



E000945

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH RESOURCES ADMINISTRATION
OFFICE OF THE ADMINISTRATOR

TO : The Assistant Secretary for Health
Through: ES/H _____

DATE: NOV 1 1974

FROM : Administrator, HRA

SUBJECT: Implementation Plan for Title I, P.L. 93-353 - INFORMATION

As requested in your memorandum dated September 17, we have prepared a scoping document concerning implementation plans related to Title I of Public Law 93-353. You will note that the document contains a draft delegation of authority which, if signed, would authorize you to exercise essentially all of the authorities related to P.L. 93-353. The delegation would also formally establish two new national centers pursuant to the law. Formal delegation documents will be submitted through channels shortly.

A formal implementation plan will be submitted after we have received your reaction to the scoping document.

Dr. John Dalton in our Office of Management is coordinating HRA staff actions related to the implementation plan. Please have your staff call Dr. Dalton on extension 33580 for any information you may need.

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Kenneth M. Endicott, M.D.

Enclosures

Tab A - Scoping Document

Tab B - Tentative Implementation Plan

Tab C - Draft Memorandum for Secretary's Signature

Prepared by: HRA:OOM, SALMON, 10/31/74, X32490

SCOPING DOCUMENT

To Implement Title I of the Health Services Research,
Health Statistics, and Medical Libraries Act of 1974

- I. TITLE: Health Services Research, Health Statistics, and Medical Libraries Act of 1974 (Public Law 93-353)
- II. DATE ENACTED: July 23, 1974
- III. NARRATIVE SUMMARY:

A. General Provisions

The general authority and provisions contained in Title I require the Secretary to undertake, through the National Centers for Health Services Research and for Health Statistics, research and statistical activities focusing on: individual health and environmental impact on it and on health care, health care accessibility, acceptability, organization, technology utilization, quality, financing and delivery, and public information concerning health care delivery systems.

The Secretary is authorized to: utilize Departmental resources and grants and contracts for health services research and health statistical activities, admit and treat non-beneficiaries at PHS facilities, make use of domestic and foreign consultants, and acquire, construct, and otherwise maintain and operate research facilities.

The Secretary is required to report to Congress by September 1 each year on the administration, current state and progress of health services research and health statistics and, in addition, to make reports on the following to the President and Congress by September 1 each year: health care costs and financing, health resources, utilization of health resources, and the health of the Nation's people.

Provisions relating to Confidentiality of Information concern both NCHS and NCHSR and require that information may not be published or released without consent of the subject if the person or an establishment is identifiable in the case of health statistics or if a person is identifiable in the case of health services research.

The Act also specifies that any NCHSR grant or contract application that is submitted for possible funding under this authority and that exceeds \$35,000 in direct costs must be reviewed for scientific merit by a panel of experts who are not employees of the United States.

The awarding of a grant or contract is prohibited for a project under the authority of Sections 304, 305, or 306 of the Act for Health Services Research and Health Statistics if authority for such a project exists elsewhere in the PHS Act. Applicants who submit applications under Sections 304, 305, or 306, for funds authorized elsewhere in the PHS Act must be notified of the other provision (or provisions) of the PHS Act under which such application may be submitted.

B. Provisions of Title I Specifically Concerning the National Center for Health Services Research

Establishes by statute the National Center for Health Services Research.

Provides authority for the Department through the National Center to undertake and support research, evaluation, and demonstration projects which deal with the problem of organizing and delivering health services.

Requires the National Center for Health Services Research to support and otherwise assist public and private nonprofit entities to plan and operate six multi-disciplinary research centers, and specifies that two of the centers must be special emphasis centers, one to focus on the application of technology to health care delivery, the other on the management of health delivery organizations.

The aggregate number of grants and contracts and aggregate amount of funds in any fiscal year are restricted to 20 and \$5 million respectively for any particular means or aspect of delivery of health services.

C. Provisions of Title I Specifically Concerning the National Center for Health Statistics

Statutorily establishes the National Center for Health Statistics in DHEW.

Provides authority to assist Federal, State, and local health agencies in designing and implementing a cooperative system for producing comparable and uniform health information and statistics at the Federal, State, and local levels.

Requires that the Secretary provide the Federal share of the data collection costs under such system and review statistical activities of the Department of Health, Education, and Welfare to assure that they are consistent with the data system developed.

Requires the collection, analysis, publication, and dissemination of statistics on a wide range of health and health related topics.

Establishes in the Office of the Secretary a fifteen-member United States National Committee on Vital and Health Statistics. The principal functions of the Committee are to advise and assist the Secretary on various health statistical matters, to cooperate with national committees of other countries and the World Health Organization on health related issues, and to advise on the annual report on the state of the Nation's health, its health services, their cost and distribution, and to make proposals for improvement of the Nation's health statistics and health information systems.

Provides for participation with other countries in cooperative endeavors with respect to health statistical activities.

IV. MAJOR ACTIONS REQUIRED BY THE PHS:

Delegation of authority (See Attachment A, draft memorandum).

Determination of the resources that will be required to implement the Act.

Establishment within the Office of the Secretary of a United States National Committee on Vital and Health Statistics, program advisory and review committees, and national health councils.

Approval of implementation plans (See Attachment B, Tentative Implementation Plan).

V. ISSUES AND PROBLEMS:

Implementation of training programs for health services researchers and health statisticians.

Early implementation of the requirement that not less than 25 percent of the monies appropriated for the National Center for Health Services Research be used to fund an intramural research program.

VI. LEGAL INTERPRETATIONS REQUIRED OR OBTAINED:

The following legal issues have been identified and are being worked on with the Office of General Counsel:

- (1) Organizational location of United States National Committee on Vital and Health Statistics--Section 306(i).
- (2) Requirements on furnishing Congress special statistical compilations and surveys--Section 306(c).
- (3) Legal requirements on all regulations and guidelines on grants, contracts, cost sharing, written agreements--Sections 305(d) and 306(f).
- (4) Status of grant and contracting authority prior to the issuance of new regulations.
- (5) Interpretation of the section prohibiting the use of National Center for Health Services Research funds for projects that could be funded under another authority.
- (6) The use of contracts as a means of conforming with the intramural research requirement.

VII. DHEW ORGANIZATIONS INVOLVED IN IMPLEMENTATION:

The law requires that the health services research and health statistical activities of units of DHEW be coordinated and that all statistical activities of the Department be reviewed to assure that they are consistent with the cooperative health statistics system. In this respect, all units of the Department involved in health services research, evaluation, or demonstration or in the collection of health data will be involved in the implementation of this law. This will include at least all H organizations, SSA, and SRS.

VIII. DELEGATIONS OF AUTHORITY REQUIRED:

(See Attachment A, already referred to)

IX. REGULATIONS REQUIRED:

Both new and revised regulations will be required. We have consulted with OGC and have identified the regulations that will have to be developed, as follows:

- (1) Regulations for grants and contracts to implement Section 306(b).

- (2) Regulations for grants and contracts for the centers under Section 305(d) (1).
- (3) Regulations for grants and contracts for activities under Section 305(b).
- (4) Regulations for both grants and contracts to implement Section 304(b) (1) (c).
- (5) Regulations for both grants and contracts to implement Section 306(b) (2).
- (6) Regulations for both grants and contracts to implement Section 306(e) (3).
- (7) Regulations to implement Section 308(d) which should deal with both the issues of consent and the circumstances under which the program would wish to authorize the material to be used for purposes other than the purposes for which collected.

X. REPORTS REQUIRED:

The Secretary is required (Section 308(a)) to submit detailed reports to Congress and the President by September 1 each year on the status and progress of NCHSR and NCHS programs.

XI. DOLLAR AUTHORIZATION PROVIDED:

Title I, Section 308(i) (1) authorized appropriations of \$65,200,000 for the fiscal year ending June 30, 1975, and \$80,000,000 for the fiscal year ending June 30, 1976, for health services research, evaluation, and demonstration activities under Sections 304 or 305. Of the funds authorized for any fiscal year, not less than 25 per centum shall be made available only for health services research, evaluation, and demonstration activities directly undertaken by the Secretary.

The aggregate number of grants and contracts made or entered into under Sections 304 and 305 for any fiscal year may not exceed 20, and the aggregate amount of funds obligated under grants and contracts under Sections 304 and 305 for any fiscal year may not exceed \$5,000,000.

Title I, Section 308(i) (2), authorized appropriations of \$30,000,000 for the fiscal year ending June 30, 1975, and \$30,000,000 for the fiscal year ending June 30, 1976, for health statistical activities under Sections 304 or 306.

XII. IMPACT ON H RESOURCES:

The impact of the law on H resources will depend on the priorities of H and the Department and the extent to which the Secretary decides to implement the authorities granted him.

For NCHS, the Department budget request for FY 1976 includes \$39.3 million and 547 positions (an increase of \$15.3 million and 23 positions). This budget is based on getting legislative approval for increases in the NCHS ceiling per the Congressional Conference Committee report on this law. The budget developed does not include implementation of the grant programs, the cost of developing the required reports, nor increased coordination and other responsibilities, which are estimated to require an additional \$6 million and 30 positions in FY 1976. A further increase of \$16 million is estimated for FY 1977. Specific position allocations will be dependent on the resolution of the implementation issues and plans for both Centers.

For NCHSR, Section 308(i) of the Act requires for health services research, evaluation, and demonstration activities undertaken or supported under Sections 304 or 305, that not less than 25 percent of the monies appropriated for health services research must be used to support such activities directly undertaken by the Secretary (intramural activities). Congress intended that such a program shall be operated by the National Center for Health Services Research. Although NCHSR cannot fulfill this specific legislative requirement immediately, we estimate that a meaningful intramural research program can be implemented at annualized end-of-fiscal-year obligation rates of \$3, \$10.5, and \$18 million for FY 1975, 1976, and 1977 respectively. Based on an examination of staffing patterns at NIH and among its own grantees, NCHSR estimates that such a program will require 20 additional positions in FY 1975 and 50 more in both FY 1976 and 1977. A research activity is much more labor-intensive than the administration of grants and contracts.

XIII. DATE OF FINAL PLAN SUBMISSION:

The date of submission of the final plan to H is highly dependent upon H and/or OS reaction to the issues raised in this scoping document.

TENTATIVE IMPLEMENTATION PLAN - P.L. 93-353

MILESTONES	COMPLETION DATE											
	JULY	AUG	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUNE
<u>BAL</u>												
Designate HRA official to be in charge of overseeing implementation		△										
Prepare and submit materials to abolish the current HS and BNSR					△							
Prepare and submit materials to establish the new HS and the NCHSR					△							
Prepare and submit necessary delegations of authority from Secretary to Assistant Secretary for Health and from Assistant Secretary for Health to the Administrator, HRA					△							
Prepare necessary delegations of authority from the Administrator, HRA, to the respective Directors of NCHS and NCHSR (this step will be accomplished two weeks after receipt of the other delegations.)					△							
Prepare and submit a list of issues requiring resolution to the Secretary				△								
Prepare regulations concerning the implementation of Sec. 304.(b)(1)						△						
Develop coordination mechanisms as specified in Sec. 304.(c); Sec. 306. (f) and Sec. 307.						△ ₁	△ ₂	△ ₃				
Distribute information regarding the provisions of the Act to the clientele						△	-----				△	
Advise DHEW Regional Offices as to the provisions of the Act and progress in implementation of the provisions					△	-----				△		

MILESTONES	COMPLETION DATE											
	JULY	AUG	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUNE
<u>NATIONAL CENTER FOR HEALTH SERVICES RESEARCH</u>												
Develop or revise and submit regulations for research grant programs							△					
Publish regulations (timing depends upon clearance in the Office of the Secretary) for grant programs										△		
Revise instructions to applicants for filing grant applications						△						
Revise or develop grant application forms if necessary						△						
Obtain OMB clearance on instructions, and application forms if necessary								△				
Announce grant program to clientele including dates for submission of applications (to be done within three weeks after OMB approval of forms and instructions)								△				
Establish peer review groups or realign current groups if necessary							△					
Develop regulations and/or guidelines for application review as necessary							△					
Review applications										△		
Award grants												△
Develop plans for implementing intramural research activities						△						

MILESTONES

COMPLETION DATE

HSR (contd.)

- 12. Implement intramural research activities
- 13. Develop regulations for contracts--Sec. 308.(b)(1)
- 14. For contract program develop work plans and RFPs
- 15. Review contracts
- 16. Award contracts
- 17. Develop regulations for the implementation of Sec.308(d)(2)

JULY	AUG	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUNE
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TO : The Assistant Secretary for Health
FR : Secretary
SUBJECT: Designation of National Centers and Delegation of Authority

Pursuant to the provisions of Public Law 93-353, the National Center for Health Services Research and the National Center for Health Statistics are hereby established as bureau-level organizations within the Health Resources Administration of the Public Health Service. The new National Centers replace the previously established Bureau of Health Services Research and the National Center for Health Statistics, respectively. The Directors of the predecessor organizations are hereby designated as Directors of the new National Centers. All delegations or redelegations to any officers or employees of the National Center for Health Services Research or the National Center for Health Statistics which were in effect prior to the effective date of this memorandum continue in effect in them or their successors, pending further redelegation.

I hereby delegate to the Assistant Secretary for Health the authority vested in me by Public Law 93-353, except for the prescribing of regulations.

These authorities may be redelegated and they supersede any delegations of authority under the sections of the Public Health Service Act amended by Public Law 93-353.

The designations and delegations outlined above are effective as of this date.

Caspar W. Weinberger