effectiveness, and the social and economic impact of particular medical technologies;

(C) after consultation with appropriate public and private entities, develop, when appropriate and to the extent practicable, exemplary standards, norms, and criteria concerning the utilization of particular medical technologies;

(D) publish, make available and disseminate, through the National Library of Medicine, promptly in understandable form and as widely as possible, but, at a minimum, to all health systems agencies, to all Professional Standards Review Organizations and to the health facilities of the Veterans' Administration the standards, norms, and criteria developed pursuant to paragraph (C); and

(E) review and approve any grant that the Center proposes to make and any contract the Center proposes to enter pursuant to this section if such grant or contract is in an amount exceeding $35,000 of direct costs.

New section 306A(f).—Defines, for purposes of this section, medical technology to mean any discrete and identifiable medical or surgical regimen or modality used to diagnose or treat illness, prevent disease, support life, or maintain patient well-being.

Section 105.—Makes a series of conforming technical amendments to Section 308 of the PHS Act, "General Provisions". Repeals requirement that Secretary submit a report to Congress respecting the administration of sections 304 through 307 during the preceding fiscal years and the current State and progress of health services research and health statistics.

New section 308(a)(1).—Requires that the Secretary, acting through the National Institutes of Health Care Research, assemble and submit to the President and Congress not later than September 1 of each year the following reports:

(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section 306(b)(1).

(B) A report on health resources. Such report shall include a description and analysis, by geographical area, of the statistics collected under section 306(b)(1).

(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1).

(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1).

New section 308(a)(2).—Provides that the Office of Management and Budget may review any report required by paragraph (1) or (2)

advance or by way of reimbursement, and in such installments and on such conditions, as the Secretary deems necessary to carry out the purposes of this section. Requires that the amounts otherwise payable to any person under such grant or contract be reduced by—

(A) amounts equal to the fair market value of any equipment or supplies furnished to such person by the Secretary for the purpose of carrying out the project with respect which such grant or contract is made, and

(B) amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the Government in connection with such project, if such officer or employee was assigned or detailed by the Secretary to perform such services, but only if such person requested the Secretary to furnish such equipment or supplies, or such services, as the case may be.

New section 308(f).—Specifies that contracts may be entered into under section 304, 305, 306, or 306A without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

New section 308(g).—Requires the Secretary to—

(A) publish, make available and disseminate, promptly in understandable form and on as broad a basis as practicable, the results of health services research, demonstrations, and evaluations undertaken and supported under sections 304 and 305;

(B) make available to the public data developed in such research, demonstrations, and evaluations; and

(C) provide indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on health services research, demonstrations, and evaluations in health care delivery to public and private entities and individuals engaged in the improvement of health care delivery and the general public; and undertake programs to develop new or improved methods for making such information available.

Except as provided in subsection (d), the Secretary may not restrict the publication and dissemination of data from, and results of projects undertaken by, centers supported under section 305(d).

Further requires the Secretary to: (A) take such action as may be necessary to assure that statistics developed under sections 304, 305, 306 and 306A are of high quality, timely, comprehensive as well as specific, standardized, and adequately analyzed and indexed, and (B) publish, make available, and disseminate such statistics on as wide a basis as is practicable.

New section 308(h).—Provides that a grant or contract under section 304, 305, 306, or 306A for a project to construct a facility or acquire equipment may not provide for payment of more than 50 percent of the cost of the facility, or equipment determined by the Secretary to be reasonably attributable to research, evaluation, or demonstration purposes, except where the Secretary determines that unusual circumstances make a larger percentage necessary to effectuate the purposes of these sections. Further specifies the Davis-Bacon requirements concerning payment of laborers and mechanics employed by contractors for the construction of facilities as well as other labor standards. Provides that these grants and contracts be subject to such additional requirements as the Secretary may prescribe by regulations.

of the new copayments required of mine workers under their recently negotiated collective bargaining agreement with the mine owners. Authorizes the use of $1,000,000 of appropriated moneys from the National Institutes budget for this study.

Section 110.—Requires the Secretary, acting through the National Institutes for Health Care Research, in cooperation with the Secretary of Labor and the Administration of the Environmental Protection Agency, to develop a plan for the collection and coordination of statistical and epidemiological data on the effects of the environment on health.

[S. 2466, 95th Cong., 2d sess.]

A BILL To amend the Public Health Service 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, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE; REFERENCE TO ACT

SECTION 1. (a) This Act may be cited as the "National Institutes of Health Care Research Act of 1978".

(b) Whenever in this Act an amendment or repeal is expressed in terms of an Amendment to, or repeal of, a section or other provision, the reference shall be considered to be made a section or other provision of the Public Health Service Act.

SEC. 101. Section 304 and the heading thereto area mended to read as follows:

"NATIONAL INSTITUTES OF HEALTH CARE RESEARCH

"SEC. 304. (a) The Secretary shall establish, in the Department of Health, Education, and Welfare, the National Institutes of Health Care Research (hereinafter in this section referred to as the "Institutes"). The Institutes shall be headed by Director appointed by the President, by and with the advice and consent of the Senate. The Director, with the approval of the Secretary, may appoint a Deputy Director and may employ and prescribe the functions of such officers and employees as are necessary to administer the activities to be carried out through the Institutes.

"(b)(1) The Secretary, acting through the Institutes, shall conduct and support research, demonstrations, evaluations, and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

"(2) In carrying out paragraph (1), the Secretary, acting through the Institutes, shall give appropriate emphasis to research, demonstrations, evaluations, and statistical and epidemiological activities respecting—

"(A) the accessibility, acceptability, planning, organization, distribution, utilization, and financing of systems for the delivery of health care,

"(B) alternative methods for measuring and evaluating the quality of systems for the delivery of health care,

"(d) The Secretary shall coordinate all research, evaluation, demonstration, and statistical and epidemiological activities referred to in subsection (b) undertaken and supported through units of the Department of Health, Education, and Welfare, Such coordination shall be carried out through the Institutes.

"(e) The Director of the Institutes shall submit a report to the Secretary for simultaneous transmittal, not later than October 30 of each year, to the President and to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives setting forth the program accomplishments of the Institutes in the preceding fiscal year and the objectives and priorities for the current fiscal year.".

SEC. 102. (a) The heading for section 305 is amended to read as follows:

"NATIONAL INSTITUTE FOR HEALTH POLICY RESEARCH".

(b) Section 305(a) is amended to read as follows:

"(a) There is established in the National Institutes of Health Care Research the National Institute for Health Policy Research (hereinafter in this section referred to as the 'Institute') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.".

(c) Section 305(b) is amended by—

(1) striking "304(a)" and inserting in lieu thereof "304(b)";

(2) striking "Center" and inserting in lieu thereof "Institute";

(3) striking "may undertake" and inserting in lieu thereof "shall undertake";

(4) striking "and" after "evaluation," and inserting in lieu thereof "and/or";

(5) striking "technology," in paragraph (1);

(6) striking "and" after "manpower;" in paragraph (2);

(7) striking the period in paragraph (3) and inserting in lieu thereof "; and"; and

(8) adding at the end thereof the following new paragraph:

"(4) the uses of computer science in health services delivery and medical information systems.".

(d) Section 305(c) is amended by striking "Center" and inserting in lieu thereof "Institute".

(e) Sections 305(d)(1) and 305(d)(2)(A) are amended by inserting ", acting through the Institute," after "Secretary" each place it occurs.

(f) Section 305 is amended by striking "304(b)" and inserting in lieu thereof "304(c)".

SEC. 103. (a) The heading to section 306 is amended to read as follows:

"NATIONAL INSTITUTE FOR HEALTH STATISTICS AND EPIDEMIOLOGY".

(b) Section 306(a) is amended to read as follows:

"(a) There is established in the National Institutes of Health Care Research the National Institute for Health Statistics and Epidemiology (hereinafter in this section referred to as the 'Institute') which

any such collections are found not to be in conformance, the Secretary shall take the necessary action to assure that any future collections (effective ninety days after the review) are in conformance,

"(4) reviewing all proposed health statistical data collections of the Department that require approval pursuant to tbe Federal Reports Act of 1942 to determine whether such proposed collections conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If any such proposed collections are found not to be in conformance, the Secretary shall take the necessary action to bring them into conformance before such proposed collections are initiated.".

SEC. 104. Title III is amended by adding after section 306 the following new heading and section:

"NATIONAL CENTER FOR THE EVALUATION OF MEDICAL TECHNOLOGY

"SEC. 306A. (a) There is established in the National Institutes of Health Care Research the National Center for the Evaluation of Medical Technology (hereinafter in this section referred to as the 'Center') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.

"(b) The Secretary, acting through the Center, shall—

"(1) establish, in consultation with the Council for the Evaluation of Medical Technology, priorities for research, demonstrations, and evaluations of medical technologies as prescribed by paragraph (2)(A). In establishing such priorities, particular emphasis should be placed on—

"(A) the actual or potential risks and the actual or potential benefits to patients associated with the use of the medical technology,

"(B) per use and/or aggregate cost of the medical technology,

"(C) the rate of utilization of the medical technology, and

"(D) the stage of development of the medical technology; and

"(2) undertake and support (by grant or contract or both) research, demonstrations, and evaluations concerning—

"(A) the safety, efficacy, effectiveness, cost effectiveness, and social, ethical, and economic impact of particular medical technologies;

"(B) the factors that affect the utilization of medical technologies throughout the United States;

"(C) alternative methods for disseminating information on medical technologies to health professionals;

"(D) alternative methods for measuring the quality of health services; and

"(E) the effectiveness, administration, and enforcement of quality assurance programs.

"(c) To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the National Institutes of Health, the Veterans' Administration and any other interested Federal departments or agencies and with State and local health departments and agencies.

"(i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

"(ii) of the members first appointed after the effective date of this section, five shall be appointed for a term of four years, five shall be appointed for a term of three years, five shall be appointed for a term of two years, and three shall be appointed for a term of one year, as designated by the Secretary at the time of appointment.

Appointed members may serve after the expiration of their terms until their successors have taken office.

"(B) A vacancy in the Council shall not affect its activities, and twelve members of the Council shall constitute a quorum.

"(C) Members of the Council who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the functions of the Council compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

"(3) The Council shall annually elect one of its appointed members to serve as Chairman until the next election.

"(4) The Director of the Center shall (1) designate a member of the staff of the Center to act as Executive Secretary of the Council, and (2) make available to the Council such staff, information, and other assistance as it may require to carry out its functions.

"(5) The Council shall meet at the call of the Chairman, but not less often than four times a year.

"(6) The Council is authorized to—

"(A) advise, consult with, and make recommendations to the Secretary, the Director of the National Institutes of Health Care Research, and the Director of the Center with respect to carrying out the provisions of this section;

"(B) after consultation with appropriate public and private entities, advice the Secretary concerning the safety, efficacy, effectiveness, cost effectiveness, and the social and economic impact of particular medical technologies;

"(C) after consultation with appropriate public and private entities, develop, when appropriate and to the extent practicable, exemplary standards, norms, and criteria concerning the utilization of particular medical technologies;

"(D) publish, make available and disseminate, through the National Library of Medicine, promptly in understandable form and as widely as possible, but, at a minimum, to all health systems agencies, to all Professional Standards Review Organizations and to the health facilities of the Veterans' Administration the standards, norms, and criteria developed pursuant to paragraph (C); and

"(E) review and approve any grant that the Center proposes to make and any contract the Center proposes to enter pursuant

appropriated under this paragraph for any fiscal year commencing after September 30, 1978, at least 15 per centum of such funds shall be available only for health statistical and epidemiological activities directly undertaken by the National Institute for Health Statistics and Epidemiology.".

(m) Section 308(i) is amended by adding at the end thereof the following new paragraph:

"(3) For medical technology research, evaluation, and demonstration activities undertaken or supported under section 304 or 306A, there are authorized to be appropriated $25,000,000 for the fiscal year ending September 30, 1979, $35,000,000 for the fiscal year ending September 30, 1980, and $50,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year commencing after September 30, 1980, at least 15 per centum of such funds shall be available only for medical technology research, evaluation, and demonstration activities directly undertaken by the National Center for the Evaluation of Medical Technology.".

SEC. 106. (a) Section 472(a)(1)(A) is amended by—

(1) striking "and" after "private institutions," in clause (iii);

(2) redesignating clause (iv) as clause (vii); and

(3) inserting after clause (iii) the following:

"(iv) research at the National Institutes of Health Care Research,

"(v) training at the National Institutes of Health Care Research to undertake such research,

"(vi) research on the matters set forth in section 304(b)(2) at public institutions and at nonprofit private institutions, and".

(b) The last sentence of section 472(a)(1) is amended by inserting ", National Institutes of Health Care Research," after "National Institutes of Health".

SEC. 107. Part K of title III is repealed in its entirety.

SEC. 108. Title IV is amended by adding at the end thereof the following new section:

"SEC. 477. The Director of the National Institutes of Health shall make available annually to the National Center for the Evaluation of Medical Technology and the Council for the Evaluation of Medical Technology a list of all technologies (as defined in section 306A(g)) of which he is aware that are under development and that appear likely to be used in medical practice in the near future.".

CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing laws made by the bill, as ordered reported, are shown as follows (existing law proposed to be

[(3) Secure, from time to time and for such periods as the Secretary deems advisable, the assistance and advice of experts and consultants from the United States or abroad.

[(4) Acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia.

[(c) The Secretary shall coordinate all health services research, evaluation, demonstration, and health statistical activities undertaken and supported through units of the Department of Health, Education, and Welfare. To the maximum extent feasible, such coordination shall he carried out through the National Center for Health Services Research and the National Center for Health Statistics.]

NATIONAL INSTITUTES OF HEALTH CARE RESEARCH

SEC. 304. (a) The Secretary shall establish, in the Department of Health, Education, and Welfare, the National Institutes of Health Care Research (hereinafter in this section referred to as the "Institutes"). The Institutes shall be headed by a Director appointed by the President, by and with the advice and consent of the Senate. The Director, with the approval of the Secretary, may appoint a Deputy Director and may employ and prescribe the functions of such officers and employees as are necessary to administer the activities to be carried out through the Institutes.

(b)(1) The Secretary, acting through the Institutes, shall conduct and support research, demonstrations, evaluations, and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

(2) In carrying out paragraph (1), the Secretary, acting through the Institutes shall give appropriate emphasis to research, demonstrations, evaluations, and statistical and epidemiological activities respecting—

(A) the accessibility, aceptability, planning, organization, distribution, utilization, and financing of systems for the delivery of health care,

(B) alternative methods for measuring and evaluating the quality of systems for the delivery of health care,

(C) the collection, analysis, and dissemination of health related statistics,

(D) alternative methods to improve and promote health statistical and epidemiological activities,

(E) the safety, efficacy, effectiveness, cost effectiveness, and social, economic, and ethical impacts of medical technologies, and

(F) alternative methods for disseminating knowledge concerning health and health related activities.

(3) The Secretary, acting through the Institutes, shall (through National Research Service Awards) undertake and support manpower training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects as set forth in sections 305, 306, and 306A.

shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Assistant Secretary for Health (or such other officer of the Department as may be designated by the Secretary as the principal adviser to him for health programs).]

(a) There is established in the National Institutes of Health Care Research the National Institute for Health Policy Research (hereinafter in this section referred to as the 'Institute') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.

(b) In carrying out section [304(a)] *304(b)*, the Secretary, acting through the [Center] *Institute*, [may undertake] *shall undertake* and support research, evaluation, [and] *and/or* demonstration projects (which may include and shall be appropriately coordinated with experiments and demonstration activities authorized by the Social Security Act and the Social Security Amendments of 1967) respecting—

(1) the accessibility, acceptability, planning, organization, distribution, [technology] utilization, quality, and financing of health services and systems;

(2) the supply and distribution, education and training, quality, utilization, organization, and costs of health manpower; [and]

(3) the design, construction, utilization, organization, and cost of facilities and equipment[.]; *and*

(4) the uses of computer science in health services delivery and medical information systems.

(c) The Secretary shall afford appropriate consideration to requests of—

(1) State, regional, and local health planning and health agencies,

(2) public and private entities and individuals engaged in the delivery of health care, and

(3) other persons concerned with health services,

to have the [Center] *Institute* or other units of the Department of Health, Education, and Welfare undertakere search, evaluations, and demonstrations respecting specific aspects of the matters referred to in subsection (b).

(d)(1) The Secretary, *acting through the Institute*, shall, by grants or contracts, or both, assist public or private nonprofit entities in meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services, research, evaluations, and demonstrations respecting the matter referred to in subsection (b). To the extent practicable, the Secretary, *acting through the Institute*, shall approve, in accordance with the requirements of this subsection and section 308, a number of applications for grants and contracts under this subsection which will result in at least six of such centers (including three national special emphasis centers, one of which (to be designated as the Health Care Tecnhology Center) shall focus on all forms of technology, including computers and electronic devices, and its applications in health care delivery; one of which (to be designated as the Health Care Management Center) shall focus on the improvement of management and organization in the health field, the training and retraining of administrators of health care enterprises, and the development of leaders, planners, and ploicy analysts in the health field; and one of which (to be designated as the

(1) collect statistics on—

(A) the extent and nature of illness and disability of the population of the United States (or of any groupings of the people included in the population), including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality,

(B) the impact of illness and disability of the population on the economy of the United States and on other aspects of the well-being of its population (or of such groupings),

(C) environmental, social, and other health hazards,

(D) determinants of health,

(E) health resources, including physicians, dentists, nurses, and other health professionals by specialty and type of practice and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions,

(F) utilization of health care, including utilization of (i) ambulatory health services by specialties and types of practice of the health professionals providing such services, and (ii) services of hospitals, extended care facilities, home health agencies, and other institutions,

(G) health care costs and financing, including the trends in health care prices and cost, the sources of payments for health care services, and Federal, State, and local governmental expenditures for health care services, and

(H) family formation, growth, and dissolution; [and]

(2) undertake and support (by grant or contract *or both*) research, demonstrations, [and] *and/or* evaluations respecting new or improved methods for obtaining current data on the matters referred to in paragraph (1),

(3) undertake and support (by grant or contract or both) epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1).

(c) The [Center] *Institute* shall furnish such special statistical *and epidemiological* compilations and surveys as the Committee on [Labor and Public Welfare] *Human Resources* and the Committee on Appropriations of the Senate and the Committee on Interstate and Foreign Commerce and the Committee on Appropriations of the House of Representatives may request. Such statistical *and epidemiological* compilations and surveys shall not be made subject to the payment of the actual or estimated cost of the preparation of such compilations and surveys.

(d) To insure comparability and reliability of health statistics, the Secretary shall, through the [Center] *Institute* provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of comfidentiality and comparability of data.

(e) The Secretary, *through the Institute,* shall (1) assist State and local health agencies, and Federal agencies involved in matters relating to health, in the design and implementation of a cooperative system for producing comparable and uniform health information and statistics at the Federal, State, and local levels *to be known as the Cooperative Health Statistics System;* (2) coordinate the activities of such Federal agencies respecting the design and implementation of [such cooperative system] *such System;* (3) undertake and support (by grant or

(4) It shall be the function of the Committee to assist and advise the Secretary—

(A) to delineate statistical problems bearing on health and health services which are of national or international interest;

(B) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;

(C) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use (i) within the Department of Health, Education, and Welfare, (ii) by all programs administered or funded by the Secretary, including the Federal-State-local cooperative health statistics system referred to in subsection (e), and (iii) to the extent possible as determined by the head of the agency involved, by the Veterans' Administration, the Department of Defense, and other Federal agencies concerned with health and health services;

(D) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health, Education, and Welfare;

(E) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

(F) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest; and

(G) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems.

(5) In carrying out health statistical activities under this part, the Secretary shall consult with, and seek the advice of, the Committee and other appropriate professional advisory groups.

(j) In carrying the requirements of sections 304(d) and paragraph (2) of subsection (e), the Secretary, acting through the Institute, shall coordinate health statistical and epidemiological activities of the Department of Health, Education, and Welfare by—

(1) developing in consultation with the National Committee on Vital and Health Statistics, promulgating by regulation, and maintaining the minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b)(1),

(2) after consultation with the National Committee on Vital and Health Statistics, establishing, by regulation, standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis,

(3) reviewing periodically all existing health statistical data collections of the Department that were previously approved pursuant to the Federal Reports Act of 1942 to determine whether such collections conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If any such collections are found not to be in conformance, the Secretary shall take the necessary action to assure that any future collections (effective ninety days after the review) are in conformance,

(2)(A) No grant or contract may be made under this subsection for planning and establishing a center unless the Secretary, acting through the Center, determined that when it is operational it will meet the requirements listed in subparagraph (B), and no payment shall be made under a grant or contract for operation of a center unless the center meets such requirements.

(B) Each center shall meet the following requirements:

(i) there shall be a full-time director of the center who possesses a demonstrated capacity for sustained productivity and leadership in research, demonstrations, and evaluations respecting the matters referred to in paragraph (2) of subsection (b), and there shall be such additional full-time professional staff as may be appropriate;

(ii) the staff of the center shall have expertise in the various disciplines needed to conduct multidisciplinary research, evaluations and demonstrations respecting the matters referred to in paragraph (2) of subsection (b);

(iii) the center shall be located within an established academic or research institution with departments and resources appropriate to the programs of the center; and

(iv) each center shall meet such additional requirements as the Secretary may by regulation prescribe.

(e)(1) There is established in the Center a National Council for the Evaluation of Medical Technologies (hereinafter in this subsection referred to as the "Council") to be composed as follows:

(A) the Surgeon General, the Director of the National Institutes of Health, the chief medical officer of the Veterans' Administration, the Chairman of the National Professional Standards Review Council (or their designees), and three other employees of the Department of Health, Education, and Welfare (or their designees) appointed by the Secretary, shall be ex officio members of the Council.

(B) Sixteen members appointed by the Secretary.

Seven of the appointed members shall be selected from among leading medical or scientific authorities; two of the appointed members shall be selected from members of the general public who are leaders in the field of economics; two of the appointed members shall be selected from members of the general public who are leaders in the field of law; and five of the appointed members shall be selected from outstanding members of the general public who, based on their interests, disciplines, and/or expertise, would be appropriate members of the Council.

(2)(A) Each appointed member of the Council shall be appointed for a term of four years, except that—

(i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

(ii) of the members first appointed after the effective date of this section, five shall be appointed for a term of four years, five shall be appointed for a term of three years, five shall be appointed for a term of two years, and three shall be appointed for a term of one year, as designated by the Secretary at the time of appointment.

Appointed members may serve after the expiration of their terms until their successors have taken office.

(B) A vacancy in the Council shall not affect its activities, and twelve members of the Council shall constitute a quorum.

and (B) the current state and progress of health services research and health statistics.]

[(2)] *(1)* The Secretary, acting through the [National Center for Health Services Research and the National Center for Health Statistics] *the National Institutes of Health Care Research*, shall assemble and submit to the President and the Congress not later than September 1 of each year the following reports:

(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section 306(b)(1)(G).

(B) A report on health resources. Such report shall include a description and analysis, by geographical area, of the statistics collected under section 306(b)(1)(E).

(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1)(F).

(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 306(b)(1)(A).

[(3)] *(2)* The Office of Management and Budget may review any report required by paragraph (1) or (2) of this subsection before its submission to Congress, but the Office may not revise any such report or delay its submission beyond the date prescribed for its submission, and may submit to Congress its comments respecting any such report.

(b)(1) No grant or contract may be made under section 304, 305, 306, *306A*, or 307 unless an application therefor has been submitted to the Secretary in such form and manner, and containing such information, as the Secretary may by regulation prescribe.

(2) * * *

* * * * * * *

(d) No information obtained in the course of activities undertaken or supported under section 304, 305, 306, *306A*, or 307 may be used for any purpose other than the purpose for which it was supplied unless authorized under regulations of the Secretary; and (1) in the case of information obtained in the course of health statistical *or epidemilogical* activities under section 304 or 306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form, and (2) in the case of information obtained in the course of health services research, evaluations, or demonstrations under section 304 or 305, such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(e)(1) Payments of any grant or under any contract under section 304, 305, 306, *306A*, or 307 may be made in advance or by way of reimbursement, and in such installments and on such conditions, as

at rates not less than those prevailing on similar work in the locality, as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 267a—267a–5, known as the Davis-Bacon Act); and the Secretary of Labor shall have with respect to any labor standards specified in this paragraph the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (5 U.S.C. Appendix) and section 2 of the Act of June 13, 1934 (40 U.S.C. 276c).

(3) Such grants and contracts shall be subject to such additional requirements as the Secretary may by regulation prescribe.

[(i)(1) For health service research, evaluation, and demonstration activities undertaken or supported under section 304 or 305, there are authorized to be appropriated $65,200,000 for the fiscal year ending June 30, 1975, and $80,000,000 for the fiscal year ending June 30, 1976. Of the funds appropriated under this paragraph for any fiscal year, not less than 25 per centum of such funds shall be made available only for health services research, evaluation, and demonstration activities directly undertaken by the Secretary under such section.]

(i)(1) For health services research, evaluation, and demonstration activities undertaken or supported under section 304 or 305, there are authorized to be appropriated $34,000,000 for the fiscal year ending September 30, 1979; $40,000,000 for the fiscal year ending September 30, 1980; and $45,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year, at least 15 per centum of such funds shall be available only for health services research, evaluation, and demonstration activities directly undertaken by the National Institute for Health Policy Research and at least 5 per centum of such funds or $1,000,000, whichever is less, shall be available only for dissemination activities directly undertaken by the Center.

[(2) For health statistical activities undertaken or supported under section 304 or 306, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1975, and $30,000,000 for the fiscal year ending June 30, 1976.]

(2) For health statistical and epidemiological activities undertaken or supported under section 304 or 306, there are authorized to be appropriated $60,000,000 for the fiscal year ending September 30, 1979, $65,000,000 for the fiscal year ending September 30, 1980, and $70,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year commencing after September 30, 1978, at least 15 per centum of such funds shall be available only for health statistical and epidemiological activities directly undertaken by the National Institute for Health Statistics and Epidemiology.

(3) For medical technology research, evaluation, and demonstration activities undertaken or supported under section 304 or 306A, there are authorized to be appropriated $25,000,000 for the fiscal year ending September 30, 1979, $35,000,000 for the fiscal year ending September 30, 1980, and $50,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year commencing after September 30, 1980, at least 15 per centum of such funds shall be available only for medical technology research, evaluation, and demonstration activities directly undertaken by the National Center for the Evaluation of Medical Technology.

* * * * * * *

ministration, in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems or Division of Nursing.

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

(iii) biomedical and behavioral research at public institutions and at nonprofit private institutions [and]

(iv) research at the National Institutes of Health Care Research,

(v) training at the National Institutes of Health Care Research to undertake such research,

(vi) research on the matters set forth in section 304(b)(2) at public institutions and at nonprofit private institutions, and

[(iv)] (vii) pre- and post doctoral training at such public and private institutions of individuals to undertake such research; and

(B) make grants to public institutions and to nonprofit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research (and training to undertake such research) in the matters described in subparagraph (A)(i).

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

* * * * * * *

SEC. 477. The Director of the National Institutes of Health shall make available annually to the National Center for the Evaluation of Medical Technology and the Council for the Evaluation of Medical Technology a list of all technologies (as defined in section 306(g)) of which he is aware that are under development and that appear likely to be used in medical practice in the near future.".

* * * * * * *

○

ministration, in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems or Division of Nursing.

(ii) training at the Institutes and Administration of individuals to undertake such research.

(iii) Biomedical and behavioral research at public institutions and to nonprofit private institutions [and]

(iv) research at the National Institutes of Health Care Research,

(v) training at the National Institutes of Health Care Research to undertake such research.

(vi) research on the matters set forth in section 304(b)(2) at public institutions and at nonprofit private institutions, and

[(iv)] (vii) pre- and post doctoral training at such public and private institutions of individuals to undertake such research, and

(vi) make grants to public institutions and to nonprofit private institutions to enable such institutions to make to individuals selected by them National Research Service Awards for research (and training to undertake such research) in the matters described in subparagraph (A)(i).

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

* * * * * * *

SEC. 477. The Director of the National Institutes of Health shall make available annually to the National Center for the Evaluation of Medical Technology and the Council for the Evaluation of Medical Technology a list of all technologies (as defined in section 308(g)) of which he is aware that are under development and that appear likely to be used in medical practice in the near future."

* * * * * * *

[PART K—QUALITY ASSURANCE

QUALITY ASSURANCE

[SEC. 399A. (a)(1) The Secretary, through the Assistant Secretary for Health, shall conduct research and evaluation programs respecting the effectiveness, administration, and enforcement of quality assurance programs. Such research and evaluation programs shall be carried out in cooperation with the entity within the Department which administers the programs of assistance under section 304.

[(2) For the purpose of carrying out paragraph (1), there are authorized to be appropriated $4,000,000 for the fiscal year ending June 30, 1974, $8,000,000 for the fiscal year ending June 30, 1975, $9,000,000 for the fiscal year ending June 30, 1976, $9,000,000 for the fiscal year ending June 30, 1977, and $10,000,000 for the fiscal year ending June 30, 1978.

[(b) The Secretary shall make an annual report to the Congress and the President on (1) the quality of health care in the United States, (2) the operation of quality assurance programs, and (3) advances made through research and evaluation of the effectiveness, administration, and enforcement of quality assurance programs. The first annual report under this subsection shall be made with respect to calendar year 1974 and shall be submitted not later than March 1, 1975. The Office of Management and Budget may review the Secretary's report under this subsection before its submission to the Congress, but the Office may not revise the report or delay its submission to the Congress, and it may submit to the Secretary and the Congress its comments (and those of other departments and agencies of the Government) with respect to such report.]

TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A * * *

* * * * * * *

PART I—GENERAL PROVISIONS

DIRECTORS OF INSTITUTES

SEC. 471. The Director of the National Institutes of Health shall be appointed by the President by and with the advice and consent of the Senate; and the Director of the National Cancer Institute shall be appointed by the President. Except as provided in section 407 (b)(9), the Director of the National Cancer Institute shall report directly to the Director of the National Institutes of Health.

NATIONAL RESEARCH SERVICE AWARDS

SEC. 472. (a) (1) The Secretary shall—

(A) provide National Research Service Awards for—

(i) biomedical and behavioral research at the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration or under programs administered by the Division of Nursing of the Health Resources Ad-

the Secretary deems necessary to carry out the purposes of such section.

(2) The amounts otherwise payable to any person under a grant or contract made under section 304, 305, 306, *306A*, or 307 shall be reduced by—

(A) amounts equal to the fair market value of any equipment or supplies furnished to such person by the Secretary for the purpose of carrying out the project with respect to which such grant or contract is made, and

(B) amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the Government in connection with such project, if such officer or employee was asigned or detailed by the Secretary to perform such services,

but only if such person requested the Secretary to furnish such equipment or supplies, or such services, as the case may be.

(f) Contracts may be entered into under section 304, 305, or [306] *306, 306A* without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

(g)(1) The Secretary shall—

(A) publish, make available and disseminate, promptly in understandable form and on as broad a basis as practicable, the results of health services research, demonstrations, and evaluations undertaken and supported under sections 304 and 305;

(B) make available to the public data developed in such research, demonstrations, and evaluations; and

(C) provide indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on health services research, demonstrations, and evaluations in health care delivery to public and private entities and individuals engaged in the improvement of health care delivery and the general public; and undertake programs to develop new or improved methods for making such information available.

Except as provided in subsection (d), the Secretary may not restrict the publication and dissemination of data from, and results of projects undertaken by, centers supported under section 305(d).

(2) The Secretary shall (A) take such action as may be necessary to assure that statistics developed under sections 304, 305, [and 306] *306, and 306A* are of high quality, timely, comprehensive as well as specific, standardized, and adequately analyzed and indexed, and (B) publish, make available, and disseminate such statistics on as wide a basis as is practicable.

(h)(1) Except where the Secretary determines that unusual circumstances make a larger percentage necessary in order to effectuate the purposes of section 304, 305, [or 306] *306, or 306A*, a grant or contract under section 304, 305, [or 306] *306, or 306A* with respect to any project for construction of a facility or for acquisition of equipment may not provide for payment of more than 50 per centum of so much of the cost of the facility or equipment as the Secretary determines is reasonably attributable to research, evaluation, or demonstration purposes.

(2) Laborers and mechanics employed by contractors and subcontractors in the construction of such a facility shall be paid wages

(C) Members of the Council who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the functions of the Council compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(3) The Council shall annually elect one of its appointed members to serve as Chairman until the next election.

(4) The Director of the Center shall (1) designate a member of the staff of the Center to act as Executive Secretary of the Council, and (2) make available to the Council such staff, information, and other assistance as it may require to carry out its functions.

(5) The Council shall meet at the call of the Chairman, but not less often than four times a year.

(6) The Council is authorized to—

(A) advise, consult with, and make recommendations to the Secretary, the Director of the National Institutes of Health Care Research, and the Director of the Center with respect to carrying out the provisions of this section;

(B) after consultation with appropriate public and private entities, advise the Secretary concerning the safety, efficacy, effectiveness, cost effectiveness, and the social and economic impact of particular medical technologies;

(C) after consultation with appropriate public and private entities, develop, when appropriate and to the extent practicable, exemplary standards, norms, and criteria concerning the utilization of particular medical technologies;

(D) publish, make available and disseminate, through the National Library of Medicine, promptly in understandable form and as widely as possible, but, at a minimum, to all health systems agencies, to all Professional Standards Review Organizations and to the health facilities of the Veterans' Administration the standards, norms, and criteria developed pursuant to paragraph (C); and

(E) review and approve any grant that the Center proposes to make and any contract the Center proposes to enter pursuant to this section if such grant or contract is in an amount exceeding $35,000 of direct costs.

(f) For purposes of this section, medical technology means any discrete and identifiable medical or surgical regimen or modality used to diagnose or treat illness, prevent disease, support life, or maintain patient well-being.".

SEC. 307.* * *

* * * * * * *

GENERAL PROVISIONS RESPECTING SECTIONS [304, 305, 306, AND 307] *304, 305, 306, 306A, AND 307*

SEC. 308. (a) [(1) Not later than December 1 of each year, the Secretary shall make a report to Congress respecting (A) the administration of sections 304 through 307 during the preceding fiscal year,

(4) reviewing all proposed health statistical data collections of the Department that require approval pursuant to the Federal Reports Act of 1942 to determine whether such proposed collections conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If any such proposed collections are found not to be in conformance, the Secretary shall take the necessary action to bring them into conformance before such proposed collections are initiated.

NATIONAL CENTER FOR THE EVALUATION OF MEDICAL TECHNOLOGY

SEC. 306A. (a) There is established in the National Institutes of Health Care Research the National Center for the Evaluation of Medical Technology (hereinafter in this section referred to as the "Center") which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.

(b) The Secretary, acting through the Center, shall—

(1) establish, in consultation with the Council for the Evalutaion of Medical Technology, priorities for research, demonstrations, and evaluations of medical technologies as prescribed by paragraph (2)(A). In establishing such priorities, particular emphasis should be placed on—

(A) the actual or potential risks and the actual or potential benefits to patients associated with the use of the medical technology,

(B) per use and/or aggregate cost of the medical technology,

(C) the rate of utilization of the medical technology, and

(D) the stage of development of the medical technology; and

(2) undertake and support (by grant or contract or both) research, demonstrations, and evaluations concerning—

(A) the safety, efficacy, effectiveness, cost effectiveness, and social, ethical, and economic impact of particular medical technologies;

(B) the factors that affect the utilization of medical technologies throughout the United States;

(C) alternative methods for disseminating information on medical technologies to health professionals;

(D) alternative methods for measuring the quality of health services; and

(E) the effectiveness, administration, and enforcement of quality assurance programs.

(c) To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the National Institutes of Health, the Veterans' Administration and any other interested Federal departments or agencies and with State and local health departments and agencies.

(d)(1) The Secretary, acting through the Center, shall, by grants or contracts, or both, assist public and/or private nonprofit entities in meeting the costs of planning and establishing new centers, and operating existing and new centers for multidisciplinary research, evaluations, and demonstrations respecting the matters referred to in paragraph (2) of subsection (b). To the extent practicable, the Secretary shall take such actions, in accordance with the requirements of this subsection and section 308, to assure that three such centers shall be operational by September 1, 1981.

contract *of both*) research, development, demonstrations, and evaluations respecting [such cooperative system] *such System;* (4) provide the Federal share of the data collection costs under such system; and (5) review statistical activities of the Department of Health, Education, and Welfare to assure that they are consistent with [such cooperative system] *such System.*

(f) To assist in carrying out this section, the Secretary, *through the Institute,* shall cooperate and consult with the Departments of Commerce and Labor and any otber interested Federal departments or agencies and with State and local health departments and agencies. For such purpose he shall utilize insofar as possible the services or facilities of any agency of the Federal Government and, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5), of any appropriate State or other public agency, and may, without regard to such section, utilize the services or facilities of any private agency, organization, group, or individual, in accordance with written agreements between the head of such agency, organization, or group and the Secretary or between such individual and the Secretary. Payment, if any, for such services or facilities shall be made in such amounts as may be provlded in such agreement.

(g) To secure uniformity in the registration and collection of mortality, morbidity, and other health data, the Secretary, *through the Institute,* shall prepare and distribute suitable and necessary forms for the collection and compilation of such data which shall be published as a part of the health reports published by the Secretary.

(h) There shall be an annual collection of data from the records of births, deaths, marriages, and divorces in registration areas. The data shall be obtained only from and restricted to such records of the States and municipalities which the Secretary, in his discretion, determines possess records affording satisfactory data in necessary detail and form. Each State or registration area shall be paid by the Secretary the Federal share of its reasonable costs (as determined by the Secretary) for collecting and transcribing (at the request of the Secretary and by whatever method authorized by him) its records for such data.

(i)(1) There is established in the Office of the Secretary a committee to be known as the [United States] National Committee on Vital and Health Statistics (hereinafter in this subsection, referred to as the "Committee") which shall consist of fifteen members.

(2)(A) The members of the Committee shall be appointed by the Secretary from among persons who have distinguished themselves in the fields of health statistics, epidemiology, and the provision of health services. Except as provided in subparagraph (B), members of the Committee shall be appointed for terms of three years.

(B) Of the members first appointed—

(i) five shall be appointed for terms of one year,

(ii) five shall be appointed for terms of two years, and

(iii) five shall be appointed for terms of three years,

as designated by the Secretary at the time of appointment. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which his prodecessor was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of his term until his successor has taken office.

(3) Members of the Committee shall be compensated in accordance with section 208(c).

Health Services Policy Analysis Center), shall focus on the development and evaluation of national policies with respect to health services, including the development of health maintenance organizations and other forms of group practice, with a view toward improving the efficiencies of the health services delivery system) being operational in each fiscal year.

(2)(A) No grant or contract may be made under this subsection for planning and establishing a center unless the Secretary, *acting through the Institute*, determines that when it is operational it will meet the requirements listed in subparagraph (B) and no payment shall be made under a grant or contract for operation of a center unless the center meets such requirements.

(B) The requirements referred to in subparagraph (A) are as follows:

(i) There shall be a full-time director of the center who possesses a demonstrated capacity for sustained productivity and leadership in health services research, demonstrations, and evaluations, and there shall be such additional full-time professional staff as may be appropriate.

(ii) The staff of the center shall represent all relevant disciplines.

(iii) The center shall (I) be located within an established academic or research institution with departments and resources appropriate to the programs of the center, and (II) have working relationships with health service delivery systems where experiments in health services may be initiated and evaluated.

(iv) The center shall select problems in health services for research, demonstrations, and evaluations on the basis of (I) their regional or national importance, (II) the unique potential for definitive research on the problem, and (III) opportunities for local application of the research findings.

(v) Such additional requirements as the Secretary may by regulation prescribe.

(a) The authority of the Secretary under section [304(b)] *304(c)* shall be available to him with respect to the undertaking and support of projects under subsections (b), (c), and (d) of this section.

[NATIONAL CENTER FOR HEALTH STATISTICS]

NATIONAL INSTITUTE FOR HEALTH STATISTICS AND EPIDEMIOLOGY

SEC. 306. [(a) There is established in the Department of Health, Education, and Welfare the National Center for Health Statistics (hereinafter in this section referred to as the "Center") which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Assistant Secretary for Health (or such other officer of the Department as may be designated by the Secretary as the principal adviser to him for health programs).]

(a) There is established in the National Institutes of Health Care Research the National Institute for Health Statistics and Epidemiology (hereinafter in this section referred to as the 'Institute') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.

(b) In carrying out section [304(a)] *304(b)*, the Secretary, acting through the [Center] *Institute*, [may] *shall*—

(4) The Secretary, acting through the Institutes, shall supervise the administration and operation of the National Institute for Health Policy Research, the National Institute for Health Statistics and Epidemiology, and the National Center for the Evaluation of Medical Technology in order to assure that (A) the programs carried out through each such Institute and Center receive appropriate and equitable support, and (B) there is cooperation among the Institutes and the Center in the implementation of such programs.

(c) To implement subsection (b), the Secretary may, in addition to any other authority which under other provisions of this Act or any other law may be used by him to implement such subsection, do the following:

(1) utilize personnel and equipment facilities, and other physical resources of the Department of Health, Education, and Welfare, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, provide technical assistance and advice, make grants to public and nonprofit entities and individuals, and, when appropriate, enter into contracts with public and private entities and individuals;

(2) secure, from time to time and for such periods as the Secretary deems advisable, the assistance and advice of experts and consultants from the United States or abroad. In addition, the Director of the National Institute for Health Policy Research and the Director of the National Institute for Statistics and Epidemiology, in order to assist each of them in carrying out the functions set forth in sections 305 and 306 respectively, and without regard to any other provision of this Act, are each authorized to obtain the services of not more than fifteen experts or consultants who have appropriate scientific or professional qualifications; and

(3) acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia.

(d) The Secretary shall coordinate all research, evaluation, demonstration, and statistical and epidemiological activities referred to in subsection (b) undertaken and supported through units of the Department of Health, Education, and Welfare. Such coordination shall be carried out through the Institutes.

(e) The Director of the Institutes shall submit a report to the Secretary for simultaneous transmittal, not later than October 30 of each year, to the President and to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives setting forth the program accomplishments of the Institutes in the preceding fiscal year and the objectives and priorities for the current fiscal year.

[NATIONAL CENTER FOR HEALTH SERVICES RESEARCH]

NATIONAL INSTITUTE FOR HEALTH POLICY RESEARCH

SEC. 305. [(a) There is established in the Department of Health, Education, and Welfare the National Center for Health Services Research (hereinafter in this section referred to as the "Center") which

omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION IN GENERAL

SEC. 301. * * *

* * * * * * *

GENERAL AUTHORITY RESPECTING HEALTH STATISTICS AND HEALTH SERVICES RESEARCH, EVALUATIONS, AND DEMONSTRATIONS

SEC. 304. (a)(1) The Secretary shall—

(A) undertake through the National Center for Health Services Research, the National Center for Health Statistics, and such other units of the Department of Health, Education, and Welfare as he may select, and

(B) support,

health statistical activities and health services research, evaluation, and demonstrations.

(2) In carrying out paragraph (1), the Secretary shall give appropriate emphasis to research and statistical activities respecting—

(A) the determinants of an individual's health,

(B) the impact of the environment on individual health and on health care,

(C) the accessibility, acceptability, planning, organization, technology, distribution, utilization, quality, and financing of systems for the delivery of health care, including systems for the delivery of preventive, personal, and mental health care, and

[(D) individual and community knowledge of individual health and the systems for the delivery of health care.

[(b) To implement subsection (a), the Secretary may, in addition to any other authority which under other provisions of this Act or any other law may be used by him to implement such subsection, do the following:

[(1) Utilize personnel and equipment, facilities, and other physical resources of the Department of Health, Education, and Welfare, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, provide technical assistance and advice, make grants to public and nonprofit private entities and individuals, and enter into contracts with public and private entities and individuals, for (A) health services research, evaluation, and demonstrations, and (B) health services research and health statistics training, and (C) health statistical activities.

[(2) Admit and treat at hospitals and other facilities of the Service persons not otherwise eligible for admission and treatment at such facilities.

to this section if such grant or contract is in an amount exceeding $35,000 of direct costs.

"(f) For purposes of this section, medical technology means any discrete and identifiable medical or surgical regimen or modality used to diagnose or treat illness, prevent disease, support life, or maintain patient well-being.".

SEC. 105. (a) The heading to section 308 is amended by striking "304, 305, 306, AND 307" and inserting in lieu thereof "304, 305, 306A, and 307".

(b) Section 308(a)(1) is repealed.

(c) Section 308(a)(2) is amended by (1) redesignating it as section 308(a) (1), and (2) striking "the National Center for Health Services Research and the National Center for Health Statistics" and inserting in lieu thereof "the National Institutes of Health Care Research".

(d) Section 308(a)(3) is redesignated as section 308(a)(2).

(e) Section 308(b)(1) is amended by inserting "306A," after "306".

(f) Section 308(d) is amended by (1) inserting "306A," before "or 307" and (2) by inserting "or epidemilogical" after "statistical" in paragraph (1).

(g) Section 308(e) is amended by inserting "306A", after "306" each place it occurs.

(h) Section 308(f) is amended by striking "or 306" and inserting in lieu thereof "306, or 306A".

(i) Section 308(g)(2) is amended by striking "and 306" and inserting in lieu thereof "306, and 306A".

(j) Section 308(h)(1) is amended by striking "or 306" each place it occurs and inserting in lieu thereof "306, or 306A".

(k) Section 308(i)(1) is amended to read as follows:

"(i)(1) For health services research, evaluation, and demonstration activities undertaken or supported under section 304 or 305, there age authorized to be appropriated $34,000,000 for the fiscal year endinr September 30, 1979; $40,000,000 for the fiscal year ending September 30, 1980; and $45,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year, at least 15 per centum of such funds shall be available only for health services research, evaluation, and demonstration activities directly undertaken by the National Institute for Health Policy Research and at least 5 per centum of such funds or $1,000,000, whichever is less, shall be available only for dissemination activities directly undertaken by the Center.".

(l) Section 308(i)(2) is amended to read as follows:

"(i)(2) For health statistical and epidemiological activities undertaken or supported under section 304 or 306, there are authorized to be appropriated $60,000,000 for the fiscal year ending September 30, 1979, $65,000,000 for the fiscal year ending September 30, 1980, and $70,000,000 for the fiscal year ending September 30, 1981. Of the funds

"(d)(1) The Secretary, acting through the Center, shall, by grants or contracts, or both, assist public and/or private nonprofit entities in meeting the costs of planning and establishing new centers, and operating existing and new centers for multidisciplinary research, evaluations, and demonstrations respecting the matters referred to in paragraph (2) of subsection (b). To the extent practicable, the Secretary shall take such actions, in accordance with the requirements of this subsection and section 308, to assure that three such centers shall be operational by September 1, 1981.

"(2) (A) No grant or contract may be made under this subsection for planning and establishing a center unless the Secretary, acting through the Center, determines that when it is operational it will meet the requirements listed in subparagraph (B), and no payment shall be made under a grant or contract for operation of a center unless the center meets such requirements.

"(B) Each center shall meet the following requirements:

"(i) there shall be a full-time director of the center who possesses a demonstrated capacity for sustained productivity and leadership in research, demonstrations, and evaluations respecting the matters referred to in paragraph (2) of subsection (b), and there shall be such additional full-time professional staff as may be appropriate;

"(ii) the staff of the center shall have expertise in the various disciplines needed to conduct multidisciplinary research, evaluations and demonstrations respecting the matters referred to in paragraph (2) of subsection (b);

"(iii) the center shall be located within an established academic or research institution with departments and resources appropriate to the programs of the center; and

"(iv) each center shall meet such additional requirements as the Secretary may by regulation prescribe.

"(e) (1) There is established in the Center a National Council for the Evaluation of Medical Technologies (hereinafter in this subsection referred to as the 'Council') to be composed as follows:

"(A) the Surgeon General, the Director of the National Institutes of Health, the chief medical officer of the Veterans' Administration, the Chairman of the National Professional Standards Review Council (or their designees), and three other employees of the Department of Health, Education, and Welfare (or their designees) appointed by the Secretary, shall be ex officio members of the Council.

"(B) Sixteen members appointed by the Secretary. Seven of the appointed members shall be selected from among leading medical or scientific authorities; two of the appointed members shall be selected from members of the general public who are leaders in the field of economics; two of the appointed members shall be selected from members of the general public who are leaders in the field of law; and five of the appointed members shall be selected from outstanding members of the general public who, based on their interests, disciplines, and/or expertise, would be appropriate members of the Council.

"(2) (A) Each appointed member of the Council shall be appointed for a term of four years, except that—

shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.".

(c) Section 306(b) is amended by—

(1) striking "304(a)" and inserting in lieu thereof "304(b)";

(2) striking "Center" and inserting in lieu thereof "Institute";

(3) striking "may" and inserting in lieu thereof "shall";

(4) striking "and" after "dissolution" in paragraph (1)(H);

(5) inserting "or both" after "contract" in paragraph (2);

(6) striking "and" after "demonstrations," in paragraph (2) and inserting in lieu thereof "and/or"; and

(7) adding at the end thereof the following new paragraph:

"(3) undertake and support (by grant or contract or both) epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1).".

(d) Section 306(c) is amended by—

(1) striking "Center" and inserting in lieu thereof "Institute";

(2) by inserting "and epidemiological" after "statistical" each place it occurs; and

(3) striking "Labor and Public Welfare" and inserting in lieu thereof "Human Resources".

(e) Section 306(d) is amended by striking "Center" and inserting in lieu thereof "Institute".

(f) Section 306(e) is amended by—

(1) inserting ", through the Institute," after "Secretary";

(2) inserting "to be known as the Cooperative Health Statistics System" after "levels" in paragraph (1);

(3) striking "such cooperative system" each place it occurs and inserting in lieu thereof "such System";

(4) inserting "or both" after "contract" in paragraph (3);

(g) The first sentence of section 306(f) is amended by inserting ", through the Institute," after "Secretary".

(h) Section 306(g) is amended by inserting "; through the Institute," after "health data, the Secretary".

(i) Section 306(i)(1) is amended by striking "United States".

(j) Section 306 is amended by adding at the end thereof the following new subsection:

"(j) In carrying out the requirements of sections 304(d) and paragraph (2) of subsection (e), the Secretary, acting though the Institute, shall coordinate health statistical and epidemiological activities of the Department of Health, Education, and Welfare by—

"(1) developing in consultation with the National Committee on Vital and Health Statistics, promulgating by regulation, and maintaining tbe minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b)(1),

"(2) after consultation with the National Committee on Vital and Health Statistics, establishing, by regulation, standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis.

"(3) reviewing periodically all existing health statistical data collections of the Department that were previously approved pursuant to the Federal Reports Act of 1942 to determine whether such collections conform with the minimim sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If

"(C) the collection, analysis, and dissemination of health related statistics,

"(D) alternative methods to improve and promote health statistical and epidemiological activities,

"(E) the safety, efficacy, effectiveness, cost effectiveness, and social, economic, and ethical impacts of medical technologies, and

"(F) alternative methods for disseminating knowledge concerning health and health related activities.

"(3) The Secretary, acting through the Institutes, shall (through National Research Service Awards) undertake and support manpower training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects as set forth in sections 305, 306, and 306A.

"(4) The Secretary, acting through the Institutes, shall supervise the administration and operation of the National Institute for Health Policy Research, the National Institute for Health Statistics and Epidemiology, and the National Center for the Evaluation of Medical Technology in order to assure that (A) the programs carried out through each such Institute and Center receive appropriate and equitable support, and (B) there is cooperation among the Institutes and the Center in the implementation of such programs.

"(c) To implement subsection (b), the Secretary may, in addition to any other authority which under other provisions of this Act or any other law may be used by him to implement such subsection, do the following:

"(1) utilize personnel and equipment, facilities, and other physical resources of the Department of Health, Education, and Welfare, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, provide technical assistance and advice, make grants to public and nonprofit entities and individuals, and, when appropriate, enter into contracts with public and private entities and individuals;

"(2) secure, from time to time and for such periods as the Secretary deems advisable, the assistance and advice of experts and consultants from the United States or abroad. In addition, the Director of the National Institute for Health Policy Research and the Director of the National Institute for Statistics and Epidemiology, in order to assist each of them in carrying out the functions set forth in sections 305 and 306 respectively, and without regard to any other provision of this Act, are each authorized to obtain the services of not more than fifteen experts or consultants who have appropriate scientific or professional qualifications; and

"(3) acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia.

New section 308(i)(1).—Provides authorizations of appropriations for health services research, evaluation, and demonstration activities undertaken or supported by section 304 or 305 as follows:

Fiscal year:	*Millions*
1979	$40
1980	45
1981	50

Requires that of the funds appropriated for these purposes for any fiscal year at least 15 percent be available only for health services research, evaluation, and demonstration activities directly undertaken by the National Institute for Health Policy Research and at least five percent or $1 million, whichever is less, be available only for dissemination activities directly undertaken by the Institute.

New section 308(i)(2).—Provides authorizations of appropriations for health statistical and epidemiological activities undertaken or supported by section 304 or 306 as follows:

Fiscal year:	*Millions*
1979	$60
1980	65
1981	70

Requires that of the funds appropriated for these purposes for any fiscal year commencing after September 30, 1978, at least 15 percent be available only for health statistical and epidemiological activities directly undertaken by the National Institute for Health Statistics and Epidemiology.

New section 309(i)(3).—Provides authorizations of appropriations for medical technology research, evaluation, and demonstration activities undertaken or supported by section 304 or 306A as follows:

Fiscal year:	*Millions*
1979	$25
1980	35
1981	50

Requires that of the funds appropriated for these purposes for any fiscal year commencing after September 30, 1978, at least 15 percent be available only for medical technology research, evaluation, and demonstration activities directly undertaken by the National Center for the Evaluation of Medical Technology.

Section 106.—Amends Section 472 of the PHS Act to authorize the Secretary to provide National Research Service Awards for research and training at the National Institutes of Health Care Research.

Section 107.—Repeals Part K of Title III, section 399A, which requires the Secretary to conduct research and evaluation programs respecting the effectiveness administration, and enforcement of quality assurance programs.

Section 108.—Adds to Title IV a new section 477 which requires the Director of the National Institutes of Health to make available annually to the National Center for the Evaluation of Medical Technology and the Council for the Evaluation of Medical Technology a list of all technologies (as defined in section 306A) of which he is aware that are under development and that appear likely to be used in medical practice in the near future.

Section 109.—Requires the Secretary, acting through the National Institute for Health Policy Research, to arrange for a study, to be completed within 30 months, of the impact on utilization of services

of this subsection before its submission to Congress, but the Office may not revise any such report or delay its submission beyond the date prescribed for its submission, and may submit to Congress its comments on any such report.

New section 308(b).—Provides that no grant or contract may be made under section 304, 305, 306, 306A, or 307 unless an application has been submitted to the Secretary in such form and manner, and containing such information, as he may prescribe by regulation. Specifies that each application submitted for a grant or contract under section 304 or 305, in an amount exceeding $35,000 of direct costs and for a health services research, evaluation, or demonstration project, shall be submitted by the Secretary for review for scientific merit to a panel of experts appointed by him from persons who are not officers or employees of the United States and who possess qualifications relevant to the project for which the application was made. A panel to which an application is submitted under this paragraph shall report its findings and recommendations respecting the application to the Secretary in such form and manner as the Secretary shall by regulation prescribe. Further specifies that if an application is submitted under section 305, or 306 for a grant or contract for a project for which a grant or contract may be made or entered into under another provision of this Act, such application may not be approved under section 304, 305, or 306 and funds appropriated under this section may not be obligated for such grant or contract. The applicant who submitted such application shall be notified of the other provision (or provisions) of this Act under which such application may be submitted.

Section 308(c).—Specifies that the aggregate number of grants and contracts made or entered into under sections 304 and 305 for any fiscal year respecting a particular means of delivery of health services or another particular aspect of health services may not exceed twenty; and the aggregate amount of funds obligated under grants and contracts under such sections for any fiscal year respecting a particular means of delivery of health services or another particular aspect of health services may not exceed $5,000,000.

New section 308(d).—Specifies that no information obtained in the course of activities undertaken or supported under section 304, 305, 306, 306A, or 307 may be used for any purpose other than the purpose for which it was supplied unless authorized under regulations of the Secretary; and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section 304 or 306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form, and (2) in the case of information obtained in the course of health services research, evaluations, or demonstrations under section 304 or 305, such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

New section 308(e).—Specifies that payments of any grant or contract under section 304, 305, 306, 306A, or 307 may be made in

(B) per use and/or aggregate cost of the medical technology,
(C) the rate of utilization of the medical technology, and
(D) the state of development of the medical technology; and

(2) undertake and support (by grant or contract or both) research, demonstrations, and evaluations concerning—

(A) the safety, efficacy, effectiveness, cost effectiveness, and social, ethical, and economic impact of particular medical technologies;

(B) the factors that affect the utilization of medical technologies throughout the United States;

(C) alternative methods for disseminating information on medical technologies to health professionals;

(D) alternative methods for measuring the quality of health services; and

(E) the effectiveness, administration, and enforcement of quality assurance programs.

New section 306A(c).—Requires the Secretary, acting through the Center, to cooperate and consult with the National Institute of Health, the Veterans' Administration and any other interested Federal departments or agencies and with State and local health departments and agencies, so as to assist in carrying out this action.

New section 306A(d).—Requires the Secretary, acting through the Center, to assist by grants or contracts, or both, public and/or private nonprofit entities in meeting the costs of planning and establishing new centers, and operating existing and new centers for the multidisciplinary research, evaluations, aud demonstrations referred to above in subparagraph (b)(2). Specifies that, to the extent practicable, the Secretary shall take such actions, in accordance with the requirements of this subsection and section 308, to assure that three such centers shall be operational by September 1981. Specifies requirements for assistance.

New section 306A(e).—Requires the establishment in the Center of a National Council for the Evaluation of Medical Technologies (hereinafter in this subsection referred to as the "Council") to be composed as follows:

(A) the Surgeon General, the Director of the National Institute of Health, the chief medical officer of the Veterans' Administration, the Chairman of the National Professional Standards Review Council (or their designees), and three other employees of the Department of Health, Education, and Welfare (or their designees appointed by the Secretary, shall be ex officio members of the Council.

(B) Sixteen members appointed by the Secretary. Seven of the appointed members shall be selected from among leading medical or scientific authorities; two of the appointed members shall be selected from members of the general public who are leaders in the field of economics; two of the appointed members shall be selected from members of the general public who are leaders in the field of law: and five of the appointed members shall be selected from outstanding members of the general public who, based on their interests, disciplines, and/or expertise, would be appropriate members of the council.

New section 306(g).—Requires the Secretary, through the Institute, to prepare and distribute suitable and necessary forms for the collection and compilation of such data, in order to secure uniformity in the registration and collection of mortality, morbidity, and other health data.

New section 306(h).—Requires an annual collection of data from the records of births, deaths, marriages, and divorces in registration areas. Specifies that the data shall be obtained only from and restricted to such records of the States and municipalities which the Secretary, in his discretion, determines possess records affording satisfactory data in necessary detail and form. Further specifies that each State or registration area shall be paid by the Secretary the Federal share of its reasonable costs (as determined by the Secretary) for collecting and transcribing (at the request of the Secretary and by whatever method authorized by him) its records for such data.

New section 306(i).—Makes a technical amendment in current law's requirement that a committee be established in the Office of the Secretary to be known as the National Committee on Vital and Health Statistics. Specifies that the Committee shall consist of 15 members and shall be appointed by the Secretary from among persons who have distinguished themselves in the fields of health statistics, epidemiology, and the provision of health services. Specifies terms of offices for members. Provides that the function of the Committee shall be to assist and advise the Secretary—

(A) to delineate statistical problems bearing on health and health services which are of national or international interest;

(B) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;

(C) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use (i) within DHEW, (ii) by all programs administered or funded by the Secretary, including the Federal-State-local Cooperative Health Statistics System, and (iii) to the extent possible as determined by the head of the agency involved, by the Veterans' Administration, the Department of Defense, and other Federal agencies concerned with health and health services;

(D) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within DHEW;

(E) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

(F) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest; and

(G) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems.

(2) public and private entities and individuals engaged in the delivery of health care, and

(3) other persons concerned with health services, to have the Institute or other units of DHEW undertake the research, evaluations, and demonstrations mentioned above in subsection (b).

New section 305(d).—Requires the Secretary, acting through the Institute to assist public or private nonprofit entities, through grants or contracts, or both, in meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, evaluations, and demonstrations, mentioned above. Specifies centers to be established and requirements for assistance.

New section 305(e).—

New section 305(f).—Makes conforming technical amendments. Specifies that the implementation authority available to the Secretary under subsection 304(c) above shall be available to him with regard to the implementation of this section.

Section 103.—Revises section 306 of the PHS Act, National Center for Health Statistics with a series of substantive and conforming technical amendments. Redesignates this Section as the National Institute for Health Statistics and Epidemiology.

New section 306(a).—Establishes in the National Institutes of Health Care Research the National Institute for Health Statistics and Epidemiology (hereinafter in this section referred to as the "Institute"). Requires that this Institute be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.

New section 306(b).—Requires the Secretary, acting through the Institute to—

(1) collect statistics on—

(A) the extent and nature of illness and disability of the population of the U.S. (or of any groupings of the people included in the population), including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality;

(B) the impact of illness and disability of the population on the economy of the U.S. and on other aspects of the well-being of its population (or of such groupings);

(C) environmental, social, and other health hazards;

(D) determinants of health;

(E) health resources, including physicians, dentists, nurses and other health professionals by speciality and type of practice and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions;

(F) utilization of health care, including utilization of (i) ambulatory health services by specialities and types of practice of the health professionals providing such services, and (ii) services of hospitals, extended care facilities, home health agencies, and other institutions;

(G) health care costs and financing, including the trends in health care prices and costs, the sources of payments for

tions, and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

New section 304(b)(2).—Requires the Secretary, acting through the Institutes, to give appropriate emphasis to research, demonstrations, evaluations, and statistical and epidemiological activities which examine—

(A) the accessibility, acceptability, planning, organization, distribution, utilization, and financing of systems for the delivery of health care;

(B) alternative methods for measuring and evaluating the quality of systems for the delivery of health care;

(C) the collection, analysis, and dissemination of health related statistics;

(D) alternative methods to improve and promote health statistical and epidemiological activities;

(E) the safety, efficacy, effectiveness, cost effectiveness, and social, economic, and ethical impacts of medical technologies; and

(F) alternative methods for disseminating knowledge concerning health and health related activities.

New section 304(b)(3).—Requires the Secretary, acting through the Institutes and with National Research Service Awards, to undertake and support manpower training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects as indicated in sections 305, 306, and 306A below.

New section 304(b)(4).—Requires the Secretary, acting through the Institutes, to supervise the administration and operation of the National Institute for Health Policy Research, the National Institute for Health Statistics and Epidemiology, and the National Center for the Evaluation of Medical Technology in order to assure that (A) the programs carried out through each such Institute and Center receive appropriate and equitable support, and (B) there is cooperation among the Institutes and the Center in the implementation of such programs.

New section 304(c).—Specifies that in implementing the above subsection (b), the Secretary may use the authorities to this enactment or any other law. Also specifies that he may do the following:

(1) utilize personnel and equipment, facilities, and other physical resources of DHEW, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of the Department, provide technical assistance and advice, make grants to public and nonprofit entities and individuals, and, when appropriate, enter into contracts with public and private entities and individuals;

(2) secure, from time to time and for such periods as the Secretary deems advisable, the assistance and advice of experts and consultants from the U.S. or abroad. Authorizes the Director of the National Institute for Health Policy Research and the Director of the National Institute for Statistics and Epidemiology, in order to assist each in carrying out his functions specified below (see Sections 305 and 306) and without regard to any other provision of this Act, to obtain the services of not more than 15

VI. Tabulation of Votes Cast in Committee

Pursuant to section 133(b) of the Legislative Reorganization Act of 1949, as amended, the following is a tabulation of votes in committee:

The motion by Mr. Kennedy to favorably report the bill as amended to the Senate carried as follows:

YEAS	NAYS	NOT VOTING
Mr. Williams		Mr. Nelson
Mr. Randolph		
Mr. Pell		
Mr. Kennedy		
Mr. Eagleton		
Mr. Cranston		
Mr. Hathaway		
Mr. Riegle		
Mr. Javits		
Mr. Schweiker		
Mr. Stafford		
Mr. Hatch		
Mr. Chafee		
Mr. Hayakawa		

VII. Regulatory Impact Statement for S. 2466

Pursuant to rule XXIX of the Standing Rules of the Senate, as amended by Senate Resolution 4 (Feb. 4, 1977), the committee makes the following statement concerning the regulatory impact that would be incurred in carrying out the provisions of section 104 of the bill as reported by the committee.

For the most part, this legislation simply extends for three years the expiring authorities for health services research. Regulations now in effect or in the process of being promulgated regarding the policies and procedures for awarding grants for health services research will not be affected by this legislation. New regulations would be required to implement the health services research training program which would be made mandatory were this bill be be enacted.

The regulations that would be developed to implement a health services research training program would apply to a few academic organizations that might undertake to develop a health services research training program in conjunction with on-going graduate programs in allied fields. The economic impact of these regulations would be minimal given the potential number of institutions and individuals involved in this effort. As required by the provisions under section 472 of the Public Health Service Act that relate to the national research service awards, the regulations would identify information that must be provided by an individual receiving a national research service award. This information would include a description of the services that the individual will provide subsequent to the training period and such personal information as might be deemed necessary by the Secretary to make a decision on which individuals should receive training support.

is carefully designed to provide the necessary input for this Department-wide function. No other agency currently has this capacity.

Second, the Center's mandate permits it to study some medical practices and procedures for which no governmental agency currently has special responsibility. Examples of these are surgical procedures and regimens which involve drugs, devices and procedures in a coordinated protocol. It is expected that the Food and Drug Administration would continue to be chiefly responsible in the Federal Government for collecting and evaluating information on the safety and efficacy of individual drugs and devices.

Third, the National Center would be the only Federal agency with the talents and the mandate to consider the costs of procedures and practices, as well as their safety and efficiency, in formulating model norms and standards. The proposed Center would also be the sole Federal agency with a mandate to conduct new research relevant to perfecting the methodology for the assessment of the costs, benefits, efficacy, cost-effectiveness and social and economic impact of medical practices and procedures.

Finally, with the creation of the National Center for the Evaluation of Medical Technologies, the Department would at last have a single agency with responsibility for surveying all on-going evaluations of medical technologies, for recommending where important gaps exist, and for providing early warning when important new practices and procedures are coming into use without appropriate testing for safety, cost and efficacy.

In order to undertake these important and unique activities, the committee has provided the National Center for the Evaluation of Medical Technologies with an authorization of $25 million for fiscal year 1979, $35 million for fiscal year 1980, and $50 million for fiscal year 1981.

V. Congressional Budget Office—Cost Estimate

May 5, 1978.

1. Bill number: S. 2466.

2. Bill title: National Institutes of Health Care Research Act of 1978.

3. Bill status: As ordered reported by the Senate Committee on Human Resources, April 28, 1978.

4. Bill purpose: An amendment to the Public Health Service Act, S. 2466 would establish within HEW the National Institutes of Health Care Research, whose director would report to the Secretary of HEW. There would be three institutes: a National Institute for Health Policy Research (NIHPR), which would replace the National Center for Health Services Research; a National Institute for Health Statis-

(4) Private industry, with its extraordinary capacity to respond to perceived needs.

(5) The individual inventor, physician innovator, or biomedical engineer.

(6) Universities offering basic discoveries for subsequent application.

(7) Health care providers, be they physicians, allied health specialists, or hospitals.

It has been estimated by some experts that as much as one-half of the annual increase in the cost of a day of hospital care can be attributed to the use of more technology in medical practice. This estimate would mean that between 1966 and 1976 expenditures for medical technology added $8 to $12 billion to the Nation's hospital bill, which totaled $55 billion in 1977. At subcommittee hearings last summer, testimony was presented on the cost and effectiveness of surgery for coronary artery disease. Each such operation costs from $10,000 to $12,500, and national expenditures for coronary artery surgery alone have approached $1 billion a year. This new surgical procedure was in widespread use before any comprehensive studies had been done to establish its efficiency and effectiveness. The result has been a growing consensus that it is overutilized, with substantial adverse consequences for the health of some patients and the costs of medical care generally.

For these several reasons, the committee proposes to establish a National Center for the Evaluation of Medical Technology. Specifically, the National Center would be required to undertake and support research, demonstrations, and evaluations concerning—

(1) The safety, efficacy, effectiveness, cost effectiveness, and social, ethical, and economic impact of particular medical technologies;

(2) The factors that affect the utilization of medical technologies throughout the United States;

(3) Alternative methods for disseminating information on medical technologies to health professionals;

(4) Alternative methods for measuring the quality of health services; and

(5) the effectiveness, administration, and enforcement of quality assurance programs.

In addition, the National Center would be required to establish priorities for the study of new and existing medical technologies, to support the training of health professionals and other personnel with the needed expertise to evaluate medical technologies, and to establish three extramural Centers for the Evaluation of Medical Technologies. For these purposes, the legislation defines "medical technology" as any discrete and identifiable medical or surgical regimen or modality used to diagnose or treat illness, prevent disease, support life, or maintain patient well-being.

The National Center would be advised in these responsibilities by a National Council for the Evaluation of Medical Technologies. The Council would be composed of representatives of agencies in the Federal government with an interest in the evaluation of medical technologies, including the Surgeon General, the Director of the National Institutes of Health, the chief medical officer of the Veterans Administration, the Chairman of the National Professional Standards Review Council (or their designees), and three other employees of

mittee has noted the substantial and persistent problems which have impeded cooperation between the Health Care Financing Administration and the Public Health Service. There is evident a pressing need to revise authorities which permit the same data to be gathered twice, which allow agencies to refuse to share data, and which provide individual agencies with an opportunity to define unique standards for data collection, with the result that statistics are frequently not comparable from one agency to another.

The committee intends to eliminate such costly and inefficient practices by establishing the National Institute for Health Statistics and Epidemiology. Specifically, the Institute would be charged with the responsibility of reviewing, throughout HEW, data collection activities in the health field. The objective of this provision is to insure that HEW programs have sufficient flexibility to meet their unique program requirements but not duplicate the collection efforts of other agencies with data that is not comparable.

With regard to the National Institute's new epidemiological responsibilities, the committee proposes that the Institute undertake an expanded program of intramural and extramural epidemiology and data analysis. The committee believes that the National Institute could make a major contribution in explaining trends in the health status of the population (for example, the cause of the dramatic recent decline in deaths from heart disease), and imperfecting the methodology of statistical work in epidemiology. Currently, the National Center for Health Statistics funds original research at a level of less than $300,000 out of budget of $36 million.

Consistent with this expanded mandate, the legislation provides the National Institute for Health Statistics and Epidemiology with an authorization of $60 million for fiscal year 1979, $65 million for fiscal year 1980, and $70 million for fiscal year 1981. It should be noted that the committee has increased authorizations at these levels for the additional reason of permitting the National Institute to expand substantially the cooperative health statistics system. Such authorizations should permit the National Institute to arrange for three components of the system to be in place in all 50 States by the end of 1979. By 1983, if the sums suggested become available, the cooperative health statistics system should be fully installed throughout the United States.

NATIONAL CENTER FOR THE EVALUATION OF MEDICAL TECHNOLOGY

The legislation proposes to establish a new agency, the National Center for the Evaluation of Medical Technology, which would be a component part of the National Institutes of Health Care Research. The new National Center would be charged with the responsibility of supporting evaluations of new and existing medical technologies. The committee believes that such evaluations are absolutely critical if the cost of medical care is to be reduced and quality of care is to be improved. Currently no Federal agency has clear responsibility for this task. As Dr. Julius Richmond, Assistant Secretary of Health at HEW, stated at subcommittee hearings on the proposed legislation (Feb. 7, 1978),

With regard to this last point on the desirability of the policy relevance of research, the committee would like to make special note of Dr. Philip Lee's testimony on the proposed legislation:

Health services research can be policy relevant if the research is designed to investigate factors amenable to policy manipulation, if the quality of the research is such that it may increase the likelihood of better policy outcomes, and if the information is available in time to contribute to policy decisions.

Health policy research deals with a wide range of biological, behavioral, environmental, and sociocultural factors, including health care, that affect the health status of individuals and populations. Unlike health services research, it involves primarily a synthesis and analysis of information relevant to specific policy problems. Policy research attempts to synthesize and interpret findings that are relevant to a policy problem, draw out implications, and make recommendations for policy consideration. Policy analysis brings the process one step closer to the decisionmaking process. The aim of policy analysis is to permit improvements in decisionmaking and policy making by permitting careful consideration of a broad set of alternatives.

In creating an institute for Health Policy Research, the committee does not intend to limit the activities of the former National Center for Health Services Research exclusively to projects that have immediate policy relevance. Though the committee believes that policy research, as defined above, is an important part of the proposed mandate of the new Institute, it also feels strongly that the National Institute should support undirected research whose policy relevance may not be clear in the short term. Currently, no other agency in the federal government has the authority to conduct such "basic" health services research. The committee feels that the proposed National Institute of Health Policy Research is the appropriate entity to continue and to expand the support of these research programs.

The committee is aware of the growing proliferation of small data management systems designed to computerize many of the management functions in small to medium sized hospitals. The committee is also aware that the National Center is currently studying large data management systems—the Technicon system at El Camino Hospital in California and the Promis system in Vermont—but it is concerned about the application of these large systems to the needs of small and medium sized hospitals. It appears likely that many of the features contained in the two systems, while appropriate for large volume hospitals, are not appropriate and would increase the management costs for smaller hospitals. The committee is concerned that relatively little is known about the various small data management systems with respect to their function, reliability or comparability with other available systems.

There is also a paucity of data regarding those functions within a small or medium sized hospital which can efficiently and cost effectively be performed by a data management system. It is clear that hospitals considering the feasibility of acquiring a data management system do not have the benefit of reliable studies which define the state-of-the-art in small data management systems, establish the cost effectiveness of computerization of specific functions within a prototype hospital.

multiple PHS and HCFA agencies have on-going and important activities in the gathering of health statistics, the conduct of epidemiology, the evaluation of clinical procedures and the conduct health services research. It is not the committee's intent to centralize all these functions in one agency, or to frustrate the mission-oriented work of the various agencies. The committee recognizes, for example, that the Center for Disease Control must retain its capacity to do epidemiological work necessary to control infectious and toxic hazards to the American people; that the NIH must continue its important epidemiological work in the disease-oriented institutes; that the Health Care Financing Administration must do health services research directly relevent to the administration of the medicare and medicaid programs and so on.

However, the committee also feels strongly that some agency in the Department must be given responsibility for making certain that the activities of these various bureaucratic entities are molded, to the maximum extent practical, into a coordinated and comprehensive plan for health research and development. The current situation, bordering on administrative chaos, cannot be permitted to persist. It wastes the scarce resources of research disciplines which have been historically underfunded and neglected. It creates a situation in which research and data which are potentially useful to many Department agencies cannot serve multiple purposes. It further discredits research activities which, though very important, have never been sufficiently appreciated within the Federal Government.

The balance between central planning and agency freedom is difficult to set in any substantive area. In the past, because of lack of administration interest and intense bureaucratic rivalries, the pendulum in the research areas we are discussing has swung dramatically toward decentralization. The committee feels that strong corrective measures are in order.

PRIVACY AND CONFIDENTIALITY

The committee is especially concerned about individual rights to privacy and the confidentiality of individual medical records or of any information which might be collected, maintained, published, or released in some other individually identifiable form. It is the committee's intent that any activities conducted under the authority of this act shall be in conformance with section 308(d) of the Public Health Service Act which protects the confidentiality and privacy of individuals and entities which submit data. In addition, the Secretary may not use any information obtained for any other purpose than the purpose for which it was supplied unless the individual or entity is so notified.

NATIONAL INSTITUTES FOR HEALTH POLICY RESEARCH

The proposed legislation would establish a National Institute for Health Policy Research whose functions would incorporate and expand current activities at the National Center for Health Services Research. The legislation would authorize an increase in appropriations for health services research, from $28.6 million in 1978 to $40 million in 1979, $45 million in 1980 and $50 million in 1981.

need policy guidance. But they must be insulated from ever fluctuating political pressure. Otherwise they will not be able to pursue excellence in their respective fields.

For the traditional biomedical sciences, the NIH fulfills these institutional requirements. To provide similar advantages to health services research, health statistics, epidemiology and the assessment of medical technology, the committee proposes the creation of the National Institutes of Health Care Research. This new Public Health Service Agency would be modelled upon and parallel to the National Institutes of Health. It would provide overall policy guidance and coordination for its component institutions. It would give new visibility and focus to the research activities listed above.

To reinforce this visibility and to underscore the importance of an independent and distinct organizational unit charged with specific research responsibilities, the committee also proposes that the National Institutes of Health Care Research be headed by a Director, appointed by the President with the advice and consent of the Senate. This provision is intended to assure not only the prominence of the newly established National Institutes, but also to attract the best-qualified experts in the field to assume the responsibilities and tasks with which the National Institutes of Health Care Research would be charged.

Finally, the committee notes the need to undertake and support manpower training programs to provide for a continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects detailed above. In addition, more of these individuals will be required as the National Institutes expands its research activities. For these reasons, the Secretary, acting through the National Institutes, would be specifically authorized to provide National, Research Service Awards for such training.

Under the new law, the NIHCR would be charged with the responsibility of supporting research, demonstrations, evaluations, and statistical and epidemiological activities which examine—

(1) The accessibility, acceptability, planning, organization, distribution, utilization, and financing of systems for the delivery of health care;

(2) Alternative 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) Alternative methods to improve and promote health statistical and epidemiological activities;

(5) The safety, efficacy, effectiveness, cost effectiveness, and social, economic, and ethical impacts of medical technologies; and

(6) Alternative methods for disseminating knowledge concerning health and health related activities.

As reported, the proposed legislation creating the National Institutes of Health Care Research would give a strong mandate to the Secretary to coordinate health services research, health data gathering, and technology evaluations through the new agency. It is the committee's view that this mandate is necessary to end needless overlap and duplication within the department with respect to these activities. The committee notes the administration's strong arguments that this coordination can be achieved administratively, and that the proposed realignment of existing agencies is not necessary. Though pleased

TUESDAY, JULY 19, 1977

Ross, Richard, M.D., dean. Johns Hopkins University Medical School; Charles A. Sanders, M.D., general director of Massachusetts General Hospital; Halsted, Holman, M.D., professor of medicine, Stanford University Medical School; Harvey Fineberg, M.D., assistant professor, health services, Harvard University School of Public Health, a panel.

WEDNESDAY, JULY 20, 1977

Richmond, Julius B., M.D., Assistant Secretary for Health, Department of Health, Education, and Welfare, accompanied by Donald S. Frederickson, M.D., director, National Institutes of Health; Seymour Perry, M.D., Director, Office of Program Planning and Evaluation, National Institutes of Health, Department of Health, Education, and Welfare; Ruth Hanft, consultant, Department of Health, Education, and Welfare; Carol Emmott, Office of the Deputy Assistant Secretary for Legislation (Health), Department of Health, Education, and Welfare; and Ms. Arnstein.

Marks, Paul A., M.D., vice president for health sciences, Columbia University; Howard Hiatt, M.D., dean Harvard School of Public Health, and David Rogers, M.D., president, Robert Wood Johnson Foundation.

FRIDAY, SEPTEMBER 16, 1977

Lauer, Ronald M., M.D., professor of pediatrics, director, Division of Pediatric Cardiology, University of Iowa, accompanied by Ernst L. Wynder, M.D., president, American Health Foundation, a panel.

Frederickson, Donald S., M.D., Director, National Institutes of Health.

Cooper, Theodore, M.D., dean Cornell Medical College; Lester Breslow, M.D., M.P.H., dean School of Public Health, University of California, Los Angeles; and Jacob Clayman, secretary-treasurer, and Sheldon W. Samuels, director, Health, Safety and Environment, Industrial Union Department, AFL–CIO, a panel.

IV. Committee Views

The proposed legislation would—

(1) Establish in DHEW a National Institutes of Health Care Research. The Institutes would be charged with the responsibility of conducting and supporting health services research, demonstrations, evaluations, and statistical and epidemiological activities for the Department.

(2) Expand, redirect, and rename the National Center for Health Services Research. This agency would become the National Institute for Health Policy Research and would be a component part of the National Institutes of Health Care Research.

(3) Expand, redirect, and rename the National Center for Health Statistics. This agency would become the National Institute for Health Statistics and Epidemiology and would be a component part of the National Institutes of Health Care Research.

States. By the end of fiscal 1978, 44 States will be participating in the cooperative health statistics system. Of these, 11 will be participating in the hospital care data component, 27 in the health facilities component, 26 in health manpower, and 38 in statistics.

The 1978 budget of the National Center for Health Statistics is $36.3 million, its authorization $33.6 million. Like the Nations Center for Health Services Research, the National Center for Health Statistics and its programs have suffered in recent years from insufficient financial support. Though the Secretary is mandated by law to coordinate health data collection activities to the maximum extent feasible through the National Center, this goal has proved impossible to attain because of inadequate funds. The cooperative health statistics system has been unable to develop as rapidly as planned, for the Center has not had the moneys necessary to support State efforts to implement the CHSS. As a result, the United States continues to lack a nationwide health data collection system.

Bureaucratic rivalries within the Department have also played a role in frustrating the implementation of the cooperative health statistics system and the development of a unified health data policy in the United States. The Department of Health, Education, and Welfare currently supports 282 health data collection programs, and these function with a remarkable degree of independence. As a result, the data collected frequently lacks comparability, and displays varying standards of quality. The Federal Paperwork Commission has estimated that the implemention of a uniform data collection system could reduce the costs of health data collection in the United States by $200 million.

Recently, the National Center has worked out agreements to coordinate data collection activities with a number of agencies within the Public Health Service. However, considerable friction remains in the relationship between the National Center and the Health Care Financing Administration in their attempts to standardize and coordinate health statistical activities.

Appropriations history—National Center for Health Statistics

	Millions
1974:	
Authorization	25.0
Appropriation	19.3
1975:	
Authorization	30.0
Appropriation	21.5
1976:	
Authorization	30.0
Appropriation	26.1
1977:	
Authorization	30.0
Appropriation	27.6
1978:	
Authorization	33.6
Appropriation	[1] 38.0

[1] This figure includes moneys for Office of Assistant Secretary.

Despite some important achievements, the National Center for Health Services Research has had a number of significant problems in recent years. First, its funding has been sharply reduced. In fiscal year 1973, the NCHSR budget was $58 million. In fiscal year 1975, subsequent to the passage of Public Law 93–353, the budget was reduced to $36 million. It was further reduced in fiscal year 1976 to $26 million, and in fiscal year 1977 to $24. The 1978 appropriation was $26 million. Taking into account inflation since 1973, there has been an 80 percent reduction in the amount of research being supported by the National Center for Health Services Research.

Second, the National Center has been repeatedly subject to reorganizations and bureaucratic relocations. This has resulted, together with funding cutbacks, in serious morale problems and an attrition of at the Center.

Third, the number of health services research programs funded in other health related programs at HEW has grown substantially but there has been very little, if any, coordination between the National Center's programs and those of other agencies. For instance, in 1978 the newly created Health Care Financing Administration will fund approximately $2 million worth of research and demonstrations in the areas of health services and statistics. Many of these programs have been instituted without the peer review built into the National Center's program and legislative mandate.

These difficulties have substantially impaired the capacity of the Federal Government to conduct a well-organized and efficient program of health services research. They have provided a significant challenge to the committee during its reauthorization of expiring authorities.

NATIONAL CENTER FOR HEALTH STATISTICS

Federal collection of vital statistics dates back to the censuses of the late 1800's. In 1902, Public Law 57–27 mandated an annual collection of data derived from the registration of births and deaths and assigned the responsibility to the Bureau of the Census. In 1946 the Census Bureau's vital statistics responsibilities were transferred to the Public Health Service, and the National Office of Vital Statistics was established to administer the program.

A significant step toward obtaining more comprehensive health-related data was taken in 1956 when Congress enacted the National Health Survey Act (Public Law 84–652) which authorized national surveys to obtain information about the health of the American people, the health services they receive, and the health resources available to provide those services.

In August 1960, the National Center for Health Statistics was organized by combining two organizational units of the Public Health Service, the National Office of Vital Statistics and the National Health Survey Division. In 1970 the authorities under which the Center was operating were amended by Public Law 91–515 to broaden the authorities for national health surveys, to provide for confidentiality of the data collected, and to establish a cooperative system for producing comparable health information and statistics at the National, State, and local levels.

In July 1974 the Health Services Research, Health Statistics and Medical Libraries Act (Public Law 93–353) statutorily established

(4) Establish within the National Institutes of Health Care Research a National Center for the Evaluation of Medical Technology. Its major purpose would be to assess the cost and effectiveness of medical practice and procedures.

(5) Would provide authorizations of appropriations for the activities of the National Institutes of Health Care Research and its component parts as follows:

Fiscal year:	*Millions*
1979	$125
1980	145
1981	170

II. History of Expiring Programs

The legislative authorities for the National Center for Health Services Research and the National Center for Health Statistics expire at the end of fiscal year 1978. Extension, along with revision and a systematic consolidation of these authorities in a National Institutes for Health Care Research, are essential at this time in order to assure the future progress of these programs as well as to guarantee continuing improvements in the quality, efficiency, and effectiveness of the Nation's health services.

Initial authority for health services research, as opposed to biomedical research, was enacted in 1976 (Public Law 90–174) and for health statistical activities in 1902 (Public Law 57–27). These authorities have been modified and extended on several occasions as the needs of the nation's health care system have changed and as the accomplishments of program activities and efforts have become clearly evident. Both authorities were last extended for 1 fiscal year by Public Law 95–83, August 1, 1977.

BACKGROUND

The National Center for Health Services Research is the principal source of support in this country for general research on problems in the delivery of health services. The National Center was originally established in 1968 at the direction of the Secretary of Health, Education, and Welfare. The organization remained an administratively created entity until 1974, when the "Health Services Research, Health Statistics, and Medical Libraries Act" (Public Law 93–353) provided it with a statutory base.

The legislation authorized the Secretary of HEW, working through the Center, to undertake a broad range of research, demonstration, and evaluation activities relating to health services delivery in the United States. The research activities of the National Center were to include subjects such as the planning, organization, distribution, financing, quality and use of health services; the training, supply, and distribution of health manpower; and the design, construction, organization, and costs of health facilities and equipment. At least 25 percent of the research effort was required to be undertaken intramurally in an effort to develop an in-house response capacity which had been lacking in the previous grant and contract monitoring approach of the National Center. The Center was also authorized to support training programs for health services researchers and mandated to assist at