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FOREWORD

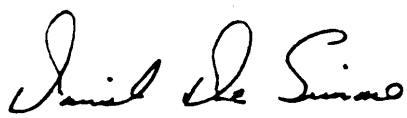
The proliferation of Federal health programs since the advent of Medicare and Medicaid some 15 years ago has spawned a vast number of separate systems for the collection of health data. The demand for information describing these programs is immense and keeps growing. It now costs an estimated $100 million a year for Federal health statistical activities.

This report reviews and assesses Federal data collection activities and finds them to be overlapping, fragmented, and often duplicative. It was prepared at the request of the Senate Committee on Labor and Human Resources and the House Committee on Interstate and Foreign Commerce.

The report is divided into two parts. Part I inventories the different health data collection systems administered by the Department of Health, Education, and Welfare and other Federal agencies, outlines the problems of duplication and fragmentation that occur, and addresses the possibilities of improving the coordination of these systems.

Part II is a directory of statutory provisions that govern the collection of health data by the Public Health Service and the Health Care Financing Administration. It is a convenient reference that Members of Congress can consult before enacting new data requirements. It may also be useful to executive agencies in the coordination of existing ones.

This study was conducted by the OTA Health Group staff. We are grateful for the advice and guidance provided in this assessment by OTA's Health Advisory Committee, chaired by Dr. Frederick C, Robbins. The report, however, does not necessarily reflect the views of any individual member of the Committee.



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GLOSSARY OF ACRONYMS

ADAMHA:	Alcohol, Drug Abuse, and Mental Health Administration
AMIS:	Automated Management Information System
ARF:	Area Resource File
ASMB:	Assistant Secretary for Management and Budget
ASPE:	Assistant Secretary for Planning and Evaluation
BCDSP:	Boston Collaborative Drug Surveillance Program
BCHS:	Bureau of Community Health Services
BCRR:	BCHS Common Reporting Requirements
BD:	Bureau of Drugs
BF:	Bureau of Food
BHE:	Bureau of Health Education
BHF:	Bureau of Health Facilities Financing, Compliance, and Conversion
BHM:	Bureau of Health Manpower
BHP:	Bureau of Health Planning
BLS:	Bureau of Labor Statistics
BMD:	Bureau of Medical Devices
BMS:	Bureau of Medical Services
BoB:	Bureau of Biologics
BRH:	Bureau of Radiological Health
BVM:	Bureau of Veterinary Medicine
CDC:	Center for Disease Control
CHAMPUS:	Civilian Health and Medical Program of the Uniformed Services
CHC:	Community Health Centers
CHSS:	Cooperative Health Statistics System
CMIS:	CHAMPUS Management Information System
CODAP:	Client Oriented Data Acquisition Process
CPSC:	Consumer Product Safety Commission
DAWN:	Drug Abuse Warning Network
DEA:	Drug Enforcement Administration
DEN:	Devices Experience Network
DOD:	Department of Defense
DOL:	Department of Labor
DOT:	Department of Transportation
EMS:	Emergency Medical Services
EPA:	Environmental Protection Agency
ESRD:	End-Stage Renal Disease
ESRD MIS:	End-Stage Renal Disease Medical Information System
FARS:	Fatal Accident Reporting System
FDA:	Food and Drug Administration
FIC:	Fogarty International Center
FP:	Family Planning
FY:	Fiscal Year
GAO:	General Accounting Office
HANES:	Health and Nutrition Examination Survey
HCFA:	Health Care Financing Administration
HDAC:	Health Data Advisory Committee
HDPC:	Health Data Policy Committee
HDS:	Hospital Discharge Survey
HES:	Health Examination Survey
HEW:	Department of Health, Education, and Welfare
HIS:	Health Interview Survey
HMO:	Health Maintenance Organization
HRA:	Health Resources Administration
HSA:	Health Services Administration
HSA:	Health Systems Agency
HSCC:	Health Statistics Coordinating Committee
HSQB:	Health Standards and Quality Bureau
HURA:	Health Underserved Rural Areas
IHS:	Indian Health Service
MEDPAR:	Medicare Provider Analysis and Review
MESA:	Mining Enforcement and Safety Administration
MCH:	Maternal and Child Health
MH:	Migrant Health
MMDS:	Medicaid Minimum Data Set
MMIS:	Medicaid Management Information System
NAMCS:	National Ambulatory Medical Care Survey
NARS:	National Accident Reporting System
NCHCT:	National Center for Health Care Technology
NCHS:	National Center for Health Statistics
NCHSR:	National Center for Health Services Research
NCI:	National Cancer Institute
NCVHS:	National Committee on Vital and Health Statistics
NDATUS:	National Drug Abuse Treatment Utilization Survey
NEI:	National Eye Institute

NEISS:	National Electric Injury Surveillance System
NEXT:	Nationwide Evaluation of X-ray Trends
NHLBI:	National Heart, Lung, and Blood Institute
NHSC:	National Health Service Corps
NHTSA:	National Highway Traffic Safety Administration
NIA:	National Institute on Aging
NIAAA:	National Institute on Alcohol Abuse and Alcoholism
NIAID:	National Institute of Allergy and Infectious Diseases
NIAMDD:	National Institute of Arthritis, Metabolism, and Digestive Diseases
NICHD:	National Institute of Child Health and Human Development
NIDA:	National Institute on Drug Abuse
NIDR:	National Institute of Dental Research
NIEHS:	National Institute of Environmental Health Sciences
NIGMS:	National Institute of General Medical Sciences
NIH:	National Institutes of Health
NIMH:	National Institute of Mental Health
NINCDS:	National Institute of Neurological and Communicative Disorders and Stroke
NIOSH:	National Institute of Occupational Safety and Health
NLM:	National Library of Medicine
NPHPRS:	National Public Health Program Reporting System
NRSFPS:	National Reporting System for Family Planning Services
OAPP:	Office of Adolescent Pregnancy Programs
OASH:	Office of the Assistant Secretary for Health
ODPHP:	Office of Disease Prevention and Health Promotion
OFSPS:	Office of Federal Statistical Policy and Standards
OHMO:	Office of Health Maintenance Organizations
OHPRS:	Office of Health Policy, Research, and Statistics
OHRST:	Office of Health Research, Statistics, and Technology
OMB:	Office of Management and Budget
OPDP:	Office of Policy Development and Planning
OPE:	Office of Planning and Evaluation
.OPPR:	Office of Policy, Planning, and Research
OSH:	Office of Smoking and Health
OSHA:	Occupational Safety and Health Administration
OSP:	Office of Statistical Policy
OSPC:	Office of State Program Coordination
OTA:	Office of Technology Assessment
PAID:	Personnel Accounting Integrated Data System
PDCC:	Program Data Coordinating Committee
PHS:	Public Health Service
PHSH:	Public Health Service Hospitals
PMIS:	PSRO Management Information System
PSRO:	Professional Standards Review Organization
PTF:	Patient Treatment File
RWP:	Reimbursable Work Program
SEER:	Surveillance, Epidemiology, and End Results Data System
SIDS:	Sudden Infant Death Syndrome
SPD:	Statistical Policy Division
SRS:	Social and Rehabilitation Service
SSA:	Social Security Administration
TRIMIS:	Tri-Service Medical Information System
UHDDS:	Uniform Hospital Discharge Data Set
Use:	United States Code
USDA:	United States Department of Agriculture
VA:	Veterans Administration

Part I
Coordination Issues

SUMMARY

The Federal role in health care has grown rapidly since the passage of Medicare and Medicaid legislation in 1965. During the past 15 years, Congress has enacted scores of programs relating to health, including those that provide medical services, train health professionals, assure access and quality of medical care, control medical care costs, and regulate the adverse effects of the environment on health. Furthermore, Congress has also broadened traditional public health programs, which were designed primarily to control communicable and preventable diseases and to support biomedical research.

The health data collection systems of the Federal Government have grown dramatically in large part because of the expanding Federal role in health care. The increase in both the numbers and types of Federal health programs has produced a concomitant growth in the demands for information. Decisionmakers demand not only more health data, but also increasingly sophisticated health data. Each new program creates unique reporting needs for effective and efficient management, planning, evaluation, and congressional and public accountability. Hence, virtually every new Federal program has spawned a data system that separately acquires data to fulfill its own program needs.

The purpose for which health data are needed largely dictates the design of a health data collection system. The Federal Government acquires health data for program management and evaluation, regulation, research, and policymaking. Attributes of a statistical system that may vary as a function of purpose include: the timeliness and availability of data, the periodicity of collection, the number and types of respondents, the geopolitical detail, and the requirements for data quality (validity and reliability). For example, necessary quality requirements of data used for management decisions are usually less rigorous than those used in research. The Department of Health, Education, and Welfare (HEW) makes a distinction between general purpose and program-specific statistical systems based on function (26). General purpose systems are defined to include baseline data that are available to multiple users; they are produced by data systems that only collect statistical information. Program-specific statistical systems, in contrast, produce data as a result of activities primarily directed toward facilitating overall project management. This distinction does not appear to be particularly useful, however; excluding the statistical projects of the National Center for HeaIth Statistics (NCHS), all data collection systems in HEW have evolved from specific program needs.

The rapid proliferation of such program-specific health data projects has exacerbated the decentralization of the Federal health statistical system. A decentralized system may increase the responsiveness of data projects to the needs of individual agencies, but it inevitably creates difficulties in planning and coordination. Too much data are collected in some areas, duplicating expensive resources, and too little data are collected in other areas. As new needs for information arise, the system leaves few alternatives to initiating more data collection activities. Other problems that currently characterize health data collection systems include fragmentation, respondent burden, inefficient use, and an inability to collect data that cut across agency jurisdictions.

Incentives for coordinating diverse data collection activities are minimal because the growth in data-gathering activities has occurred to meet the program needs of administrative agencies and regulatory efforts. The limited ability of existing statistical policy offices to orchestrate and plan data activities of administrative agencies is another obstacle to coordination. The information collected for, and used by, individual agencies also may be difficult to organize because Congress does not consider and coordinate data requirements as it passes legislation. In fact, many Federal agencies cite legislative requirements as the reason for the proliferation of health data systems. Part II of this report presents a directory of statutes that authorize the collection of health data by the Public Health Service (PHS) and the Health Care Financing Administration (HCFA) in HEW. It is designed to determine the extent to which legislation creates or furthers fragmentation and duplication in Federal health data systems.

SCOPE OF THE REPORT

This report discusses the, need and opportunities for coordinating health statistical activities of the Federal Government. It focuses, in particular, on the variety of HEW data collection activities and coordination attempts.

The purpose of this report dictates the use of a broad definition of "health data. " The terms "data, " "information, " and "statistics" are used interchangeably. Health data are defined as information describing the health status of people, their use of medical care services and resources, and the costs and sources of funding for these services. Data relating to health effects of the workplace and the environment, diseases, health problems, and health conditions are included in this definition. Finally, data on public knowledge and attitudes about health, perceived health needs, and behavior related to health, health care, and health practices are also included.

The report does not address the quality and the value of individual data collection systems. The discussion is also limited to Federal endeavors; health data systems operated by the private sector and those administered by other levels of government are not examined. Consideration of how the Federal statistical system should relate to other data collection activities is outside the scope of this report.

A number of other important issues that relate to health data policy are not specifically addressed in this study. For example, there are problems of consistency in policies regarding confidentiality of health data. Provision of data on a small area basis is another area of national concern that is not discussed. This report considers various possibilities for structuring efforts in HEW to achieve comprehensive and consistent policies relative to health data collection systems.

FINDINGS AND CONCLUSIONS

The growth in Federal data activities is demonstrated by the increase in the number of health data projects operated by PHS, the major collector of health statistics. In FY 1977', PHS administered 153 data projects, more than a one-quarter increase over the number operated the previous year. HCFA, the other principal component within HEW concerned with health issues, operated at least an additional 13 large statistical projects that year. Seven agencies and departments outside of HEW also conduct major health statistical activities in pursuit of their missions.

Accurate figures on the costs of administering this great variety of health data systems are difficult to obtain. The Office of Management and Budget (OMB) estimates that total expenditures for Federal health statistical activities in FY 1977 were $100 million. PHS agencies, which all operate health data programs, spent more than $80 million of this amount. OMB'S estimates are conservative, however, because available information severely underreports the costs and numbers of data collection projects.

The Federal Government lacks a coherent policy to organize and manage the increasing numbers of assorted data collection projects. Activities relating to the acquisition, analysis, and use of statistical data that describe the health of people and the utilization of medical care services and resources are unstructured and decentralized. There is no systematic and comprehensive appraisal of the adequacy or use of health data presently collected.

The U.S. statistical system, although sophisticated and generally responsive to the needs of those who operate Federal health programs, is characterized by a number of serious problems. The range of deficiencies in the health statistical systems highlighted in this report are outlined below. As indicated above, the majority of these problems stem from the fact that the growth in Federal health data efforts has occurred primarily outside agencies with major statistical responsibilities.

s The categorical design of Federal endeavors results in duplicative and fragmented data collection efforts.

- There is no central body, accountable to Congress and the public, that serves as a reference for providing information regarding what and how health data can be located.
- Data projects designed for the administration, evaluation, or regulation of specific health programs are not responsive to the needs of the spectrum of potential users.
- The potential utility of available data is not being realized because of limited access to data.

Q Decisions regarding data collection, use, timeliness, and publication are made on an ad hoc basis by the acquiring agency.

- The lack of common nomenclature, definitions, classifications, codes, and units of measurement creates serious obstacles to fully linking data systems, and results in an increasing incidence of data overlap, gaps, and underutility.
- The inability to integrate and link diverse data files for analyses that require more than one data source makes it difficult to assess program achievements, to compare programs, to determine the relevance or meaning of data, and to form statistical profiles about a particular issue or problem.

. Staff of administrative agencies often do not have the necessary statistical and analytical skills to utilize the latest statistical technologies. The effective and efficient supervision of data projects may also be hindered by the Federal Government personnel system, which restricts interagency movement of statisticians.

- The Federal health statistical system lacks an overarching set of principles and objectives that can be employed to rationally plan data activities, to allocate resources for data collection, and to comprehensively and systematically evaluate current data projects.

- The absence of an administrative unit that supervises statistical activities and gathers and provides accurate information regarding the type of data collected and the method and cost of data collection is one of the system's major deficiencies.

A number of offices currently have authority to establish policy concerning health data systems. OMB and the Department of Commerce have responsibilities relating to statistical oversight for the entire Federal Government. The coordination activities of these offices are authorized under the Federal Reports Act of 1942 and the Budget and Accounting Procedures Act of 1950. At least five offices and three committees within HEW also have been delegated some coordination duties. However, a number of these offices are charged with similar health data policy, oversight, and coordination responsibilities, and consequently, their activities tend to be duplicative.

There is a need to assign formal responsibility for the functions related to the coordination and planning of Federal health statistics to a central coordinating body within HEW. Such a unit should have sufficient authority to impose decisions on agencies and offices in the department, the necessary statistical and analytical capabilities to conduct activities requiring technical expertise, and adequate resources to build a viable core effort. The coordinating unit should perform three essential functions: developing an analytical framework for planning the statistical system, improving the efficiency of data collection activities, and ensuring data accessibility for potential users.

A number of offices within HEW could assume responsibility for comprehensively supervising Federal health statistics. Different offices could be accountable for activities requiring authority over substantive program agencies and for activities requiring technical capabilities. Additional staff and funding would be required regardless of which office or offices are selected. The fundamental requirement in assigning responsibility is an unambiguous mandate to manage health statistics.

ORGANIZATION OF THE REPORT

The report is organized into two major parts. Part I consists of three remaining chapters, Part 11 is a directory of statutory authorities that may be used to justify health data collection by agencies within PHS and HCFA.

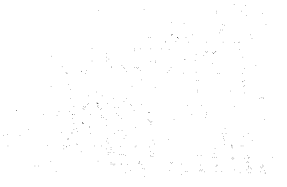
Chapter 2 of Part I presents and briefly describes a number of existing data collection systems administered by HEW and other major Federal departments and agencies, such as the Department of Defense (DOD) and the Veterans Administration (VA). Within HEW, the health data activities of PHS and HCFA are reviewed. The overview of data collection systems is designed to be illustrative, not exhaustive.

Chapter 3 discusses activities presently conducted by Federal agencies that have responsibilities for health data policy, oversight, and coordination. The responsible Federal agencies are described hierarchically, beginning with OMB and the Department of Commerce—the two executive branch components charged with Government-wide statistical oversight responsibilities. The remaining sections of the chapter describe offices and committees within HEW.

Chapter 4 of Part I describes a structure designed to improve the coordination of Federal health statistics. Requisite functions and activities are delineated. The need to formally assign responsibilities is discussed and alternative locations within HEW for such delegated authority are identified.

Part II of this report focuses on legislation that may be used to generate health data collection projects. The directory is designed to determine the extent to which legislation creates or amplifies fragmentation and duplication in HEW health data collection. Data collection authorities are listed according to PHS and HCFA agencies that have been delegated responsibilities for their implementation. This directory contains all the relevant statutory authorities enacted before January 15, 197'9.

Chapter 2.
OVERVIEW OF EXISTING HEALTH DATA COLLECTION ACTIVITIES



2.

OVERVIEW OF EXISTING HEALTH DATA COLLECTION ACTIVITIES

INTRODUCTION

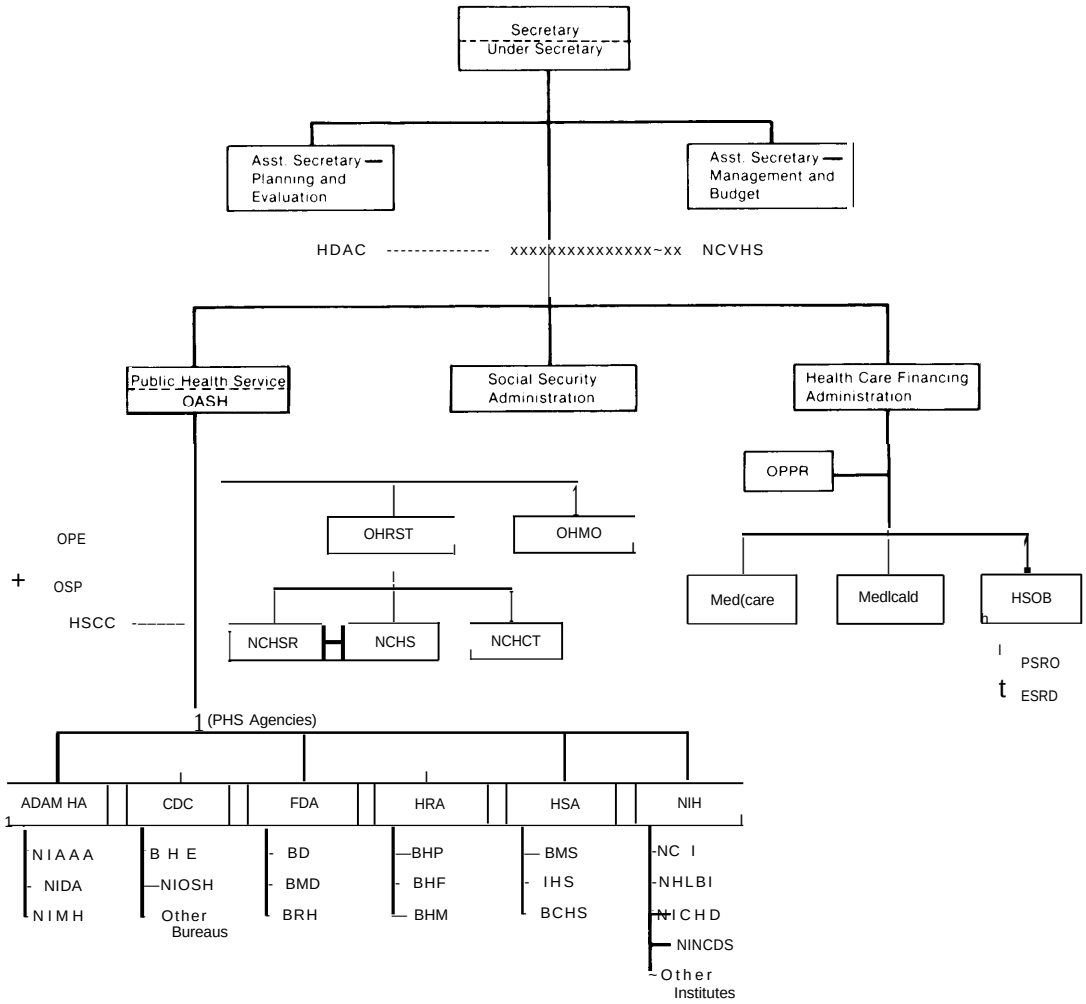
The Department of Health, Education, and Welfare (HEW) is the major collector of health statistics. Authority to administer data projects has, for the most part, been delegated to the Public Health Service (PHS) and the Health Care Financing Administration (HCFA), the two principal operating components of HEW concerned with health. In FY 1977, PHS operated 153 data projects, a 25- to 35-percent increase over the number of projects operated in the previous fiscal year (41, 42). HCFA administered at least an additional 13 large statistical projects. Other Federal agencies and departments, such as the Veterans Administration (VA), the Department of Defense (DOD), and the Consumer Product Safety Commission (CPSC), also operate a number of health statistical systems, independently of HEW, to meet their needs for information.

This chapter begins with a discussion of health data systems and health data collection. It provides background information on Federal expenditures for health statistics and describes a number of health data collection activities. The inventory of Federal data systems presented here is meant to be illustrative and descriptive, not inclusive and analytical. The focus of chapter 2 is on the statistical projects and systems administered by HEW; they are described first. Within HEW, the health data collection activities of PHS and HCFA are highlighted. Figure 1 illustrates the organizational position of HEW agencies discussed in this chapter. A discussion of data activities managed by other Federal agencies, including those mentioned above, follows. These agencies are illustrated in figure 2.

A health data system is defined as an organized, systematic acquisition and classification of health information. This definition encompasses a broad spectrum of data systems that are difficult to tally and compare because of the diversity in their purpose, scope, and cost. Data for these systems may be collected on a continuing or a periodic reporting basis; or, they may be gathered in a survey, conducted at a point in time or over a specified time interval. Data can be collected on a sample, or on a universe of respondents. They may be acquired either from a primary source, such as a questionnaire, an interview, or a physical examination, or from a secondary source, such as a billing claim or a health professional license. When data are obtained for, or as a result of, an activity not specifically related to data collection (i. e., a secondary source), these data are frequently referred to as byproduct statistics.

A major expansion has occurred in the area of byproduct statistics because more data are being obtained either for the administration of Federal programs or for regulatory purposes. The statistical output of the Medicare Bureau, for example, is derived from four basic computer files that are centrally maintained for paying the medical bills of eligible beneficiaries. Determining the number of health data systems in the Medicare

Figure g .—Department of Health, Education, and Welfare Organizational Components Involved in Health Data Activities*##



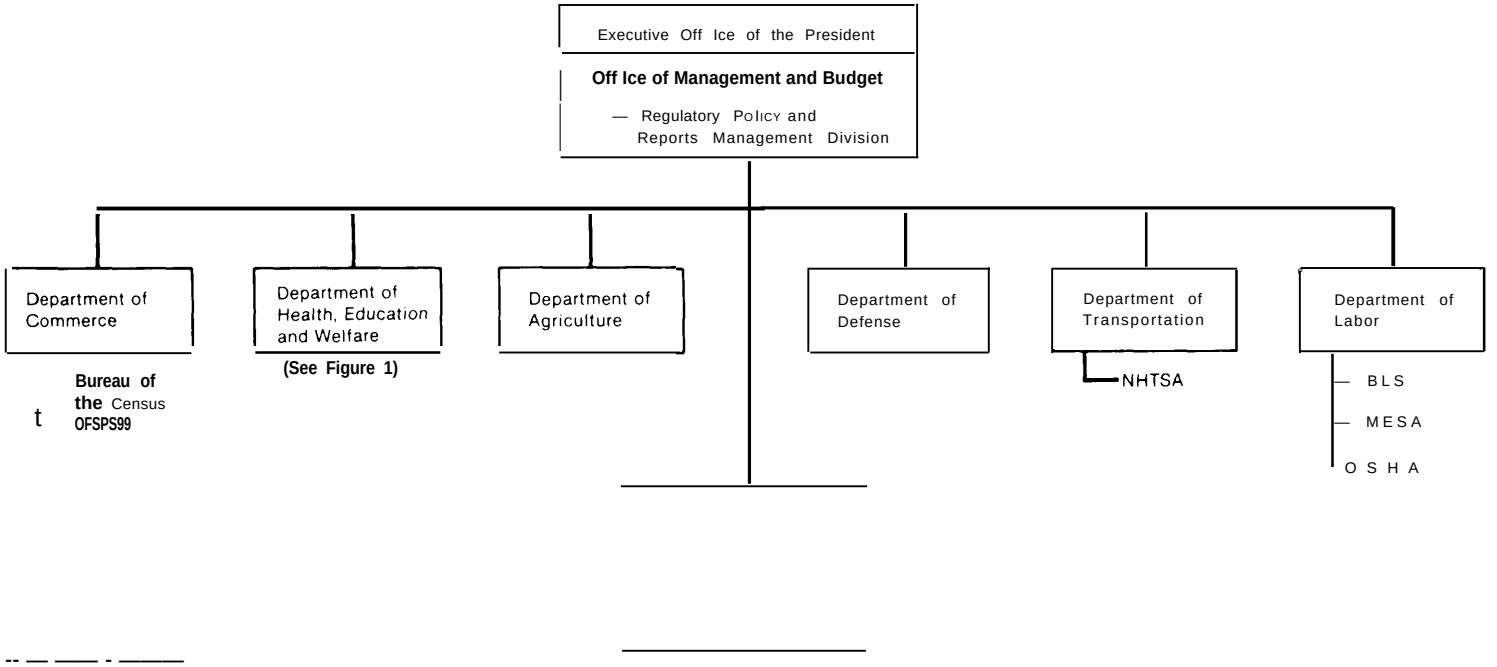
" This diagram depicts only those parts of HEW that have major responsibilities for health data policy, collection, or coordination.

 # Full names of components are given in the Glossary of Acronyms, p. xi.

Code" ------ Internal Advisory Committee

XXXX External Advisory Committee

Figure 2.—Federal Executive Branch Components Involved in Health Data Activities*



*This diagram depicts only those parts of the executive branch that have major responsibilities for health data policy, collection, or coordination

Full names of components are given in the Glossary of Acronyms, p. xi.

program is problematic. The program's four basic files or its computer programs, which are written to retrieve, integrate, and display data, could be counted individually as discrete data systems.

As the numbers and types of health data systems increase, so do their costs. HEW is the primary source of information about health data systems because it administers the majority of Federal health programs. Under the auspices of a departmentwide committee, descriptive, cost, and other information on individual data projects are collected through questionnaires distributed to agencies and are published in the HEW annual inventory of statistics **(40, 41, 42).** In an attempt to be inclusive, data projects, rather than data systems, are used as the criteria for inclusion in the inventories. Single-time surveys and evaluation and research studies that contain a large data collection component are listed in HEW's statistics plans. Biomedical research and studies funded by Federal grants are explicitly excluded from these inventories.

The Office of Management and Budget (OMB) also supplies information on the costs of Federal health statistical projects. OMB derives its figures from the budget review process, which requires every agency to submit statistical budget requests for data collection projects. Table 1 illustrates FY 1976 and FY 1977 PHS expenditures for statistical projects as reported in the HEW statistics plans mentioned above. OMB'S data on PHS expenditures for the same fiscal years are contrasted in table **2.** OMB'S estimate is approximately 20 percent greater than HEW's; estimates for individual PHS agencies vary even more.

Different administrative mechanisms used by OMB and HEW to collect agency cost figures partially explain the variation in their estimates. Budgeting personnel prepare statistical budget requests for OMB, and agencies that incur obligations of less than $300,000 for statistical programs are exempted from filing budget requests. Program planning staff complete the questionnaires for HEW's statistical plans. HEW reports direct costs associated with individual data projects. OMB'S cost estimates include the substantial administrative expenses of maintaining data systems. OMB'S estimate for the National Center for Health Statistics (NCHS), for example, includes that agency's entire budget; HEW reports costs only for NCHS surveys.

The accuracy of OMB and HEW estimates is questionable because of the difficulty of obtaining complete cost figures for Federal data activities. Available information severely underestimates Federal expenditures on health statistical projects. Information pertaining to expenditures for a number of statistical activities are often omitted by agencies in their reports to both OMB and HEW; and expenditures for statistical projects supported by Federal grants and contracts are vastly underreported. Administrative costs for statistical activities conducted by HEW-supported categorical programs, such as medical treatment centers in underserved population groups and health planning agencies, are usually not reported. For example, HCFA reported to OMB total obligations of **$4.8** million in FY **1977** for health statistics (25). However, data processing expenditures by local Professional Standards Review Organizations (PSROS), although covered under Federal contract, are not included in HCFA'S statistical budget request to OMB. Rather, HCFA reports expenditures only for processing and analyzing data sets forwarded to the central PSRO office. In FY 1977, local PSROS spent $2.2 million for data processing; HCFA central office costs were only $380,000 (7). If all these costs were included in

Table 1 .—Public Health Service Expenditures for Health Statistics Projects, as Reported by the HEW Health Statistics Plans* (in millions of dollars)

Agency	I% 1976a	w 1977b
Alcohol, Drug Abuse, and Mental Health Administration.	5.7	6.5
Center for Disease Control.	2.7	2.8
Food and Drug Administration	1.3	1.9
Health Resources Administration.	21.5	1.5
Health Services Administration.	3.7	3.2
National Institutes of Health	19.9	33.2
Office of the Assistant Secretary for Health	2.6	20.0
Total	57.4	69.1

‘ **PHS** warns that their cost estimates may not be comparable from year to year and that they represent “order of magnitude” figures
[a] **SOURCE** Public Health Service, U S Department of Health, Education, and Welfare health Statistics *Plan, fiscaLFmca/ Years* 1978.1982 Washington, D.C : U S. Government Printing Off Ice, 1977
b SOURCE publlc Health Service, u s, Department of Health, Education, and Welfare Health STATISTICSfatlSfKs *~ePorf, Fiscal Year 1978 washlngton,G9GTONon,* D. C.: U.S. Government Prlntlng Office, 1978,

Table 2.—Public Health Service Expenditures for Health Statistics Projects, as Reported by the Office of Management and Budget (in millions of dollars)

Agency	FY 1976a	FY 1977b
Alcohol, Drug Abuse, and Mental Health Administration	6.8	8.5
Center for Disease Control.	2.5	3.0
Food and Drug Administration	1.6	1.9
Health Resources Administration.	32.0	4.5
Health Services Administration.	2.4	4.1
National Institutes of Health	23.4	29.3
Office of the Assistant Secretary for Health	—	32.4
Total	68.7	83.7

[a] SOURCE: Office of Management and Budget *Speclal Analyses, Budget of the United* States *Government,Fiscal Year 1978* Washington, D C U.S. Government Printing Office, 1977
b SOURCE. Of flee of Federal StatlstIcal Policy and Standards, U.S Department of Commerce “Federal Statistics 1977.” *Stat/sf/ca/ Reporter* 78-5 121-140, February 1978

estimates of Federal expenditures for statistical projects, OMB's total estimate of $100 million for health statistics could triple. *

Neither OMB nor HEW provides adequate followup on its requests to agencies for information on statistical projects, and no uniform methods for calculating the costs of data collection are imposed. Agencies have difficulty in isolating cost figures solely related to data gathering activities that are a part or a byproduct of a program’s administrative expenses. Without appropriate guidelines, definitions, standards, and followup, inconsistencies among costs reported by HEW agencies for their statistical programs are inevitable, and inaccurate and noncomparable estimates will continue.

DATA COLLECTION ACTIVITIES OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

The Department of Health, Education, and Welfare (HEW) administers the majority of Federal health programs and health data systems. The following material outlines data collection projects and systems in the Department’s two principal health-related operating components, PHS and HCFA, and in the Social Security Administration (SSA).

*OMB includes under health statistical programs, in addition to the Public Health Service and the Health Care Financing Administration, certain programs of the HEW Assistant Secretary for Planning and Evaluation, the Consumer Product Safet, Commission, the Drug Enforcement Administration, and the Veterans Administration (12, 25).

Within PHS, data activities conducted by the Office of Health Research, Statistics, and Technology (OHRST), the Office of Health Maintenance Organizations (OHMO), and the six agencies are emphasized. Data collection activities supervised by HCFA'S Medicare and Medicaid Programs, Health Standards and Quality Bureau (HSQB), and Office of Policy, Planning, and Research (OPPR) are then discussed. Finally, SSA'S health-related statistical activities are outlined.

Public Health Service: Office of Assistant Secretary for Health

The Office of Health Research, Statistics, and Technology (OHRST) was created as part of an executive reorganization in January 1979. It has responsibility for NCHS, the National Center for Health Services Research (NCHSR), and the National Center for Health Care Technology (NCHCT). Formerly the Office of Health Policy, Research, and Statistics (OHPRS), OHRST was established to strengthen the relationship between health technology assessment, health statistics, and health services research.

The National Center for Health Statistics (NCHS) is the only Federal agency established specifically to collect and disseminate data on the health of the American people. Congress first authorized a continuing survey and special studies of sickness and disability in the National Health Survey Act of 1956, Public Law 84-652. In 1960, the National Health Survey merged with the National Office of Vital Statistics, which was established in 1946, to form NCHS. Since that time, NCHS has played a major role in the development of national health statistics policy and programs. Organizationally, the Center has moved several times within PHS; it is now located in OHRST.

The Health Services Research, Health Statistics, and Medical Libraries Act of 1974, Public Law 93-353, established NCHS statutorily and expanded its responsibilities. The law both listed the categories of general-purpose statistics to be collected by NCHS and mandated that a detailed report analyzing the country's health care costs and financing, health resources, health resource utilization, and health status be submitted annually to the President and Congress.

To fulfill its mission, NCHS conducts a number of data activities that provide vital statistics and health facility, health manpower, and health status and health care utilization statistics. NCHS also has the primary administrative responsibility for the Cooperative Health Statistics System (CHSS), * a joint Federal, State, and local program for the collection of health data.

The NCHS Division of Vital Statistics collects natality, mortality, marriage, and divorce statistics. These statistics are derived either from microfilm copies of State certificates of marriage and divorce and State records of births and deaths, or from the computer tapes supplied through the vital statistics component of the CHSS program. NCHS then publishes statistical summaries based on this State-supplied information. In addition, NCHS periodically conducts "followback" surveys that are based on samples of birth or death records. They are designed both to provide national estimates for a range of items that are not usually included in vital records, such as demographic characteristics, and to evaluate the quality of data contained in the vital records.

The NCHS Master Facility Inventory, initiated in 1962 and updated biennially, furnishes information on all inpatient health facilities that provide medical, nursing, personal, or custodial care, Data are collected on facility ownership, finances, patient population, provision of services, number of beds, and pattern of staffing. Another facil-

*See chapter 3 for a detailed discussion of the CHSS program.

ity inventory, also updated biennially, supplies information regarding family planning clinics. A third example of a facility data system is the National Nursing Home Survey. Conducted every 2 years, it gathers data from a sample of nursing homes, their residents, and their staff.

NCHS manpower statistics consist of periodic inventories of various health professionals, including physicians, registered nurses, pharmacists, and optometrists. The manpower inventories are conducted only in States that have not implemented the CHSS program. In 1975 and 1976, for example, NCHS conducted a survey of hospital staff. This survey covered 110 health occupations and was used both to identify manpower shortages or oversupply and to assess trends in the recruitment and the employment of allied health personnel.

NCHS also operates five major general-purpose surveys that provide statistics on the health status of the U.S. population and on their use of health care services. The Health Interview Survey (HIS), performed annually since 1957, provides data on the incidence of illness and accidental injuries, the prevalence of diseases and impairments, the extent of disability, the utilization of hospitals and other health care services, and other health-related topics. These data are obtained through interviews conducted in a probability sample of households.

The Health and Nutrition Examination Survey (HANES), * which was initiated in 1971, obtains standardized data from direct physical examinations of a sample of the U.S. population. Data are collected periodically to estimate the prevalence of chronic diseases, to establish physiological standards for various tests, to determine the nutritional status of the population, and to assess exposure Ievels to certain environmental substances. Data are also collected, through interviews, on self-perceived health needs and health practices. The National Survey of Family Growth acquires data on childbearing and family growth patterns. These data are needed to interpret current trends in the birth rate, to aid in the planning, management, and evaluation of family planning programs, and to provide guidance for efforts in the areas of infant and maternal health. Data are collected through personal interviews with women of childbearing age. NCHS began this survey in 1973.

The Hospital Discharge Survey (HDS), begun in 1965, collects data from the medical records of a sample of patients discharged from a number of the Nation's short-stay hospitals. Data abstracted from patients' medical records include demographic characteristics, diagnoses, surgical procedures, and administrative information about the hospital stay. Annual profiles on national and regional hospital use, organized according to diagnoses, procedure, patient characteristics, and other variables, are then published by NCHS. The National Ambulatory Medical Care Survey (NAMCS), first conducted in 1973, gathers data on a number of patient visits from a probability sample of office-based physicians. Participating physicians complete a brief encounter form that requests information regarding patient characteristics, reason for visit, diagnoses, treatment and services, and disposition.

The National Center for Health Seruices Research (NCHSR) shares responsibility with NCHS, the Assistant Secretary for Planning and Evaluation (ASPE), and HCFA for the National Medical Care Expenditure Survey. This survey represents a cooperative effort between PHS and HCFA to supply data to users who require information on health

*The Health Examination Survey (HES) Was the precursor to HANES. HES collected data on the health status of adults, between 1960 and 1962: of children, between 1963 and 1965: and of teenagers, between 1967 and 1968.

care costs. Begun in 1976, this large, one-time survey is collecting information from households, physicians, hospitals, and health insurance companies. The survey is acquiring information on expenditures for health care by different population subgroups in relation to utilization, health status, and health conditions. The survey is expected to be completed this year.

The Office of Health Maintenance Organizations (OHMO) requires quarterly and annual reports from qualified health maintenance organizations. Data are collected on enrollment, financing, staffing patterns, and use of services. The reporting system is used for program management, planning, and evaluation.

Public Health Service Agencies

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) has the major responsibility within the Federal Government for the prevention and treatment of alcohol abuse and alcoholism, drug abuse, and mental and emotional illness. Its three Institutes, the National Institute on Alcoholism and Alcohol Abuse (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH), award grants and contracts for research, prevention, training projects, and treatment service delivery in community-based programs.

NIAAA has specific legislative authority to collect information on the cause, treatment, and consequences of alcohol abuse. Its primary data system, the Alcoholism Program Monitoring System, collects data that describe the clients, the services, and the costs of alcoholism treatment programs funded by NIAAA. Data are used to plan, manage, and evaluate programs.

NIDA, which is required by statute to collect uniform statistics related to drug abuse and the availability of treatment resources, operates three major health data collection systems: the Client Oriented Data Acquisition Process (CODAP), the National Drug Abuse Treatment Utilization Survey (NDATUS), and the Drug Abuse Warning Network (DAWN). The CODAP system, also used by the VA and the Bureau of Prisons, gathers client-related data at the time of admission to, and discharge from, federally supported drug abuse treatment and rehabilitation programs. These programs are required to report to NIDA. Data on nationwide resources devoted to drug abuse treatment, their use, and their distribution are gathered through NDATUS. All drug abuse treatment facilities are surveyed annually; however, participation in the NDATUS survey is voluntary. Finally, data on drug-related deaths, medical emergencies, and psychological crises are collected from participating emergency rooms and medical coroners in DAWN, which is jointly sponsored by NIDA and the Drug Enforcement Administration (DEA).

NIMH, through its Division of Biometry and Epidemiology, conducts annual inventories of public and private mental hospitals and community mental health centers. Hospital psychiatric divisions, halfway houses, outpatient mental health clinics, and other mental health facilities are inventoried biennially to collect data depicting caseload, services, and expenditures. Sample surveys are also conducted periodically to gather detailed data about patient characteristics and the use of services. Participation by institutions in NIMH surveys is voluntary.

Presently, NIMH is developing a statistics improvement program that would enhance State and local capabilities for statistical collection and analysis. This Federal-State-local system would be operated independently from the NCHS Cooperative Health Statistics System. Consequently, NIMH and NCHS have established a joint coordinating

committee. At present, NIMH's inventory data on mental health facilities are integrated with the NCHS Master Facility Inventory to avoid duplication.

The Center for Disease Control (CDC) is responsible for monitoring and reducing the incidence of preventable diseases. Its two major data reporting systems, the National Disease Surveillance Program and the Morbidity and Mortality Weekly Report, are used to examine disease patterns and trends, to identify regional problems, and to evaluate the effectiveness of control measures. Through a variety of reporting systems, CDC receives summary data from State, county, and city health authorities on 45 specific conditions. These reporting systems are authorized primarily by State laws enacted to control communicable diseases.

CDC maintains special data programs to monitor congenital malformations, abortion-related complications, birth defects, diabetes, tuberculosis, and venereal diseases. The manufacture rates of biologics is also monitored by CDC. Data regarding children's immunity levels against vaccine-preventable diseases are obtained from the U.S. Immunization Survey, which is conducted by the Bureau of the Census under contract to CDC. CDC analyzes the Bureau of the Census data and prepares the reports.

For program evaluation purposes, CDC receives summary data from Federal grant recipients who administer State and local health programs for disease prevention and control. These programs are designed, for example, to prevent venereal disease and lead poisoning, to control rats, and to immunize individuals against preventable diseases. CDC'S Bureau of Health Education (BHE) and the Office of the Assistant Secretary for Health (OASH) are responsible for informing the public about health practices and disease prevention. BHE therefore conducts surveys to determine public attitudes and knowledge on topics such as smoking and immunizations.

Finally, CDC provides support for the regulatory functions of several other Federal agencies. For example, CDC evaluates the qualifications and quality control practices of clinical laboratories for the Medicare program. The National Institute of Occupational Safety and Health (NIOSH), within CDC, assists the Department of Labor's Occupational Safety and Health Administration (OSHA) in identifying occupational health hazards and in establishing workplace health standards. The National Occupational Hazard Survey, conducted by NIOSH between 1972 and 1974, provides estimates of the proportion of employees exposed to potential health hazards in various industries. In addition, NIOSH periodically conducts special industrywide studies to identify the health effects of particular industrial processes and to determine the health experience of selected employee populations. NIOSH also operates the National Surveillance Network which receives data from State safety and health inspection programs that describe empIoyee exposure to health hazards. Finally, an X-ray examination program for coal miners to determine the prevalence of black lung disease (pneumoconiosis) and to provide epidemiological data for research is operated by NIOSH.

The Food and Drug Administration (FDA) is responsible for evaluating the safety of food, drug, cosmetic, and medical device products before their introduction into the marketplace. It evaluates the efficacy as well as the safety of new drug and medical device products. FDA also monitors manufacturer compliance with its regulations.

FDA conducts a number of special surveys and studies on topics ranging from consumer attitudes on, and knowledge of, nutrition to the use of selected drug products in clinical practice and the health effects of exposure to specific types of radiation.

FDA supports four major ongoing health data collection projects. The FDA Bureau of Drugs (BD), in collaboration with the National Institute of General Medical Sciences

in the National Institutes of Health (NIH), funds the Boston Collaborative Drug Surveillance Program (BCDSP). BCDSP monitors selected inpatient populations to determine rates of adverse reactions to certain drugs and provides data on overall drug use in the sampled population. BD also maintains a central system for reporting the incidence of adverse drug reactions. However, statistical analyses of data are not possible because reporting is voluntary and there is no sampling plan.

The Bureau of Radiological Health (BRH), operates the Nationwide Evaluation of X-ray Trends (NEXT) system, the second major health data collection project operated by FDA. NEXT is designed to detect and evaluate the extent of the population's exposure to X-rays used in medical and dental examinations. Data are collected from a sample of hospitals, private offices, and clinics in States that participate in the survey.

The Medically Oriented Data System, the third data project, is operated by the Bureau of Medical Devices (BMD). It is designed to analyze data collected from a small sample of hospitals on drug abuse, medical device injuries, and other hospital-based health hazards. BMD also operates the Medical Devices and Laboratory Product Problem Reporting Program; this system uses information collected by other agencies that participate in the Devices Experience Network (DEN), a central network for all reports concerning problems with medical devices.

The Health Resources Administration (HRA) is concerned with the identification, development, and effective use of national health resources. A new administrative unit, the Bureau of Health Facilities, Financing, Compliance and Conversion (BHF), was established in HRA by an executive reorganization in 1978. BHF operates a data system that contains information on all health care facilities seeking grant or loan support under the Hill-Burton program. The Hill-Burton reporting system has been modified a number of times reflecting some conflict over the specific purposes it should serve.

The Bureau of Health Planning (BHP) oversees a nationwide network of local and State health planning agencies. These planning agencies are expected to compile and analyze data on the health status of residents in their area and on the effect of the area's health care resources. Federal guidelines establish minimum requirements specifying categories of data to be collected, but these data are not required to be forwarded to BHP. However, local and State agencies must submit annual health plans to BHP.

To the extent possible, local agencies are expected to rely on data assembled from other sources. Although substantial progress has been made, health planning agencies have had difficulty in obtaining data of appropriate geopolitical detail. They do not have the funding resources necessary to undertake major data collection activities that would fulfill their needs for small area data. Therefore, plans are underway to obtain selected program data for the areawide agencies from the Medicare program and from NIMH. In the future, CHSS is expected to provide much of the data needed by the planning agencies.

The Bureau of Health Manpower (BHM) is mandated by its enabling legislation to meet extensive data requirements relating to health manpower supply, demand, specialty, productivity, and geographic distribution. Data that may be used to delimit the critical level of health manpower needed to adequately serve areas are also required from BHM. Special studies and surveys of various categories of health manpower are conducted by BHM to fulfill some of its requirements. Examples of such surveys include a national sample of registered nurses and studies on the delivery of dental care by various types of dental personnel. BHM and NCHS have a formal agreement under which inventory data on various categories of health manpower are supplied by CHSS; this agree-

ment is restricted, obviously, to the States in which the CHSS system now operates. BHM also maintains the Area Resource File (ARF) system. ARF is a county-specific data system that contains a wide range of health and socioeconomic information that are compiled from secondary sources. The ARF system is used to assist both Federal and nongovernmental planning efforts.

The Health Services Administration (HSA) is responsible for Federal programs that, either directly or under grants or contracts, provide health care services to targeted population groups. Statutory language mandating collection of specific data apply, for the most part, to grantees or contractors operating health services delivery projects sponsored by HSA.

The Bureau of Medical Services (BMS) is responsible for health care services provided in PHS hospitals. It operates several data systems to provide planning and management information both for PHS hospitals and outpatient clinics. BMS also operates a data system that provides information about services delivered to eligible PHS beneficiaries in non-Federal contract programs. Finally, BMS is responsible for the emergency medical services program for which a uniform reporting system is not yet operational.

The Indian Health Service (IHS) provides comprehensive health services to American Indians and Alaskan Natives. Nine data collection systems managed by IHS supply information on services provided both by IHS hospitals, clinics, clinical laboratories, and by community, social, and mental health workers for planning, management, and evaluation purposes. IHS also administers sophisticated automated medical record systems in two of its service areas. These systems allow health team members to obtain detailed patient information immediately through computer terminals. Most data processing for the variety of data collection systems is done centrally at the IHS computer facility in Albuquerque, N. Mex.

The Bureau of Community Health Services (BCHS) oversees a number of categorical programs that provide medical services for underserved populations. In **1977,** BCHS instituted a management data system called the Bureau of Common Reporting Requirements (BCRR). This system collects uniform program data from all health services delivery projects, such as migrant or community health centers, that are funded by BCHS. Aggregate data are collected on patient characteristics, service utilization, staffing, and costs.

BCHS funds several other ongoing data collection projects, including one that collects data from a sample of clinics providing sickle cell anemia screening programs. BCHS and NCHS jointly administer another system that collects detailed clinical information from a sample of patients who visit family planning clinics. BCHS contracts with the Association of State and Territorial Health Officers for the operation of the National Public Health Program Reporting System (NPHPRS). This system is a summary report of State expenditures for public health activities by program categories. The qNPHPRS also provides data on State expenditures for activities under the Maternal and Child Health and Crippled Children's programs. Finally, BCHS also operates a data base that uses existing data sources, including NCHS, the United States Census, and the American Medical Association, to meet its legislative mandate to identify and designate medically underserved areas.

The National Institutes of Health (NIH) is composed of 11 research institutes dedicated to biomedical research on the cause, prevention, diagnosis, and treatment of disease. These institutes both conduct research in their own facilities and support research projects in universities, hospitals, and other non-Federal organizations.

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Excluding laboratory research, NIH data collection projects are primarily epidemiological studies designed to trace the patterns of disease, to test specific hypotheses regarding the conditions and factors associated with significant disease rates, to identify risk factors in the population, and to determine the effectiveness of various diagnostic and treatment modalities. A small number of data collection projects focus on the incidence, prevalence, and related morbidity of specific diseases. NIH requires these data in an effort to establish research priorities for the study of diseases, to apportion research resources, and to determine population subgroups that may be at highest risk levels.

The National Cancer Institute (NCI), which is solely responsible for administering more than one-fifth of all Federal health research funds, conducts the largest data collection activities within NIH. Several of NCI'S more extensive epidemiological studies relate to screening for breast and cervical cancer. NCI also operates the Surveillance, Epidemiology, and End Results (SEER) data system to provide information for planning its research, control, and evaluation programs. Data are obtained in the SEER program from cancer registries that sample about 10 percent of the U.S. population. Data are available by site of cancer on cancer incidence, trends in therapy, and associated changes in patient survival.

Other NIH institutes that conduct numerous data activities are the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Child Health and Human Development (NICHD) and the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS). NINCDS has conducted major national surveys to obtain data regarding the incidence and prevalence of brain tumors, head and spinal cord injury, multiple sclerosis, stroke, and epilepsy. NINCDS is now leading the efforts of several institutes to explore the feasibility of using a revised NCHS Hospital Discharge Survey to fulfill a substantial portion of their statistical needs.

Health Care Financing Administration

The Health Care Financing Administration (HCFA) was created as a part of an executive reorganization in March **1977** to unite public payment programs for health care under a single administration (3). * HCFA has three divisions, the Medicare Bureau, the Medicaid Bureau, and the Health Standards and Quality Bureau, each of which operates large, ongoing health data collection projects. HCFA'S staff office, the Office of Policy, Planning, and Research (OPPR), also operates a number of data projects.

The Medicare Bureau has primary responsibility for the Medicare program, which consists of two separate national health insurance programs for the aged and for certain other eligible categories of beneficiaries. The hospital insurance program, Part A of Medicare, reimburses medical facilities for a large portion of the costs of inpatient hospitalization and related services. The supplementary medical insuranc~ program, Part B of Medicare, pays for a range of services furnished by physicians or other health care professionals.

Program statistics for Medicare are collected as a byproduct of the claims review and payment process. Four basic data files—the enrollment file on eligible beneficiaries, the joint Medicare-Medicaid file on participating certified facilities, the Part A claims record, and the Part B payment record—form an extensive data base for the Medicare

*Before IW7, the Medicare, Medicaid, and quality assurance programs were administered in three separate Federal agencies: the Social Security Administration (SSA), the Social and Rehabilitation Service (SRS), and the Health Services Administration (HSA).

program. Because beneficiaries and providers are identified in the data files, the Medicare statistical system is the only nationwide data system that, for example, permits linkage of hospital discharges with individual persons.

The diagnoses and surgical procedures contained in the Part A claims file are coded for 20 percent of the beneficiaries. The data from these bills are then matched to the enrollee and the provider data files so that use of medical services can be analyzed by both the demographic and geographic characteristics of the aged population and by the provider characteristics. The Medicare Provider Analysis and Review (MEDPAR), a separate statistical system, restructures these data for use by PSROS and local health planning agencies. For subsequent analytical use, MEDPAR generates statistical packages containing data on hospital utilization, inter-area facility comparisons, and utilization trends.

The Medicaid Bureau provides Federal financial support, through the Medicaid program, to State programs that pay for the medical care of low-income people. Each State defines income eligibility criteria for its own program; Federal financial support ranges from 50 to 83 percent of the State program's cost.

In 1972, legislation was passed to encourage States to use an automated data system in their Medicaid programs, the Medicaid Management Information System (MMIS). MMIS, a generally designed system that can be adopted in whole, or in part, by States, is a claims processing and information retrieval system composed of six subsystems: recipient file, provider file, claims processing, reference file, surveillance and utilization review, and management and administrative reports. Federal guidelines specify the use of 114 standard data elements in the system, but only a small portion of these data are required to be forwarded to the Federal level. These Federal reporting requirements by States are called the Medicaid Minimum Data Set (MMDS). Because State Medicaid programs vary in their eligibility requirements, services covered, and payment methods, and, therefore, in program data requirements, reports produced from MMIS are not necessarily comparable from State to State.

The Health Standards and Quality Bureau (HSQB) certifies health care facilities for participation in the Medicare and Medicaid programs, and administers HCFA programs that monitor the quality of care provided to beneficiaries. HSQB administers a variety of data systems, including the Medicare/Medicaid Automated Certification System, the End-Stage Renal Disease Medical Information System (ESRD MIS), and the PSRO Management Information System (PMIS), that are designed to assess health care institutions and the health care services provided to Medicare and Medicaid recipients.

The Medicare/Medicaid Automated Certification System collects data on the number, type, characteristics, and geographic distribution of institutions that participate in Medicare and Medicaid. Hospitals, home health agencies, independent laboratories, skilled nursing facilities, and several other categories of providers are included in the data base.

The ESRD MIS assesses the appropriateness of treatment and quality of care given ESRD patients. Data are collected on medical support and treatment processes and on patient demographic characteristics, diagnoses, and outcomes. All ESRD patients whose treatments and rehabilitation costs are reimbursed by Medicare are included in the system.

Under the PSRO program, local physician-controlled organizations contract with HCFA to review the quality and appropriateness of medical care services provided to Medicare, Medicaid, and Maternal and Child Health program participants. The PMIS,

the national PSRO data system, collects a minimum set of hospital discharge data that describe certain characteristics of every patient covered under a Federal payment program. With personal identifiers deleted, these data are forwarded to the Federal Government, along with summary information about the operation, the rev~ew process, and the costs of each PSRO. The data are used at the Federal level for evaluating the management and effectiveness of the PSRO program. Local PSROS use the data to generate profiles on patients, practitioners, and institutions. These profiles serve as an analytical base for developing standards for medical care. The PMIS data set requirements are established by Federal guidelines; individual PSROS may collect information that is not federally mandated to meet locally defined needs.

The Office of Policy, Planning, and Research (OPPR), a HCFA staff office, operates an extensive research and demonstration program related to the administration and operation of Medicare and Medicaid, to experimental methods of reimbursement, and to models for national health insurance. Data are gathered that describe costs, benefits, and operations of hospitals and skilled nursing facilities, uniform hospital accounting systems, physicians' practices and fees, and long-term care facilities. OPPR also analyzes data collected in the Medicare program.

Social Security Administration

The Social Security Administration (SSA) manages the Disability Insurance Trust Fund. The fund is used for paying monthly cash benefits to disabled workers who qualify as beneficiaries and their dependents. It also provides rehabilitation services to the disabled. Since 1937, SSA has maintained all employee records submitted by each company covered by the fund. These records, secured on microfilm, contain, at a minimum, the name and social security number of each employee and specific information regarding benefit computation and actions related to employee entitlement. SSA publishes annual statistical supplements and periodically prepares detailed analyses in its special report series. These reports are based on a sample of disability records and present data depicting the basic characteristics of individuals who apply for disability benefits. Several reports regarding specific disease entities have been published in this series. Characteristics of workers disabled by diabetes, emphysema, heart disease, cancer, and accidents, as well as mental illness, have been presented.

DATA COLLECTION ACTIVITIES OF OTHER FEDERAL AGENCIES AND DEPARTMENTS

The U.S. Department of Agriculture (USDA) is responsible for measuring and appraising trends and variations in U.S. food consumption. Since 1936, large-scale surveys have been conducted by USDA to study variations in household food consumption. In 1965, USDA expanded its efforts and initiated the Food Consumption Survey. This survey, measuring not only household but also individual food consumption, has been conducted twice. The information generated by the USDA surveys is used widely to evaluate the supply and use of food, per capita food consumption, and the nutritional status of the U.S. population. USDA also collects data relating to the purchase of food stamps and to participation in child nutrition programs.

The Consumer **Product Safety Commission (cpsc''SC)** is an independent agency empowered to regulate certain products that may be hazardous. To identify the cause, frequency, and severity of injuries related to the use of particular products, CPSC operates

the National Electronic Injury Surveillance System (NEISS). NEISS obtains data through a network of telecommunications terminals located in emergency rooms across the country. Another ongoing statistical system administered by CPSC collects data from poison control centers.

The Department of Defense (DOD) provides or funds health care services for over 9 million persons and operates more than 180 military hospitals for the benefit of active-duty personnel. The Assistant Secretary of Defense for Health Affairs is responsible for overall planning and coordination, but each service branch, Army, Navy, and Air Force, operates its own health services program. The General Accounting Office (GAO) evaluated the DOD health care program in 1976 and reported that over 400 health information systems were in various stages of development or operation within the Department (11). The Tri-Service Medical Information System (TRIMIS) program was established by DOD in 197'4 to improve the effectiveness and economy of DOD's health care services through the use of computer technologies. At present, prototypic systems are being evaluated by TRIMIS before systemwide implementation takes place.

In addition, DOD periodically conducts special studies, including those that examine the health education needs of the military services, the perceived value of health care used by beneficiaries, and the feasibility of peer review for assuring quality of health service delivery. DOD also operates the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). CHAMPUS, similar to private medical insurance programs, reimburses dependents of active duty personnel, retired members of the armed services, and other eligible beneficiaries for private fee-for-service health care. DOD is developing the CHAMPUS Management Information System (CMIS) to provide information for programmatic needs. A major element of CMIS is a computer file of all eligible beneficiaries; the system will also contain files on providers, claims processing, utilization review, and management and administrative reporting.

The Environmental Protection Agency (EPA) is charged with the regulation of environmental pollutants. EPA recently completed the Community Health Environmental Surveillance Studies System. This system used large-scale epidemiological methods to monitor the health of people in areas of high concentrations of air pollutants. EPA also conducts a small ongoing project, the National Human Monitoring Program, that collects and analyzes human blood, urine, and adipose (fatty) tissues for residues of regulated pesticides.

The Department of Labor (DOL) operates, through the Bureau of Labor Statistics (BLS), the Occupational Safety and Health Survey, an annual Federal/State cooperative survey that records the incidence and severity of occupation-related injuries and illnesses. The survey relies upon employers and employees to identify work-related illnesses. Because of the long latency period of many diseases, however, illness rates are inevitably underreported in this survey. BLS also conducts occupational employment surveys that sample specific categories of health manpower. The Mining Enforcement and Safety Administration (MESA), also in DOL, produces mine injury data and data on black and brown lung diseases.

The Department of Transportation (DOT) operates the Fatal Accident Reporting System (FARS) through its National Highway Traffic Safety Administration (NHTSA). This system provides annual data on all fatal motor vehicle accidents in the United States. FARS, fully automated and operational for more than a year, gathers information from sources maintained by States. The National Accident Reporting System (NARS), now being developed by NHTSA, will provide information on the rate of nonfatal motor

vehicle accidents. NARS will be supplemented by the National Accident Sampling System, which will provide detailed information on a sample of accidents.

The Veterans Administration (VA), an independent Federal agency, operates the largest centrally directed hospital and clinic system in the United States. Its Department of Medicine and Surgery conducts a number of medical research and other special studies. The VA also operates several major automated information systems. The Automated Management Information System (AMIS), for example, provides information on VA hospitals for central planning and management purposes. Aggregate data are collected on admissions, the provision of services, and other categories of hospital operations. The Patient Treatment File (PTF) collects discharge data on all VA beneficiaries treated in hospitals, nursing homes, or domiciliary care facilities. PTF provides information on the use of the health care system and on patient diagnoses, surgical procedures, and other characteristics. A separate system gathers data on a sample of patients receiving outpatient care provided by VA facilities. The Personnel Accounting Integrated Data (PAID) system contains data on all VA personnel, including health professionals.

Chapter 3.

CURRENT COORDINATION ACTIVITIES

3.

CURRENT COORDINATION ACTIVITIES

INTRODUCTION

The U.S. Federal statistical system is decentralized and complex. Such decentralization often creates problems of fragmentation, redundancy, and user access. Furthermore, priorities for current and future data collection projects are determined largely on an ad hoc basis because major decisions regarding data collection activities usually are made or implemented by Federal agencies that administer specific programs.

Some legislative authorities, particularly the Federal Reports Act of 1942 and the Budget and Accounting Procedures Act of 1950, address the issues of health data policy and coordination. However, no single congressional mandate exists for developing health data systems in a coordinated and comprehensive fashion. In fact, a number of offices and agencies have been charged with similar health data policy, oversight, and coordination responsibilities.

There is increasing congressional and executive branch concern, however, about health data coordination and policy. In 1974, for example, Congress established a special Commission on Federal Paperwork to investigate problems associated with Federal reporting requirements, including health information requests. In addition, the 95th Congress passed legislation, Public Law 95-623, to encourage coordination among various health statistical systems.

Executive branch concern is evidenced in four executive reorganizations (March, October, and December 1977, and January 1979) that realined many of the responsibilities of Federal agencies concerning health data policy. These organizational changes are described in this chapter; however, it is difficult to predict their effect. As part of an overall reorganization effort, the President also established the Reorganization Project for the Federal Statistical System. In December 1978, the reorganization project distributed a draft report that identifies shortcomings in Federal data systems. Final recommendations of the reorganization project are expected in **1979.**

In this chapter, administrative units responsible for coordinating health statistical systems are described according to their position within the Federal Government, beginning with major departments and agencies. * They are described in terms of their mission, accomplishments, limitations, and problems. The analysis begins with the Office of Management and Budget (OMB) and the Department of Commerce—the two executive branch units charged with statistical oversight responsibilities for the entire Federal Government. The Regulatory Policy and Reports Management Division in OMB is highlighted, as is the Office of Federal Statistical Policy and Standards (OFSPS) within the Department of Commerce. The two administrative mechanisms used for supervising sta-

'Figures 1 and 2 in chapter 2 show the organizational positions of the offices and committees described here.

tistical projects, statistical budget requests and the reports clearance process, are discussed in detail.

The rest of the chapter describes offices and committees in the Department of Health, Education, and Welfare (HEW) that have health data coordination responsibilities. The description begins at the level of the Secretary with the Offices of the Assistant Secretary for Management and Budget (ASMB) and the Assistant Secretary for Planning and Evaluation (ASPE). The functions and responsibilities of a number of offices within the two principal health-related operating components of HEW, the Health Care Financing Administration (HCFA) and the Public Health Service (PHS), are then depicted. Within HCFA, the Office of Policy, Planning, and Research (OPPR), a staff office to the Administrator, is featured.

The review of PHS coordination and planning activities focuses on the activities of the Office of Health Research, Statistics, and Technology (OHRST), the Office of Statistical Policy (OSP) in the new Office of Planning and Evaluation, and the six PHS agencies. Finally, the efforts of the three HEW Committees, the PHS Health Statistics Coordinating Committee (HSCC), the Health Data Advisory Committee (HDAC), and the National Committee on Vital and Health Statistics (NCVHS), to increase coordination of statistical activities within the Department are outlined.

THE DEPARTMENT OF COMMERCE AND THE OFFICE OF MANAGEMENT AND BUDGET

Two major pieces of legislation, the Budget and Accounting Procedures Act of 1950 and the Federal Reports Act of 1942, authorize the President to coordinate and manage Federal statistical activities. Section 103 of the Budget and Accounting Procedures Act provides authority "to develop programs and to issue regulations and orders for the improved gathering, compiling, analyzing, publishing, and disseminating of statistical information for any purpose by the various [Federal] agencies . . ."(2). The Federal Reports Act, as amended, mandates review and prior approval of Federal information requests that will sample 10 or more individuals (4).

Until October 1977, the Statistical Policy Division (SPD), located in OMB, had primary responsibility for the coordination and review functions required by legislation. As the central office responsible for the direction and coordination of Federal data activities, it had the opportunity to survey and oversee all data collection programs. Its organizational position within the Executive Office of the President permitted it to foster interagency collaboration and cooperation. However, its broadly defined responsibilities and its limited staff resources hindered its ability to comprehensively and continuously address problematic issues within any single statistical area. *

Under the President's Reorganization Plan No. 1, some of SPD'S statistical policy duties were transferred to the Commerce Department. Responsibility for section 103 of the Budget and Accounting Procedures Act was delegated to the newly created Office of Federal Statistical Policy and Standards (OFSPS) in Commerce. SPD'S successor in OMB, the Regulatory Policy and Reports Management Division, retained authority for the review and clearance of most Federal data collection forms and reporting requirements. * * It also maintained responsibility for coordinating administrative data collec-

*In 1976, 2 outof the 29 staff members assigned to SPD worked in the specific area of health statistics.

* *Responsibilities for clearing reporting requirements mandated by certain regulatory activities are held by the General Accounting Office (GAO), not OMB.

tion and managing paperwork burden (16). Despite the reorganization, overlapping responsibilities for some statistical policy functions still remained. Consequently, a memorandum of understanding was exchanged in July 1978 between OMB and Commerce to clarify the respective functions of each office (27).

Under the authority of the Budget and Accounting Procedures Act, OFSPS is specifically responsible for the establishment of uniform statistical definitions, guidelines, and standards for conducting surveys and for publishing and releasing Federal statistics. In the past, SPD issued these standards through OMB Circular No. A-46. However, SPD never set guidelines relating solely to health statistics. SPD had only one staff person, who also was assigned other responsibilities, to develop statistical classifications and standards (24). OFSPS had requested and received additional staff positions so that its work in developing standards and guidelines can be expanded beyond that of SPD (9).

OFSPS conducts planning sessions with major statistical agencies, such as the National Center for Health Statistics (NCHS), to fulfill part of its mandate. It also manages interagency committees involved in statistical issues. OFSPS has just published ***A Framework for Planning U.S. Federal Statistics for the*** *1980's,* the result of an interagency planning effort begun several years ago by OMB **(26).** The ***Framework*** examines the entire range of Federal statistical activities, delineates statistical problems and areas of unmet needs, and recommends general priorities and objectives for the Federal statistical system. The chapter on health statistics outlines areas in which more comparable and integrated data systems are necessary. It also recommends some methods for improving the coordination, the development, the utility, and the overall quality of health data.

OFSPS and OMB rely on two administrative mechanisms to oversee Federal statistical projects: statistical budget requests and the reports clearance process. Both budget examiners in OMB and staff in OFSPS review statistical budget requests. These requests, required under the authority of the Budget and Accounting Procedures Act for Federal agencies incurring annual obligations of **$300,000** or more for statistical activities, are submitted to OMB (Exhibit 54 of Circular No. A-n). They consist of budget data and a short narrative statement describing each data activity supervised by an agency. * Both OFSPS and OMB may seek clarification of, or require additional information about, any budget request.

Until 1978, OMB published a yearly analysis of the principal Federal statistical programs ***(Special Analysis G, Budget of the United States Government)*** based on these budget requests. The special analysis displayed expenditures according to broad subject areas and noted major changes in program funding levels. These analyses provided useful information to policymakers regarding Federal resource allocation to general statistical areas (e. g., health, energy, labor) but they lacked sufficient detail to determine the appropriateness of funding levels for specific program-related data activities within a subject area. The only figure in the area of health, for example, was the total Federal obligation. Expenditures by various agencies and bureaus in HEW for specific data systems were not shown. Although OMB discontinued the special analysis of statistical programs, it plans to continue examining statistical budget requests. OFSPS plans to conduct its own analysis of statistical budgets which will be published in the ***Statistical Reporter,*** a monthly journal primarily designed for the exchange of information among Government employees engaged in statistical and research activities.

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*As noted in chapter 2, the value of these budget requests for determining costs for Federal statistical activities is suspect because many data projects are omitted from them.

OMB'S Regulatory Policy and Reports Management Division retains responsibility for the review of reports clearance requests, the second administrative mechanism for supervising statistical projects. * Federal agencies and groups that contract with the Federal Government may not collect information from the public without prior clearance approval of the Director of OMB. Although OMB makes the final decision regarding project clearance, OFSPS offers technical advice on statistical and methodological aspects of requests and is responsible for the substantive review of all statistical surveys.

The objectives of the reports clearance procedure are to avoid duplicate or unnecessarily burdensome reports, to ensure the use of sound statistical procedures, and to improve the quality and general usefulness of the statistics obtained (11). The review and clearance process also is being used now as the primary tool for implementing a special Presidential initiative intended to reduce the Federal reporting burden on the public **(13).**

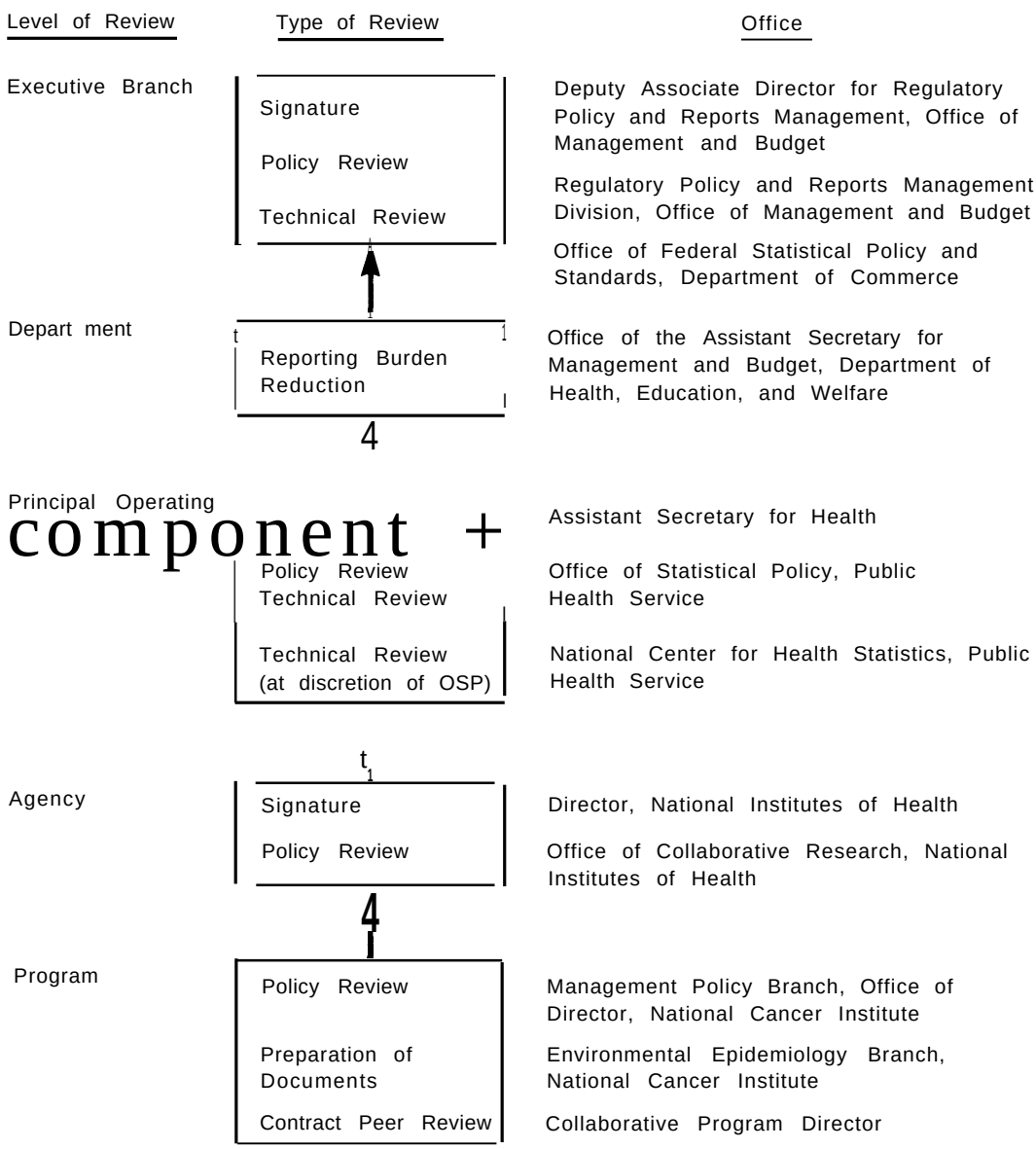
Forms or reporting plan requests are submitted to the OMB clearance office (Standard Form 83), and contain fairly comprehensive information about projected statistical activities. OMB maintains and periodically circulates a list of approved projects that are currently in use. The OMB files containing the clearance requests and sample forms or reports are open to the public; however, no attempt has been made to computerize them, nor are they available for use outside OMB offices. Currently, OMB is testing the feasibility of a computerized keyword system to retrieve information on projects approved by the clearance office.

The clearance process has been partially effective in preventing data collection activities of obviously inadequate quality and design. However, this process has a number of limitations. First, certain reports are exempted from the process, including clinical trials, data projects conducted under grants, and data collection projects mandated under the Health Professions Educational Assistance Act of 1976. In fact, the Commission on Federal Paperwork estimated that fewer than **50** percent of the reports requested by the Federal Government are reviewed by OMB **(23).** Second, the clearance process is extremely slow. Each level of the bureaucracy, from originating office to OMB, reviews every proposed project (see figure 3). Third, the clearance procedure does not set priorities for choosing reports to review, and the result is a backlog of requests which vary in significance. Finally, although agencies' clearance procedures vary, review by OMB begins at the final stage of an agency's planning process. Delaying an active review of a project until its final planning stages is untimely and inappropriate, given the large investment of resources already made in the project. Until the clearance and planning processes are linked, little improvement in coordination can be expected.

OMB also has authority, under the Federal Reports Act, to determine the necessity for collecting information, to designate a central collection agency if doing so would more efficiently serve the needs of two or more agencies, and to require the cooperation of Federal agencies in exchanging and sharing information. In practice, OMB has rarely exercised this broad authority for coordinating statistical activities in the health area. One of the few OMB attempts to provide coordinating leadership in this area met with mixed success. In 1975, OMB ruled that, in order to reduce the burden on respondents, a Bureau of Labor Statistics (BLS) survey, which focused on employees in hospitals working in nonhealth occupations, should be incorporated into a joint survey of hospital staff conducted by NCHS and supported by the Bureau of Health Manpower (BHM) (35). A survey of nursing personnel, normally conducted by a professional society, was also in-

* Requests to conduct statistical activities may also go through other clearance mechanisms, including those for grants and contracts and internal evaluation reviews.

Figure 3.— Reports Clearance Process for a Cancer Epidemiology Study Conducted Under Contract and Requiring Household or Telephone Interviews



corporate. The response rate to this survey, conducted by NCHS in 1976, was only sO percent. The volume of data the survey instrument attempted to capture caused the unacceptably low response rate. Other factors, such as lack of support from professional groups, may also have contributed to the low response rate. This example illustrates that coordinating data collection activities solely to achieve maximum efficiency and minimal respondent burden may not always provide necessary data of adequate quality for the community of users.

The implications of the 1977 reorganization that transferred certain responsibilities for statistical policy from OMB to Commerce are unclear. Under the reorganization,

OMB'S Regulatory Policy and Reports Management Division was assigned 24 positions and Commerce's OFSPS, 15 (17). * Core staff of the new Commerce office, including the Director, are former members of the OMB Statistical Policy Division. Both this transfer of staff and the active commitment of the Commerce Department to fulfill a Government-wide statistical policy function could result in the improved planning and coordination of Federal statistical activities. The fact that OMB retains sufficient authority to resolve any interagency differences that cannot be handled by Commerce increases the likelihood of success (14). However, the division of oversight responsibilities, all of which were formerly administered by OMB, between OMB and a Federal agency that itself collects data, could reduce the intended effectiveness of the reorganization. The President's Reorganization Project for the Federal Statistical System indicated in its preliminary report that it would recommend reunifying statistical policy functions in a strengthened central office (16).

THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

The Department of Health, Education, and Welfare (HEW) has a number of offices with responsibilities relating to health data policy and coordination. Authority to coordinate data projects has, for the most part, been delegated to the Health Care Financing Administration (HCFA) and the Public Health Service (PHS). However, two staff offices at the level of the Secretary, ASMB and ASPE, maintain some oversight responsibilities for health data activities throughout the Department.

The Assistant Secretary for Management and Budget (ASMB) is responsible for the implementation of reports clearance procedures throughout HEW. ASMB has delegated this authority to the Assistant Secretary for Health and to the Administrator of HCFA. This office also has overall responsibility for the development of policies and standards concerning public use of reports and reviews departmental statistical budget requests as part of its budgeting function. In 1976, ASMB instituted a special review of large new data projects (those requiring 20,000 or more reporting hours) to comply with the Presidential directive to reduce reporting burden on the public.

The Assistant Secretary for Planning and Evaluation (ASPE) provides guidance for the planning activities of the Department. The ASPE staff also conducts several large surveys in conjunction with their planning and evaluation responsibilities, and are involved in basic research on statistical methodologies. Presently, ASPE is one of several participants preparing a departmentwide health statistics plan for FY 1978.

Health Care Financing Administration

Each of the three major HCFA divisions, the Medicare Bureau, the Medicaid Bureau, and the Health Standards and Quality Bureau (HSQB), maintains large ongoing health data collection activities. The Office of Policy, Planning, and Research (OPPR), a staff oftice to the HCFA Administrator, has primary responsibility for data policy and coordination of statistical activities throughout the agency. However, the final reports clearance unit before transmittal to OMB is in the HCFA Office of Management and Budget, another staff office to the Administrator. OPPR has recently established the HCFA Health Data Policy Committee to serve as a forum for discussing internal data policy

*As mentioned previously, OFSPS has subsequently received additional staff members.

issues, including coordination. Representatives from each of the HCFA bureaus will serve on the Committee, which has not yet met to discuss its plans and functions.

OPPR is already leading efforts to develop common statistical reporting requirements for Medicare and Medicaid. Uniform billing and discharge data requirements were mandated by section 19 of the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977. Duplicative collection of discharge data by several agencies in HCFA and by other programs in PHS has been a source of problems for a number of years. In 1978, the Secretary of HEW delegated responsibility for development and collection of uniform billing and discharge data to HCFA. Two internal task forces, one on uniform billing and another on discharge data, have been formed by OPPR. The agency is now in the process of drafting proposed regulations concerning the implementation of the task forces' recommendations.

OPPR and NCHS, a PHS agency, are collaborating on another important statistical activity. They have proposed a joint, expanded survey to replace both the former Current Medicare Survey of the Medicare program and the Medical Care Expenditures Survey, a single-time survey conducted by NCHS and the National Center for Health Services Research (NCHSR). The expanded survey, the Medical Utilization and Expenditures Survey, will be initiated in FY 1980. HCFA and NCHS will both provide funding for the new survey; NCHS will administer its data collection activities.

Public Health Service: Office of Health Research, Statistics, and Technology

The Office of Health Research, Statistics, and Technology (OHRST) was created by a January 1979 reorganization of the Office of the Assistant Secretary for Health (OASH) to replace the Office of Health Policy, Research, and Statistics (OHPRS). This new Office will supervise the activities of NCHS, NCHSR, and the National Center for Health Care Technology (NCHCT). The Office was established to augment PHS'S ability to foster and assess technological developments in health and to strengthen the relationship between health statistics, health services research, and health technology assessment.

The 1979 reorganization transferred the Office of Statistical Policy (OSP), which was located in OHPRS before the reorganization, to another new office, the Office of Planning and Evaluation (OPE). The responsibilities of OPE and the ongoing activities of OSP will be discussed in a later section.

The National Center for Health Statistics is the only Federal agency expressly established to collect and distribute information describing the health of Americans. NCHS was created statutorily* by the Health Services Research, Health Statistics, and Medical Libraries Act of 1974, Public Law 93-353. This Act directed the Secretary of HEW to use NCHS to coordinate, to the maximum extent possible, all health statistical activities begun and supported by HEW. The law also authorized NCHS to design and implement a cooperative health statistics system to produce comparable and uniform health data and statistics at the Federal, State, and local levels.

NCHS'S latest enabling legislation, the Health Services Research, Health Statistics, and Health Care Technology Act of 1978, Public Law 95-623, mandated the establishment of standardized means for collecting all health information and statistics that are authorized by laws administered by HEW. It also directed the review of all health data collections that are subject to the reports clearance process to insure their ***conformance***

*As noted in chapter 2, NCHS was first created in 1960 by the merger of the National Health Survey with the National Office of Vital Statistics.

not only to promulgated standards, but also to the minimum data sets that have been established for several substantive areas. NCHS began conducting technical reviews for some proposed health data collections as part of the reports clearance process in 1978.

It is too early to predict NCHS'S effectiveness in fulfilling its new responsibilities. The Secretary has not yet formally delegated authority for Public Law 95-623, but it could be interpreted as considerably strengthening NCHS'S role within the Department for coordinating health statistics. In addition, this legislation may create the statutory base for NCHS participation in the reports clearance process and provide authority for taking corrective action should data projects fail to conform to the standards.

Public Law **95-623** also authorized NCHS to expand its epidemiological activities and to coordinate the development of a Government-wide statistical program on the health effects of the environment. However, no additional funds were appropriated to NCHS in FY 1979 for these tasks.

NCHS administers two programs that are designed expressly to improve the efficiency and coordination of health statistics. These programs, the Cooperative Health Statistics System (CHSS) and the Reimbursable Work Program (RWP), were created to fulfill the Agency's legislative mandate to produce comparable and uniform health information and statistics. Despite NCHS'S latest enabling legislation, both CHSS and RWP are likely to continue to be the primary NCHS programs for coordination.

CHSS is an organizational mechanism for the development of health data systems that can be shared by data producers and users at the local, State, and Federal levels. The conceptual basis of the program is that data should be collected and processed by the level of government or by the agency best equipped to collect them, and that the data should be shared with all other levels and users in machine-readable form. The long-range strategy of this hierarchical and linked data collection approach is to reduce cost and respondent burden while meeting informational needs of users at all levels of government.

When fully developed, CHSS will include seven components, each of which will provide a different type of health-related data: vital statistics, health manpower, health facilities, hospital care, ambulatory care, long-term care, and health survey data. Within each component, standard definitions, comparable methods, and a core data set will be established to ensure the quality and comparability of data across States. Operationally, the system will work through either a State center for health statistics or a consortia of data users and producers within a State. NCHS provides contracts to these State agencies or data consortia for the development of statistical components, conducts technical assistance and training programs, and pays the appropriate Federal share of the costs. NCHS also is coordinating efforts among Federal agencies so they will link their data needs to CHSS. This program may be unable to fulfill its intended purpose, however, because participation by these various data users and producers is voluntary.

Although receiving a statutory base in Public Law **95-623** and high priority from NCHS, CHSS is developing slowly. By the end of FY **1978, 44** States had contracts for the vital statistics component, and **36** States had contracts for both the health manpower and the health facilities components. Hospital discharge data systems, the fourth active CHSS component, were being implemented in 9 States (19). Even if CHSS were completely implemented in all the States, national data would not be available for at least 4 to 5 years, and time series data would take even longer to develop. In addition, within the data components that are operational in some States, many problems of comparabil-

ity, completeness, data element uniformity, and periodicity of data collection are evident (21, 35).

NCHS is seeking additional Federal funds to accelerate the implementation of CHSS. In FY 1978, Federal expenditures for CHSS totaled $14.3 million (25). If additional funds are allocated to the program, NCHS plans to implement the vital statistics, health manpower, and health facilities components in all States by **1979** and all seven CHSS components by 1983 (34). OSP has awarded a contract to fully evaluate CHSS, including its concept, organization, and costs. A preliminary report is anticipated in 1979 and a full report in 1980.

RWP allows NCHS, with its superior technical capabilities and expertise, to be reimbursed for performing statistical activities that supply data to other Federal agencies. For example, RWP derived estimates of "problem drinkers" by States for the National Institute on Alcoholism and Alcohol Abuse (NIAAA). These estimates were used by NIAAA in decisions concerning the allocation of Federal funds to alcoholism treatment centers. Through the Health Interview Survey (HIS), NCHS also collected data for the Office of Smoking and Health (OSH). NCHS views the RWP as an important mechanism for increasing the reliability and validity of data, eliminating overlap, and reducing overall Federal costs (34). Its statistical services include not only methodology design, technical assistance, and data analysis but also the actual data collection for other Federal programs.

NCHS established the RWP in FY 1976 under the authority provided by section 601 of the Economy Act of 1932. Staff restrictions on NCHS, however, have limited its growth and hindered the performance of its duties. In RWP'S first year, NCHS allotted 25 positions for the program. This allocation increased the total number of staff positions to 34. Previously, NCHS had informally delegated nine positions to the program in order to begin responding to Federal agencies' requests for technical assistance. Since 1976, no new staff positions have been created.

Public Health Service: Office of Planning and Evaluation

The Office of Planning and Evaluation (OPE), as mentioned previously, was created as part of the January 1979 reorganization of OASH. The health policy, evaluative, and legislative development responsibilities of the Office of Health Policy, Research and Statistics (OHPRS), now OHRST, were transferred to the Office of Planning and Evaluation. The Office of Statistical Policy (OSP), the focal point within PHS of efforts to develop and coordinate health data and statistical policy, was also transferred from OHPRS to the new office. Statutory authority for the activities of OSP derives from section **301** of the Public Health Service Act which requires the Surgeon General to promote the conduct and coordination of data collection activities.

The Office of Statistical Policy (OSP) has responsibilities for coordinating and standardizing all health data policy for PHS and acts as a liaison for statistical policy with other Federal agencies concerned with health issues. OSP reviews and makes recommendations on PHS statistical budgets, plans, evaluation studies, and legislative proposals, and is responsible for the final reports clearance within PHS. It reviews and comments upon reports, papers, and studies relative to statistical policy issues for the Surgeon General and provides a statistical perspective to the PHS policy development process. OSP was instrumental in the development of, and now provides staff support for, both the PHS Health Statistics Coordinating Committee (HSCC) and the Health

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Data Advisory Committee (HDAC). The direction, coordination, and much of the work of the HEW annual inventory of health data projects are being conducted by OSP.

OSP was established by a December **1977** reorganization of OASH that gave special attention to data policy. Before 1977, OSP was part of the Office of Policy Development and Planning (OPDP), a predecessor of OHPRS. Despite subsequent reorganizations, OSP has retained many of the same broad responsibilities, delegated by the Secretary for statistical coordination and planning, as OPDP **(43).** Thus, the accomplishments and problems of OSP can best be viewed in an historical context.

OPDP concentrated its staff resources on final clearance activities, and its efforts were successful in reducing Federal reporting burden. Approximately 340 data projects were initially reviewed by the Office in FY 1974, the number of projects submitted for review in FY **1977** had decreased to approximately 170. In FY 1978, OSP reported the submittal of 156 projects (48).

The reports clearance process, which reviews projects for technical, substantive, and policy concerns, has improved the technical quality of surveys and other data collection activities conducted by PHS. To further enhance technical quality, OSP initiated a procedure by which any project submitted for clearance that contains complex methodological or sampling designs is routed to statisticians in NCHS for technical review. OSP also routes data projects involving surveys of hospitals or health manpower to NCHS, which then checks samples to assure they do not duplicate selection of the same health professionals or hospitals responding to current data projects.

OSP'S successes in planning and coordinating data projects are less clear than its achievements in reducing reporting burden. Limited authority and insufficient staff in both OPDP and OSP have prevented aggressive planning for the majority of health data systems and projects. Presently, there is little indication that OSP will provide greater leadership in health data policy matters than its predecessor.

Public Health Service Agencies

The six agencies of the Public Health Service independently and jointly conduct some activities related to the coordination of health data. A representative of each agency is a member of PHS'S HSCC. Each agency has its own clearance officer who reviews agency forms, reports, and data systems before their transmittal to OSP. In addition, several agencies have made substantial efforts toward improving the coordination and compatibility of their own data systems.

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) is planning to establish a new data-related committee to replace the recently abolished Program Data Coordinating Committee (PDCC). During its existence, PDCC examined the conceptual and definitional compatibility of data elements used in the client-oriented data systems of ADAMHA's three institutes. Goals of the PDCC included determining minimum data sets and, while not combining Federal-level data systems, encouraging individual States to develop an integrated data system for all programs administered by ADAMHA. As part of a mental health statistics improvement program in the National Institute of Mental Health (NIMH), one of the three ADAMHA institutes, uniform data sets for mental health facilities, manpower, and client data are being developed. To ensure consistency with CHSS, a memorandum of understanding was exchanged between NIMH and NCHS and an interbureau committee was established to maintain coordination.

The Center for Disease Control (CDC) has a staff activity that evaluates current national surveillance systems in an effort to coordinate them. Currently, a number of surveillance systems obtain data from various sources, including city and county health departments, State health departments and vital registrars, hospitals, physicians, and clinical laboratories. The CDC staff activity, organized in early 1978, has initiated several studies to determine the best methods for obtaining unduplicated counts of different health conditions. Results of the studies, which are expected within 3 years, are meant to indicate which surveillance systems should be combined or eliminated.

The Health Services Administration (HSA) maintains no formal data coordinating committee for its three major divisions, the Indian Health Service (IHS), the Bureau of Medical Services (BMS), and the Bureau of Community Health Services (BCHS). However, BCHS has successfully consolidated the requirements for its health services programs into a common program management reporting system. The new data system, the BCHS Common Reporting Requirements (BCRR), became operational in early 1977, replacing six diverse program data systems.

The Health Resources Administration (HRA) and two of its bureaus, the Bureau of Health Planning (BHP) and the Bureau of Health Manpower (BHM), work closely with NCHS to determine and meet the data needs of their programs. Enabling legislation for BHP, Public Law 93-641, and for BHM, Public Law 94-484, mandated this cooperation with NCHS. Currently, NCHS is assisting BHP in the preparation of manuals about data resources for local and State planning agencies; and BHM and NCHS are jointly developing methods to gather data for extensive manpower-related requirements. Successful coordination may have been facilitated by NCHS'S former location within HRA.

The National Institutes of Health (NIH) has customarily allowed each of the 11 individual institutes to assume responsibilities for their own data needs. In **1977,** NIH formed an inter-Institute coordinating committee of epidemiologists to encourage the efficient use of funds in meeting the data needs of the 11 institutes and to respond to the increase in epidemiological research. The committee, which also has representatives from other PHS agencies, serves as a forum for discussing major epidemiological research projects during the early stages of planning. A second committee, the Cost of Illness Coordinating Group, was formed at NIH to investigate methods for developing data on the incidence, prevalence, and cost of diseases.

Advisory Committees

The PHS Health Statistics Coordinating Committee (HSCC) was established in mid-1978 to ensure greater technical and operational coordination of statistical activities within PHS. It acts as an internal forum for information exchange and operational and technical coordination. Representatives from each of the six PHS agencies serve on the Committee. The Director of NCHS chairs the Committee, and OSP serves as executive secretariat.

HSCC meets on a monthly basis and has formed several task forces. One task force, concerned with comparability and standards, has just completed guidelines for standard definitions and minimum categories for data collection for eight data items. HSCC will serve as the conduit for agency comments on the guidelines as well as for their promulgation through PHS reports clearance channels. Another task force is reviewing the NIMH Mental Health Demographic Profile System in terms of its ability to fulfill various PHS agency needs.

The Health Data Advisory Committee (HDAC) was formed to ensure that the health statistical systems of HEW are coordinated, produce complementary statistics, and minimize the impact of Federal reporting requirements on health care institutions. HDAC is responsible for evaluating data policies and systems, encouraging the coordination of statistical activities between HEW and other Federal agencies, recommending requirements and reviewing proposals for uniform data sets and for standard definitions of data elements, and advising the Secretary on cross-cutting issues relative to health statistical systems (28).

HDAC is a newly established committee; its charter was signed by the Secretary on February 3, 1979. HDAC was created to replace and augment the work of its predecessor, the Health Data Policy Committee (HDPC). In light of the recent signing of the charter, it is premature to assess the new Committee's impact. The accomplishments and limitations of HDPC are instructive in understanding HDAC'S anticipated role.

The Assistant Secretary for Health established HDPC in March **1974** to provide policy guidance and coordination for HEW health data activities. Identified as the focal organization within HEW for health data policy, the HDPC charter assigned the Committee major responsibilities that were very similar to those now delegated to the new HDAC (29). Until mid-1977, HDPC met on a monthly basis. HDPC ceased functioning at that time, pending the reorganization of OASH.

HDPC essentially served a reactive function because its activities centered around general and specific statistical issues brought to its attention. Its major accomplishment was the sponsorship of an annual health statistics plan for HEW. The initial health statistics plan, issued in 1976, represents the first inventory of HEW health data projects. The second and final HDPC plan was issued in 1977 and included a descriptive framework for health statistics. It also inventoried HEW health data collection projects and described health data systems operated by VA and DOD.

A fundamental problem of HDPC was its lack of authority to force decisionmaking or implement policies, especially those decisions involving agencies outside PHS. Although composed of agency representatives from throughout the Department, the Committee was dominated, in terms of the composition of its membership and its organizational placement, by PHS. Consequently, each member functioned as a peer within HDPC, usually without relinquishing agency viewpoints. In addition, the anticipated role of HDPC in setting priorities for remedial actions in data projects was not realized; it did not function as a policymaking body (5). This shortcoming was recognized by members of HDPC. In interviews with the Office of Technology Assessment (OTA), one member expressed the view that, although the Committee was a useful forum for expressing agency interests, the group was not successful in reaching consensus. Other members expressed frustrations with the lack of Committee progress.

HDAC was formed to correct some of the more fundamental shortcomings of HDPC. Therefore, HDAC'S members are more broadly representative of the entire Department and less representative of PHS. The Committee will be chaired, on an annual rotating basis, by the Deputy Assistant Secretary for OHRST in PHS and the Associate Administrator for OPPR in HCFA. The Director of OSP will serve as the executive director of the Committee and provide the necessary staff. The new Committee will have members from ASPE, ASMB, the Office of the Assistant Secretary for Human Development, the Office of Inspector General, HCFA, PHS, and NCHS. In addition, representatives of OFSPS in Commerce, VA, and DOD will be invited as nonvoting members to participate in the Committee's meetings. The Assistant Secretary for

Management and Budget will arbitrate issues that cut across agency jurisdictions when they cannot be resolved within the Committee **(28).**

The need for a departmentwide committee is partially demonstrated by the absence of an inventory of health data systems during the year no committee existed. PHS did publish a statistics report for FY 1977, but it included only PHS data systems. A statistical plan for FY 1978 is now being prepared under the auspices of HDAC. The plan includes an inventory of the health data activities of PHS, HCFA, ASPE, and the Office of Human Development Services.

The National Committee on Vital and Health Statistics (NCVHS) was mandated by the Health Services Research, Health Statistics, and Medical Libraries Act of 1974, Public Law 93-353, to serve as an external public advisory committee on health statistical matters to the Secretary of HEW. NCVHS was originally chartered, at the request of the World Health Organization, in the late 1940's to represent the United States at international meetings. Although NCVHS still continues to serve in an advisory role for international statistical and classification activities, its statutory authority considerably expanded the role of the 15-member advisory committee (30). Its membership, selected by the Assistant Secretary for Health, is composed of nongovernmental experts representing several health-related disciplines.

To assist and advise the Secretary, NCVHS is charged by legislation with three primary functions: to delineate statistical problems bearing on health and health status and to stimulate studies of such problems whenever possible; to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing heaIth status, health services, and health service distribution and cost; and to counsel on the design and approval of health information systems concerned with the collection, processing, and tabulation of health statistics within HEW. Legislation passed in **1978,** Public Law **95-623,** added advisory responsibilities relating to both CHSS and the formulation of standardized means for the collection of health information and statistics. This Committee's ability to fulfill such a large mandate is limited, however, because it meets only three times a year and has few staff resources.

NCVHS reviews and comments upon the various documents concerning health data prepared by HEW and OMB. It is briefed on the health data activities of various agencies within HEW and makes suggestions for their improved coordination with NCHS. Finally, it examines specific problem areas brought to its attention, including the need for promulgating and implementing the uniform hospital discharge data set throughout HEW and the lack of a single departmentwide policy on confidentiality. NCVHS has made strong recommendations for the solution of these data problems. It has also suggested several HEW reorganization plans that would facilitate coordinating and monitoring health data systems.

Substantive contributions are made primarily through its subcommittees. A number of subcommittees are currently designing uniform data sets for basic categories of health data that can be used by various Federal agencies. The subcommittee on hospital discharge data has completed its work and serves as a model for other NCVHS subcommittees concerned with uniform data sets for ambulatory care, long-term care, manpower, and facilities. Four other subcommittees are also active: One is evaluating the NCHS Health Interview Survey (HIS); another is considering needs for health information under national health insurance; a third is advising on issues related to CHSS; and the fourth is examining the needs for mental health statistics and the best methods to meet these needs.

A problem confronted by NCVHS is its traditional association with PHS, despite the fact that its enabling legislation established it in the Office of the Secretary. The Assistant Secretary for Health appoints its members and staff support is provided by NCHS. Furthermore, the Committee spends a majority of its time inspecting programs of NCHS *(26).* NCVHS has not been assigned clear responsibility for monitoring statistical activities outside PHS. In particular, it has not exercised oversight responsibilities for the data collection activities of HCFA, although HCFA maintains large data collection programs in the area of health cost and expenditure data. In early 1978, the NCVHS charter was rewritten to explicitly state that the Committee must report to the Secretary and must act as an advisor to the Department on all health statistical matters. The Secretary has not yet acted upon this new charter.

Chapter 4.

STRUCTURING COORDINATION ACTIVITIES

4.

STRUCTURING COORDINATION ACTIVITIES

INTRODUCTION

The Federal health statistical program is a patchwork of numerous data collection projects, each of which addresses different needs or purposes, Individually designed projects prevent easy linkage of data and, therefore, the formation of statistical profiles. Excluding the data systems of the National Center for Health Statistics (NCHS), which provide baseline, general-purpose health data, Federal data activities are geared to the programmatic needs of agencies that operate them. There is no systematic appraisal of the content, adequacy, needs for, or uses of health data currently collected. Rather, decisions regarding data collection, use, and release are made primarily by the acquiring agency.

Uses and needs for statistical information cut across agency jurisdictions; yet, there is no central control over health data activities, even those supervised by the Department of Health, Education, and Welfare (HEW). The two primary administrative mechanisms for monitoring data projects—statistical budgeting and the reports clearance process—exert some pressure against increased proliferation of different types of health data collection projects. However, insufficient attention has been given to coordinating the numerous data collection activities of various Federal health programs.

The lack of a systemwide approach in Federal endeavors is not unique to the area of statistics. The generic problem of fragmentation is a result of each agency's pursuit of its own specific mission; consequently, no constituencies and few incentives for coordinating agency activities exist. HEW, however, has recognized the problem of fragmentation in the area of health technologies and has begun to address it. To systematically link the activities of various agencies, HEW has proposed a major initiative for managing the lifecycle of technology development, evaluation, transfer, diffusion, utilization, and phaseout (38). A similar strategy for managing and coordinating health data projects throughout the Federal Government is also needed.

This chapter describes a structure that would coordinate health statistics according to three constituent functions: developing an analytical framework for planning the statistical system, improving the efficiency of data collection activities, and ensuring data accessibility for potential users. Activities that might be undertaken to fulfill each of these three functions are suggested. The need to formally delegate and institutionalize responsibility for coordinating activities is highlighted. The characteristics and resources that such a coordinating body would require are delineated and possible alternative organizational locations within the Federal bureaucracy are identified.

CONCEPTUAL FRAMEWORK

Designing a conceptual framework is a critical prerequisite to the development of a unified, comprehensive health statistical system. Planning the design of such a frame-

work should initially entail defining the objectives of a comprehensive health statistical system, determining the kinds and amounts of data needed to meet the various goals of the system, and applying a set of organizing principles to the data. Long-term comprehensiveness, flexibility, and balance in statistical coverage of substantive areas should be built into the framework in order to identify ongoing statistical systems that have little further utility and to respond to changing needs for information.

A conceptual framework would establish an analytical foundation for rational planning. With a definitive list of specific items of information being collected, the framework could further serve a clearinghouse function by providing information about what and how data can be located. Careful analysis of the framework would permit identification of overlapping jurisdictions in data collection and areas in which there are gaps in our knowledge. Decisionmakers who examine the framework could both determine how Federal statistical dollars are spent and what uses are made of data collected, and, as necessary, shift priorities for data collection. They could also use the framework as the basic tool for administering and allocating resources to the Federal health information system.

Devising the conceptual framework requires much initial theoretical work by technically skilled staff, who are familiar with the diversity of health statistics, in order to develop the matrix and methods for systematic analyses of data in each cell. Thereafter, staff would be needed both to collect and maintain information about existing data collection activities and to respond to requests directed to the clearinghouse. Personnel with statistical expertise and analytical abilities also would be required to determine the needs of data producers and users, to identify data gaps, and to aid in setting data collection priorities. These latter activities are integral to the planning process, and staff would have to be able to exercise sufficient authority to effect results based on their analyses.

Once the design of the conceptual framework is completed, a detailed inventory or audit of existing data systems must be conducted with the objective of integrating them into the framework. The survey could take the form of periodic requests to Federal agencies or it could be institutionalized as part of an existing administrative mechanism, such as the statistical budget request or the reports clearance procedure. If one of the current mechanisms for auditing data activities was used to build the analytical framework, it would need to be modified to ensure coverage of all health data systems and to permit the exhaustive collection of information about each data system. The framework should include all data systems that could potentially meet broad purposes; therefore, projects operated by State and local governments and by private national organizations should also be inventoried.

Information derived from such inventories would form the data base for the creation of a matrix that illustrates the relationships among existing health data systems. To be a worthwhile planning tool, the matrix must be comprehensive and permit the interaction of many health data system variables, including:

- class of data collected (such as demographic characteristics, facilities, manpower, service usage, costs, health status, lifestyle, and environmental measures);
- standard variables and/or identifiers collected;
- type of respondent and coverage;
- method of collection (mandatory or voluntary);
- collector of data (Federal, State, local, or private), level of aggregation at each stage, and data flow;
- statistical methodology;
- costs of the project for data collection, processing, analysis, and publication;

- provisions for confidentiality;
- periodicity of data collection;
- users of data and their requirements for timeliness and geopolitical detail; and
- determinants of access to data (such as official publications and availability of computer tapes).

The establishment of a clearinghouse of information on statistical systems has been advocated periodically. In 1971, the President's Commission on Federal Statistics recommended that the Bureau of the Census be funded to maintain a catalog of Federal statistics that would list the activities of all agencies (15). In 1977, the Commission on Federal Paperwork, echoing the earlier recommendation, suggested the development of a Federal Information Locator System that would provide a reference point for Federal agencies and others wishing to know what data are collected **(23).** Citing deficiencies in available data for estimating reporting burden, the Federal Paperwork Commission also recommended that a detailed register of all Federal reports, to be derived from improved clearance request forms, be designed, automated, and used for planning by the Office of Management and Budget (OMB) **(24).** Specifically noting duplicative requests for information about the health industry, this Commission urged OMB to develop a comprehensive inventory of data already collected in the health field (22). Finally, the President's Reorganization Project recommends, in its 1978 draft report, locating a Federal Data Locator Service and data user inquiry service in a central statistical organization (16).

Recognizing the need for a systematic data base, the HEW Health Data Policy Committee published a list of all health data projects conducted by the Department in FY **1975** and FY 1976 (40, 41). The Public Health Service (PHS) prepared a similar inventory for FY 1977 but limited the list to PHS data activities (42). The newly created Health Data Advisory Committee (HDAC) is preparing another departmentwide inventory that includes data projects administered in FY 1978. These inventories provide a brief description of each data project and reference staff to contact for further information.

Some attempt has been made to use these inventories as the basis for a conceptual framework. PHS, for example, presented its **1975** health statistics plan as a descriptive framework for arraying all health program management data systems (4o). Also, the 1976 health statistics plan incorporated elements of a preliminary conceptual framework for health statistics by organizing data projects into four primary subject-matter categories: health status, health care resources, health services utilization, and health care expenditures. It was proposed that the framework be used to promote cross-program analysis, to identify opportunities for standardizing data collection, and to facilitate future decisions on the development and modification of statistical systems (41). It is not clear, however, whether the health statistics plans have been used for such analytical purposes.

EFFICIENCY

Once the conceptual framework has been developed, efforts can begin to improve the efficiency of data collection activities, the second coordinative function. Efficiency means conducting health data collection activities in the most cost-effective manner possible. To achieve cost-effectiveness in health data collection, existing health data projects may need to be modified, combined, or terminated. New data collection systems also may be needed. Three specific problems are addressed with regard to efficiency: inadequate technical design, overlapping data collection, and lack of comparability.

Inadequate Technical Design

The appropriate use of the latest technical capabilities is one method of ensuring optimal efficiency. Sophisticated statistical methods may obviate the need for costly repetitive data collection efforts. For example, synthetic estimates derived from data gathered on a regional or national basis, despite certain recognized limitations, may be sufficient for the statistical needs of local jurisdictions. Sampling procedures often serve statistical purposes as well as, or better than, responses from an entire universe of respondents. Recent advances in survey research, such as computer-assisted telephone interviewing techniques, offer cost-cutting alternatives in the field of statistical surveys.

Efficiency can also be improved by redesigning independently conducted surveys or studies to meet the needs of several users. In FY 1976, the National Center for Health Services Research (NCHSR) and the National Center for Health Statistics (NCHS) spent more than $5 million on a large national survey that examined the sources and amounts of health care expenditures by various population groups for episodes of illness. The National Cancer Institute (NCI) spent **$500,000** in the same year on a survey designed to provide similar types of information, but the NCI survey focused on costs solely associated with the care of cancer patients. Several institutes in the National Institutes of Health (NIH) now are working on a collaborative effort with NCHS to "piggyback" some of their data needs on the Hospital Discharge Survey of NCHS. The impetus for this cooperative endeavor came from several researchers at NIH in an effort to obtain data that they could not have gathered themselves given the budgetary constraints of their respective institutes.

NCHS has the greatest number of statistical experts within HEW. NCHS provides technical statistical services to Federal agencies through its Reimbursable Work Program (RWP). However, the effectiveness of the RWP in assuring the use of appropriate methods is limited because it has a small staff and its services must be requested by other agencies. NCHS also does technical reviews of some new data projects at the request of the PHS forms clearance office. Technical reviews appear to be an effective mechanism for identifying major statistical deficiencies in data activities, but they further delay an already lengthy clearance process (43).

Overlapping Data Collections

Agencies tend to collect data that meet their specific program needs for planning, monitoring, and evaluation without regard for the needs of other agencies. Because most Federal health programs are categorical in approach, that is, designed to serve carefully defined groups, the activities of various programs often overlap.

The magnitude of the problem should not discourage efforts to reach the goal of one-time collection of the same or similar data from the same respondents. Grouping data in a conceptual framework by the class of information collected and by type of respondent would aid in identifying overlapping data collection activities. Careful analysis of total costs for each project should indicate the most cost-effective methods for collecting necessary data.

Addressing the issue of overlapping data collection, the Commission on Federal Paperwork advanced the concept of the "cognizant" agency (22). A "cognizant" agency is the one assigned to lead data collection activities and provide appropriate data to other Federal agencies collecting similar data. The Commission also advised that a separate agency collect data that have applications for multiple users. Regarding the latter recom-

mendation, the Commission specifically mentioned the Bureau of the Census. However, in the area of health statistics, NCHS a-rid its program, the Cooperative Health Statistics System q(CHSS), must also be considered as suitable candidates.

At present, OMB has the authority, provided by the Federal Reports Act, to designate a central collection agency; the Secretary of HEW also has the authority to coordinate statistical activities within the Department. OMB has recognized inefficiencies in the statistical systems of HEW and has suggested organizational changes. In 1971, OMB recommended that collection and processing of statistical information be combined in a service-oriented data collection and processing center in HEW *(20).* Informational requests would be channeled to this center, which would then review these requests and decide how they could best be fulfilled. The service center was intended to provide necessary statistical services, including staff and equipment, for the substantive program agencies throughout the Department. HEW did not reorganize, however, in response to the OMB request. OMB maintains the principle that major and continuing multipurpose data collections should be undertaken through statistical collection centers. However, it traditionally has deferred responsibility to HEW for deciding agency roles in statistical matters *(26).*

One attempt to coordinate HEW data activities through the Federal Reports Act mechanism was successful. In 1968, OMB'S predecessor, the Bureau of the Budget, assigned responsibility for a uniform and coordinated system of reports on family planning programs to the Office of the Assistant Secretary for Health. At that time, Federal funds for programs in family planning were provided by at least four different Federal agencies. Potential users of the data included a wide range of both public and private groups. The Assistant Secretary delegated operating responsibility to q4NCHS, and a uniform reporting system, which collected encounter data from both private and publicly funded family planning clinics, was operational by 1972.

Data collected on hospital use is the most dramatic example of overlap in health data collection systems. The Medicare administrative program, the Medicaid Management Information System (MMIS), the Professional Standards Review Organization (PSRO) Management Information System (PMIS), the CHSS hospital care component, and the NCHS Hospital Discharge Survey all collect discharge data concerning patients whose hospital costs are reimbursed under Federal programs. Private organizations, such as insurance companies and abstracting services, also collect similar data.

Federal officials have long been aware of duplication in the collection of hospital use data. However, as the requirements of each agency differed with respect to timeliness of data reporting, completeness of coverage of hospitals and patients, and specificity of data elements, consensus on a single data collector could not be obtained. Despite the fact that the claims payment process in the Medicare program has been operational since 1966, planning and implementation of the other major data systems—MMIS, PMIS, and the hospital care component of CHSS—occurred concurrently during the mid-seventies. During this period, efforts were made to incorporate a core of common data elements, the Uniform Hospital Discharge Data Set (UHDDS), into each system. In April 1975, the Secretary of HEW approved the policy of implementing the UHDDS in all appropriate Department data systems.

As of October 1978, none of the three newer data collection systems was operational countrywide. * Total Federal expenditures through FY *1978* exceed $7 million for the

*Of a total 171 PSROS, 10.s had operating data systems (7); 17 States had an HEW-approved MMIS (44); and the hospital care component of the CHSS was funded in 9 States (19).

PSRO data system and $3 million for the hospital care component of the CHSS (7, 19). Information on costs for the hospital discharge data component of MMIS are unavailable. Under the MMIS program, the Federal Government provides matching grants to States for the development and operation of the automated information system. Similarly, the Medicare program is unable to separate its statistical system costs from its administrative costs for claims processing.

Because the agencies collecting discharge data are located in both the Health Care Financing Administration (HCFA) and PHS, the Secretary of HEW is responsible for resolving conflicting interests. Under the Carter administration, the Secretary has actively pursued a solution to this 6-year problem. HCFA and PHS submitted a joint memorandum of understanding on the subject to the Secretary in the spring of 1978. Lacking other resources with unbiased interests, the Office of the Secretary sought technical advice and options from two staff offices, the Assistant Secretary for Management and Budget (ASMB) and the Assistant Secretary for Planning and Evaluation (ASPE). A tentative decision regarding the method of collecting discharge data for Federal purposes was reached in late summer, 1978; an implementation plan hopefully will be forthcoming.

Fortunately, such evident duplication does not characterize other components of the Federal health statistical system, although there does appear to be redundancy in the activities of the Medicare and Medicaid programs, NCHS, the Bureau of Health Planning, and the Bureau of Health Facilities regarding health facility data. The hospital discharge data systems example, along with the one on family planning data, illustrate that if the problem is of sufficient magnitude, action will be taken eventually. However, the weaknesses of present policy mechanisms for combating such duplication are underscored in three respects.

First, there was a complete failure to address the duplication problem during the planning period for the data collection systems. Planning for statistical projects proceeds as an internal agency activity, and involvement by other levels of government usually comes only at the later stages of the process when clearance is sought. In the case of the hospital discharge data systems, officials were aware of the duplication problem during the planning stages but unable to resolve the conflicts in perceived data needs among the different agencies. Consequently, millions of taxpayer dollars were spent for data systems that, even today, do not meet total programmatic needs. If planned data collection activities are not obviously overlapping, duplication may not even be recognized, much less appropriately reduced.

Second, the attention, interest, and intervention of the Secretary of HEW was required before resolution of the problem began. Duplicative Federal hospital discharge data systems have spanned three administrations. Knowledge and interest in the subject have changed and hindered reaching what is basically a management decision. Secretarial involvement comes only when a binding decision is sought by agencies. If data systems are operating and meeting programmatic needs, the interests of the agencies are not served by elevating the debate to the level of the Secretary.

Third, no impartial staff with statistical expertise and indepth knowledge about the varying needs of programs were available to the Secretary when a decision was made to act. Sporadic involvement of planning and management staff may be adequate in the hospital discharge data systems case, but such erratic activity constitutes neither a timely nor ongoing policy mechanism.

Lack of Comparability

Numerous data collection systems, serving both general and programmatic needs, are likely to continue given the decentralized nature of the health statistical system. Much of the data now collected are of good quality, but their utility is seriously limited by the inability to link data systems. Most analyses require more complete information than any single data system is able to provide. For example, examining the use of U.S. hospitals requires the integration of data from the American Hospital Association’s annual survey, the Medicare summary utilization file, and the NCHS Hospital Discharge Survey.

There are at least two barriers to linking, or “networking,” data systems. First, the majority of Federal health data systems are referenced to differing base populations (the denominator figure in ratios). Again, the referencing difference results from the categorical approach of the Federal Government in targeting programs to particular groups, facilities, or disease categories. Even with the general-purpose statistical program of NCHS, researchers have difficulties linking data collected in surveys that use sampling methods with mortality data, which are collected on the total U.S. population.

The linkage of data systems can be partially improved by referencing existing data systems to national, regional, or local-area populations. However, the long-term solution to this problem is probably the creation of a totally integrated information system. A technical panel of the National Committee on Vital and Health Statistics (NCVHS) is developing criteria and guidelines for such an integrated system to be used under national health insurance. The panel recommended in an interim statement that the information system be population-based and have the ability to count “persons” **(36).** An information system based on “persons” would not only allow calculation of rates for specific populations but also provide identifiers (such as Social Security numbers) that permit linkage to measures of resources, use, costs, and health status.

A second barrier to linking heaIth data systems is the lack of common nomenclature, definitions, codes, and units of measurement. It is difficult to assess program achievements, compare programs, or even relate data from a particular program to the situation in the country generally without comparable terminology and measures. Standardization is the critical prerequisite to this type of linkage.

The need for standard definitions in HEW data collection systems is highlighted by a study conducted under the auspices of the Health Data Policy Committee (37). Forty-two common data elements in 73 of HEW’s major repetitive statistical systems were analyzed in the study. Over *800* variations were found in the way the data elements were collected or displayed.

The Office of Federal Statistical Policy and Standards (OFSPS) in the Department of Commerce is responsible for the development and implementation of statistical standards and guidelines. Excluding the designations for geographic areas and ethnicity, no uniform definitions that are applicable in the health area have been issued as guidelines. The Office of Statistical Policy (OSP), in the Office of Planning and Evaluation, serves as a focal point for coordinating statistical standards within PHS. OSP has the authority to mandate use of standards by agencies within PHS through the forms clearance procedure, but has no authority over Federal agencies outside PHS, such as those in HCFA. OSP has only recently developed guidelines for eight data elements: sex, race, date of birth, marital status, residence, date of admission, date of discharge, and type of ownership. These guidelines are expected to be promulgated through PHS reports clearance channels in the near future.

A related effort in standardizing data is the development and implementation of uniform minimum data sets for well-defined substantive areas. These minimum data sets represent the basic items of information considered useful by major providers and users in a particular area of statistics. Each data element has a uniform, standard definition, and as a group, these elements form a core of information that facilitates linkage among data systems. The use of minimum data sets is a basic concept underlying CHSS, which establishes an organizational mechanism for sharing data among multiple users.

Responsibilities for the minimum data sets are shared by a number of offices and committees within HEW (31). NCVHS, through its technical subpanels, develops and designs the minimum data sets. NCHS provides staffing and technical advice for these groups. OSP has responsibility for promulgating the data sets within PHS once they have been established as a policy of HEW. Finally, the departmentwide Health Data Advisory Committee (HDAC) is supposed to provide leadership in advising the Secretary of HEW on policy and procedures for the establishment, implementation, and review of the minimum data sets. Only the Secretary has authority to approve the policy of implementing the minimum data sets throughout the Department. Both NCVHS and the Commission on Federal Paperwork have recommended that a single, central office have responsibility for promulgating and monitoring implementation of all minimum data sets (22, 33).

DATA AVAILABILITY

The third coordinative function is ensuring that the data collected in ongoing statistical projects are both accessible and responsive to the needs of potential users. Data dissemination and interpretive analyses normally are discrete from data collection. Efforts to ensure that data are, in fact, analyzed and used should parallel activities designed to improve the efficiency of data collection.

Most Federal agencies with large ongoing data projects conduct inhouse analyses and publish statistical summaries for the public. Improvements have been made in the dissemination of routinely collected data. An important example of improved dissemination efforts is the annual publication of ***Health, United States,*** a report mandated under the Health Services Research, Health Statistics, and Medical Libraries Act of 1974. The report, compiled jointly by NCHS and NCHSR, comprehensively addresses selected health issues and relies on data sources throughout HEW.

Published statistical documents, however, often do not contain sufficient detail for research and policy analyses. Computer tapes designed for public use provide the greatest flexibility to users because they contain fully disaggregated microdata with individual identifiers removed. Obtaining computer tapes of disaggregated data, which are not routinely made available by the sponsoring agency, presents many difficulties for analysts. If special computer programing is required to merge data from several files, insurmountable problems may be encountered.

The statistical system of the Medicare program in HCFA illustrates problems of data availability. Four basic data files, the enrollment file on eligibile beneficiaries, the file on certified facilities, the hospital and skilled nursing facility use record, and the physician payment record, form an extensive data base. These files can be linked through provider and beneficiary identifiers and could potentially produce a wealth of information for health care researchers and decisionmakers. Operating statistics, such as aggregate reimbursements by number of beneficiaries, are published monthly in the Social ***Security Bulletin-***

Ietin, and, periodically, summary volumes are produced for public use. Special statistical tabulations are difficult, however, to obtain from these data. Thus a single user—the Medicare program—defines what information is extracted from this large data base.

The Medicare program does attempt to accommodate the needs of other Federal programs and users. A special staff is maintained in the Office of Policy, Planning, and Research (OPPR) in HCFA to respond to individual requests. In 1978, over 2,000 requests for data were promptly answered (6). In addition, the first set of statistical tables specifically designed for use by local-area PSROS and planning agencies was generated in mid-1978 from the Medicare statistical system. Years of planning preceded the publication of this initial set of statistical tables that contained data for 1975. This lack of timeliness results partially from the technical problems of linking and merging large data files.

Administrative priorities within the Medicare program also function to constrain the ready availability of data. Because statistical projects do not directly aid the primary mission of the Medicare program, administrators who are involved with daily program operations are sometimes unaware or unconvinced of the contribution that statistical efforts can make. As a result of increasing budgetary controls, administrative policy often dictates that statistical operations have a low priority. Consequently, the research office within the Medicare program, itself, has had periodic difficulties in obtaining computer services for inhouse statistical analyses, and computer time for users outside the Medicare program has been extremely limited. Outside work is permitted only when it does not interfere with program-related activities, and restrictions protecting the confidentiality of information preclude the release of unedited computer tapes (1). Under the reorganization that established HCFA in 1977, computer services for the Medicare statistical program remained in the Social Security Administration (SSA). SSA does not have a formal statistical service function. The necessity of crossing bureaucratic lines to obtain data will probably increase problems of availability in future statistical projects.

Like the Medicare statistical system, most other Federal statistical activities are components of larger programs. Programmatic statistical and data processing units increase the utility of data tabulations and analyses for programmatic needs. Data usually are gathered in response to expressed management interests; consequently, definitions and data categories are tailored to specific problems. However, the availability and responsiveness of data decreases for users outside the organization. In light of the fact that each program must pay for statistical services within the constraints of its overall budget, statistical output and analyses not directly related to the program cannot be justified.

Even if a health data system is operated by a statistical agency, the program that funds it determines its scope and viability. The National Reporting System for Family Planning Services (NRSFPS) illustrates this point. As previously described, NCHS began operating this system in 1972 because no single agency had responsibility for the diverse Federal programs related to family planning services. Since 1972, most family planning projects have been administratively reorganized under the Bureau of Community Health Services (BCHS) in the Health Services Administration (HSA). Although the Planned Parenthood Federation of America, a private organization, was a primary user of NRSFPS, BCHS became its main source of funding. In 1976, BCHS paid three-quarters of the total $1 million cost, NCHS funded the remainder and provided staffing.

A report by the General Accounting Office (GAO) in 1975 questioned the utility of data produced in NRSFPS *(46).* It found that reports often were incomplete, inaccurate, and tardy, and that many family planning projects did not participate in the system. Moreover, KHS had no programmatic need for the detailed clinical data provided by

the system because the management needs of BCHS are met through another reporting system. As a result, BCHS recommended adoption of a more economical sample system that would permit better quality control. In 1977, the NRSFPS was converted to a sample system; some observers question its continued survival (47).

Under the Budget and Accounting Procedures Act of 1950, OFSPS has the authority to issue regulations for the improved analysis, publication, and dissemination of statistical information. OMB is mandated under the Federal Reports Act to ensure that information collected by Federal agencies is tabulated to maximize the usefulness of information for other Federal agencies and for the public. OMB also has authority to require sharing of information among agencies.

Although both OFSPS and OMB have responsibilities for statistical activities across the Federal Government, neither organization has sufficient staff resources to adequately address the problems of access in the area of health data. Furthermore, OMB'S involvement comes only when an agency seeks clearance for a data project. In the example of the family planning reporting system, OMB did hold several special hearings before approving conversion to a sample system. However, OMB'S powers primarily reside in its ability to disapprove projects. OMB cannot force an agency to collect data for which it has little or no use.

Improvements in data responsiveness and availability for the spectrum of users are necessary to obtain maximum utility from data that are collected in the Federal statistical system. Examination of a conceptual framework would allow identification of potential users for various types of data. In addition, user requirements for reporting levels and periods, timeliness, and other data specifications could be analyzed. If a central organization with adequate resources and sufficient authority over agency statistical activities was established, it could implement the results of such analyses. In addition, data collection activities could be modified to meet the needs of multiple users. Arrangements also could be made for sharing data among programs, and computer tapes with appropriate specifications for authorized users could be provided automatically.

Excessive time lags in availability of data could be reduced if necessary resources, such as personnel and computer services, were partially controlled by a central organization. If demands for statistical information were justified, additional facilities and manpower could be provided to the agencies processing data. Alternatively, processing of multipurpose data could be done centrally in facilities designed for such purposes. Confidentiality provisions restricting use of agency data should be considered carefully under the latter alternative.

CENTRAL COORDINATING UNIT

There is a clear need to assign formal responsibility for the functions relating to the coordination of Federal health statistics. Agencies that independently operate programmatic statistical projects can neither resolve interagency jurisdictional disputes nor comprehensively address systemwide needs. Institutionalizing the coordinative functions within the Federal bureaucracy will not solve all the problems associated with the fragmentation of the health statistical system. The complexity and breadth of Federal health programs make solutions that are easy and widely accepted extremely difficult to attain. Delineating clear lines of authority regarding statistical matters, however, would provide the basis for more rational, knowledgeable, and impartial decisionmaking.

The Regulatory Policy and Reports Management Division in OMB and the Office of Federal Statistical Policy and Standards (OFSPS) in the Department of Commerce together have sufficient statutory authority to conduct coordination activities. Their responsibilities extend over the entire Federal statistical establishment; yet, they have not had the necessary resources for extensive involvement in subject areas or the data activities of individual departments. Reconstituting these offices only to improve statistical operations in the health area is not a realistic option. The Commission on Federal Paperwork recommended that these offices should be strengthened and continue to monitor departmental actions. However, the Commission also recommended assigning planning and coordinating responsibilities to focal organizations within each department (23, 24).

There are a number of advantages to vesting authority over statistical matters in a central coordinating body within HEW. An organization clearly responsible for coordinating statistical activities could at least ensure that appropriate activities are undertaken. A necessary degree of continuity and public accountability also would be provided by institutionalizing coordination responsibilities. The coordinating unit could serve to encourage data users to participate in the Federal health statistical system. Users could depend on this central coordinating body both to learn about the availability of data and to mediate conflicting needs. The central unit could advocate and help ensure balance and comprehensiveness in the Federal health statistical system.

A potential disadvantage to centralizing coordinative functions is decreased responsiveness to the substantive needs of program managers. Giving planning powers for statistical operations to staff in an office that does not use data could reduce the relevance and utility of the data collected. Professional statisticians are experts in the methods of data collection, not in the use of statistics for decisionmaking purposes. Consequently, trade-offs may be necessary between coordination and efficiency and programmatic responsiveness.

Characteristics

A strengthened coordinating and planning unit within HEW should embody three basic characteristics: sufficient authority to impose decisions on agencies, the necessary statistical and analytical capabilities to conduct activities requiring technical expertise and judgement, and adequate resources to build a viable core effort.

The coordination activities that require authority over Federal agencies are shown in table 3. Statutory authority for such activities already is provided by the Federal Reports Act and the Budget and Accounting Procedures Act (2, 4). These authorities could be delegated either legislatively or administratively to an HEW coordinating unit. To exercise its authority effectively, the coordinating body should also have final responsibility for, and control over, the statistical budgeting and the forms clearance procedures. The ability to approve, veto, or reallocate resources among data collection projects is crucial for setting priorities and planning rationally for a Federal health statistical system. Moreover, giving control over the existing administrative tools to the coordinating body would expedite the implementation of its decisions.

Table 3 also shows those coordination activities requiring technical skills. Planning, managing, and coordinating the health statistical system is a staff function, and therefore, the quality and competence of personnel is essential. A critical level of manpower is necessary to accomplish the various tasks associated with coordination activities. HEW is bureaucratically complex, technically diverse, and politically dynamic. Staff of the coordinating office need to be isolated from both operational and organizational pres-

Table 3.—Coordination Activities

Activities Requiring Authority *Over* Federai Agencies

- Collect complete information on health data projects from Federal agencies.
- Establish priorities for data collection projects.
- Designate appropriate agencies to collect health data.
- Modify, combine, or terminate data collection projects, or parts thereof, as necessary.
- Initiate new data collect ion projects.
- Determine and implement standards for terms, definitions, codes, and units of measurement for use in health data projects.
- Determine and implement uniform minimum data sets where appropriate.
- Release health data and statistical information to appropriate users.
- Detail technical support to agencies.
- Allocate supplemental funds and manpower among agencies for data collection, processing, analysis, dissemination, and publication.

Activities Requiring Technical Capabilities

- Develop conceptual framework for health statistics.
- Collect and maintain information about health data projects.
- Respond to requests for information about health data collection activities and data availability.
- Examine existing data collection projects for duplication and inefficiencies.
- Analyze alternatives for data collection to determine most cost-effective methods.
- Conduct technical reviews of data projects for statistical methodology and quality; propose alternative methodologies if suitable.
- Develop standards for terms, definitions, codes, and units of measurement used in health data projects.
- Identify user problems in areas of data responsiveness and access.
- istical and other technical services for agencies.

sures. Addressing the lack of coordination in Federal statistical activities, past commissions have stressed the necessity of leadership by strong, independent professional staff (15, 23, 24).

Adequate funding and staff resources are the third prerequisite for building an effective coordinating unit. To utilize existing statistical programs to the fullest possible extent, supplemental funds should be appropriated for discretionary use by the coordinating unit in an effort to realize systemwide goals. Such funds would support core staff, provide extra resources to meet emerging statistical needs and fill gaps, and permit flexibility in arrangements for integrating data sources and sharing data among programs.

In addition to a special appropriation, the central organization could manage funds now allocated for the performance of multi-purpose data collection. At present, each agency determines its own statistical needs and funds activities from its programs' budgets. If an agency conducting a data project is also the sole Federal user of the statistical product, that agency should fund and operate the data project. However, if statistical information can be used by a number of agencies, the data project's operating costs should be shared. Channeling funds for such data systems through a central organization would facilitate the equitable distribution of costs for data collection, processing, and dissemination among various Federal users. Federal agencies can now, and sometimes do, reimburse one another; but the necessity of negotiating and signing formal agreements prolongs and complicates the process. If the central coordinating unit had the authority to allocate funds, it could create an ongoing, simple administrative mechanism for exchange among agencies and non-Federal public and private users.

The central organization should not only receive and disburse funds but also provide statisticians on an as-needed basis to agencies requiring technical assistance in survey design, computer programing, or special analyses of data. Restrictions on agency staffing

levels by the personnel system of the Federal Government currently limit opportunities for transferring staff to different agencies as their programmatic needs change. Designating specific staff positions in the central coordinating unit for such roving assignments would alleviate this problem.

Location

A number of offices within HEW could possibly assume responsibilities for coordinating health statistics. The offices described below as possible alternatives should not be considered mutually exclusive. Placing authority with several offices may be appropriate. Some activities for coordinating health statistics are already performed by offices in HEW. Different offices could be delegated responsibilities for activities requiring authority over substantive program agencies and for activities requiring technical capabilities. No office now performs all the necessary tasks, and therefore, additional staff and funding would be required regardless of which office or offices are selected. The fundamental requirement in assigning responsibility is an unambiguous mandate to manage health statistics.

A New Office Within the Office of the Secretary. Establishing a new staff office that reports directly to the Secretary of HEW would highlight the importance of coordinating health statistics. Location in the Office of the Secretary would both facilitate necessary negotiations with agencies outside HEW that collect health data and provide the necessary jurisdiction over the HEW bureaucratic hierarchy. An office whose sole function is to coordinate health statistical activities would have no competing tasks and programs to interfere with the fulfillment of its mission. Its decisions would not be biased by programmatic interests. However, the risk of politicizing coordinative activities is increased if they are located in the Office of the Secretary. In addition, attracting skilled and knowledgeable personnel to an office without an established statistical and analytical reputation may be difficult, and building adequate resources is a lengthy process.

The Office of the Assistant Secretary for Management and Budget (ASMB). This Office has established ongoing relationships with the principal operating components in HEW as well as with other departmental staff agencies. ASMB is responsible for making recommendations to the Secretary concerning the allocation of budgeted funds to all programs in the Department. It also advises the Secretary on matters relating to the delegation of legislative authorities to HEW agencies. ASMB now functions as the final reports clearance office for HEW. It also has major responsibilities in the area of automated data processing. The Commission on Federal Paperwork has recommended that units coordinating the several functions relating to information resources management be placed in offices, such as ASMB, that are responsible for general management (23). A possible disadvantage of placing such units in ASMB is that this Office is budget-oriented and might give statistical matters only secondary attention.

The Office of the Assistant Secretary for Planning and Evaluation (ASPE). Like ASMB, ASPE is a staff office to the Secretary that has established communication lines with agencies throughout HEW. It has experience in conducting objective policy analysis, planning, and evaluation. However, in the area of health statistics, its responsibilities have been limited. Before their transmittal to the Secretary, it reviews and comments on major new data projects originating from the health bureaucracy. ASPE also conducts some basic methodological research in the statistical area. ASPE'S major responsibility is planning departmental initiatives for health programs and, therefore, it has some substantive interests. As a result, it might not be impartial if it had responsibility for determining statistical priorities among all programs.

The Office of Statistical Policy (OSP). The Public Health Service (PHS) is the principal operating component of HEW that is concerned with health matters; it operate: the great majority of health statistical projects. OSP, as a staff office to the Surgeon General, relates closely with the six PHS agencies. It is the final PHS reports clearance office. Furthermore, the Office now serves, at least nominally, as the departmental focal point for the coordination of health data and statistical policy. The ability of OSP to effectivelyarbitrate disputes among agencies over statistical matters may be hindered, however, by its position in the same administrative level as other operating components of HEW.

The National Center for Health Statistics (NCHS). NCHS is also in a staff office to the Surgeon General. The advantages and disadvantages of its placement within the bureaucracy are similar to those of OSP. NCHS is described separately because it has the largest number of health statisticians in HEW. For coordination activities requiring technical capabilities, it is the logical agency within which to place such responsibility. Furthermore, PHS has stated that NCHS should function as the key agency for coordinating the collection of health statistics (3 I). NCHS now administers two programs designed to improve the efficiency and coordination of health statistics: the Cooperative Health Statistics System (CCHS) and the Reimbursable Work Program (RWP). Also, legislation passed in the 95th Congress, Public Law **95-623,** apparently authorizes new responsibilities for NCHS in relation to setting standards and coordinating health statistical activities. In the past, however, NCHS has been unable to fulfill the coordinating role adequately (26). Agencies collecting data have sought advice from NCHS at their own discretion and on an irregular basis. Because NCHS itself operates large data collection projects, its ability to be impartial may also be questioned.

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Part II

Directory of Statutory Authorities for the Collection of Health Data

Public Health Service and Health Care Financing Administration

Through January 15,1979

CONTENTS

Summary

INTRODUCTION

This section of the report is a directory of statutory authorities that may be used to authorize the collection of health data within the two principal health-related operating components of the Department of Health, Education, and Welfare (HEW), the primary collector of Federal health data. Legislation establishing new health programs or supplementing existing programs frequently contains data requirements. Some statutes even specify the office or entity responsible for collecting new data. These statutes may cause responsible agencies to collect data that are the same, or similar to, data currently being gathered. Federal agencies, such as HEW, frequently cite such legislative requirements as the reason for the proliferation of health data systems (1, 2, 3). Executive officials also argue that the legislation, not its implementation, causes the coordination and planning problems discussed in Part I of this report.

The primary goal of Part II is to determine the extent to which legislation creates or exacerbates fragmentation and duplication in Federal health data collection. The directory is designed to 1) present the relevant statutory authorities that support HEW data collection activities, 2) provide a reference of existing authorities that Members of Congress may consult before passing new data requirements, 3) allow executive agencies to match current data systems with legislative authorities for coordination and planning purposes, and 4) analyze what influence these authorities have had in intensifying the problems that currently characterize HEW data collection.

Addressing the issue of legislative influence in creating problems within the Federal health statistical system initially requires the compilation of all relevant statutory authorities for Federal data collection. This document is designed to make a major contribution to such a compilation. Specifically, the directory lists data collection authorities for agencies within the Public Health Service (PHS) and the Health Care Financing Administration (HCFA). Legislative authorities for the collection of health-related data in other Federal departments and agencies, particularly the Departments of Defense (DOD), Labor (DOL), Agriculture (USDA), Interior, Justice, and the Veterans Administration (VA), the Environmental Protection Agency (EPA), and the Consumer Product Safety Commission (CPSC) are not listed.

SCOPE AND DEFINITIONS

The purpose and design of this directory dictate the use of a broad definition of "health data." The terms "data," "information," and "statistics" are considered synonymous. Health data are information describing the health status of people, their use of medical care services and resources, and the costs and sources of funding for these services. Data relating to health effects of the workplace and the environment, diseases, health problems, and health conditions are included in this definition. Finally, data on public knowledge and attitudes about health, perceived health needs, and behavior related to health, health care, and health practices are also included.

The directory focuses on legislation that may generate health data collection. The terms "legislation," "sections," and "statutory authorities" are used interchangeably. Statutes chosen by OTA for inclusion in this document reflect a loose interpretation of the way in which legislation can "authorize" data collection. Legislation that either

directly or indirectly specifies any action resulting in health data collection is listed. Some statutory sections are explicit in mandating the collection of information (for example, sec. *438* of the Public Health Service Act, 42 U.S. C. $289c-5, which establishes an Arthritis Data System); other authorities are more indirect. General program mandates to conduct research, for example, are frequently cited by agencies as authorizing the collection of certain statistics and are, therefore, listed in this directory.

Agency use of general program mandates to authorize data collection is justified by the legal principle of delegation of authority. This principle holds that explicit authority to perform an act is generally accompanied by implied authority to fulfill any subsidiary tasks necessary to complete the act. Data collection is often viewed as such a subsidiary function.

Three criteria were used to determine the type of statutory requirements included in this directory. First, statutory requirements that result in data that will be used exclusively for administrative or managerial purposes, such as program budgeting, grants management, and personnel payroll data, are excluded. However, data used primarily for administrative purposes may serve several other functions; for example, they also may provide useful information about topics such as health status. Legislation that authorizes the collection of data that may be used for a variety of health-related purposes are contained here.

Second, OTA focused on requirements for data used primarily by the Federal Government. Consequently, statutory requirements for data collection at the non-Federal level are included only if all, or part, of the data are ultimately channeled to HEW, or, at least, are available for Federal Government use.

Third, statutes authorizing one-time data collection with a specific deadline, at which point the legislative authority expires, are excluded except in cases where the data can be accessed subsequently. An example of this type of authority is section *sos* of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355). This section explicitly requires investigators to include certain information in new drug applications to the Food and Drug Administration (FDA). The application itself is a single-time endeavor. FDA, however, retains the information, thereby creating a data base on the safety and efficacy of new drugs. The directory concentrates on ongoing and repetitive data activities because these have the greatest potential for being coordinated.

OTA classified the statutory authorities that meet these three criteria into three types to determine the extent of congressionally mandated data collection. The three types are specific, general, and implied authorities.

Specific authority explicitly mandates (1) the initiation of a data collection system and/or (2) the collection of explicitly identified data.

General authority mandates the performance of a function, such as research or the preparation of a report, that requires the collection of original data. The required data, however, are not identified; only the subject area for which the data are to be gathered is indicated.

Implied authority mandates a particular function that may require collecting original data if the data necessary to fulfill the function are unavailable. Examples are mandates to establish information clearinghouses, disseminate information about particular topics, or prepare reports summarizing available data.

Tables 1, 2, and 3 below, catalog the specific, general, and implied authorities listed in this directory according to United States Code citation and administering agency.

Table I.— List of Specific Authorities and Administering Agencies

U.S. Code citation	Administering agency
15 USC $793	NIH (NIEHS)
21 USC $346a	FDA (BF) & EPA
21 USC ~348	FDA (BF)
21 USC $355	FDA (BD)
21 Usc 51173	ADAMHA (NIDA)
21 USC $1176	ADAMHA (NIDA)
25 USC $1653	HSA (IHS)
29 USC $657	CDC (NIOSH) & DOL
29 USC $669	CDC (NIOSH) & DOL
29 USC $673	CDC (NIOSH) & DOL
30 USC S813	CDC (NIOSH) & DOL
30 USC $843	CDC (NIOSH) & DOL
30 Usc $951	CDS (NIOSH) & DOI
42 USC $241(b)(4)	NIH (NCI)
42 USC $242 b(a-c)	OASH (NCHS) & (NCHSR) & (NCHCT)
42 USC $242b(e)	OASH (NCHS)
42 USC $242k	OASH (NCHS)
42 USC $242m(a)	OASH (NCHS) & (NCHSR)
42 USC $242p	OASH (NCHS)
42 USC $ 246(ci)	CDC & HSA (BCHS)
42 USC $246(g)	ADAMHA (NIMH)
42 USC S247a note.	NIH (NIEHS)
42 USC S247C.	CDC
42 USC $247d	HSA (BCHS)
42 USC $254c.	HSA (BCHS)
42 USC $254f	HRA (BHM) & HSA (BCHS)
42 USC s254i	HRA (BHM) & HSA (BCHS)
42 USC ~263e.	FDA (BRH)
42 USC ~263/	FDA (BRH)
42 USC 45285	NIH (NCI)
42 USC $289c-5	NIH (NIAMDD)
42 USC $289k-4	NIH (NIA)
42 USC $291d	HRA (BHF)
42 USC $292h	OASH (NCHS) & HRA (BHM)
42 USC $295h-2	OASH (NCHS) & HRA (BHM)
42 USC ~295h-4	OASH (NCHS) & HRA (BHM)
42 USC $296 note,	HRA (BHM)
42 USC $300a-6a	HSA (BCHS)
42 USC $300a-26	OASH (OAPP)
42 USC $300 b-6	CDC & HSA (BCHS)
42 USC S300d-5	HSA (BMS)
42 USC $300d-7	HSA (BMS)
42 USC $300e.	OASH (HMO)
42 USC ~300/-2	OASH (NCHS) & HRA (BHP)
42 USC ~300n-2	HRA (BMP)
42 USC $300n-2(d).	HCFA (OPPR)
42 USC ~300n-4	HRA (BHP)
42 USC $j3000-2	HRA (BHF)
42 USC $300u-l(b)	OASH (ODPHP) & CDC
42 USC $300u-4	OASH (ODPHP) & CDC
42 USC $1320a.	OASH (NCHS) & HCFA
42 USC $1320c-5	HCFA (HSQB)
42 USC $1320c-21	HCFA (HSQB)
42 USC $1395x.	HCFA (OPPR)
42 USC ~1395rr	HCFA (Medicare)
42 USC $1396a.	HCFA (Medicaid)
42 USC ~2689	ADAMHA (NIMH)
42 USC $2689e.	ADAMHA (NIMH)
42 USC $2689q	ADAMHA (NIMH)
42 USC $4585	ADAMHA (NIAAA)

Agencies listed within parentheses are components of the larger HEW agencies listed on their left

Table 2.—List of General Authorities and Administering Agencies

U.S. Code citation	Administering agency
21 USC $355	FDA (BD)
21 USC $357	FDA (BD)
21 USC $360b	FDA (BVD)
21 USC ~360i	FDA (BMD)
21 USC $360j	FDA (BMD)
21 USC $1164	ADAMHA (NIDA)
21 USC $1172	ADAMHA (NIDA)
21 USC $1176	ADAMHA (NIDA)
21 USC ~1191	ADAMHA (NIDA)
22 USC $2103	NIH (Fogarty International Center)
25 USC $1655	HSA (IHS)
29 USC $669	CDC (NIOSH) & DOL
29 USC ~71	CDC (NIOSH)
29 USC $813	CDC (NIOSH) & DOL
42 USC s218(e)	ADAMHA (NIDA)
42 USC $241(a)	OASH
42 USC $241(b)(l)	NIH (NCI)
42 Usc ~241(b)(2),(3)	NIH (Director's Office)
42 USC $242	ADAMHA (NIDA) & FDA & DEA
42 USC $242a	ADAMHA (NIDA) & (NIMH) & FDA
42 USC ~242c	OASH (NCHSR)
42 USC 52421	CDC
42 USC $242n	OASH (NCHCT)
42 USC $247b	CDC & HSA (BCHS)
42 USC $247b-2	OASH (OSH) & ADAMHA (NIAAA)
42 USC $247d	HSA (BCHS)
42 USC ~256	HSA (BCHS)
42 USC ~263a	HCFA (HSQB) & CDC
42 USC ~263d	FDA (BRH)
42 USC ~263i	FDA (BRH)
42 USC $268	CDC
42 USC ~282	NIH (NCI)
42 USC $287a	NIH (NHLBI)
42 USC $287b	NIH (NHLBI)
42 USC ~287h	NIH (NHLBI)
42 USC $288a	NIH (NIDR)
42 USC $288b	NIH (NIDR)
42 USC ~289c-1	NIH (NIAMDD)
42 USC $289c-2	NIH (NIAMDD)
42 USC s289c-3a	NIH (NIAMDD)
42 USC ~289c-6	NIH (NIAMDD)
42 USC ~289c-7	NIH (NIAMDD)
42 USC $289d	NIH (NICHD)
42 USC $289k	NIH (NEI)
42 USC ~289k4	NIH (NIA)
42 USC ~291d	HRA (BHF)
42 USC $295g-1	HRA (BHM)
42 USC ~300a-2	HSA (BCHS) & NIH (NICHD)
42 USC ~300b	HSA (BCHS)
42 USC ~300b-1	HSA (BCHS) & NIH (NIGMS)
42 USC ~300c-11	HSA (BCHS)
42 USC ~300d-4	HSA (BMS)
42 USC $300d-21	HSA (BMS) & NIH (NIGMS)
42 USC $300e-14	OASH (HMO)
42 USC ~300f-2	OASH (NCHS) & HRA (BHP)
42 USC $300m-1	OASH (NCHS) & HRA (BHP)
42 USC ~300u	OASH (ODPHP) & CDC
42 USC $300u-l(a)	OASH (ODPHP) & CDC
42 USC $300u-3	OASH (ODPHP) & CDC
42 Usc 5300U-5	OASH (ODPHP)
42 USC $300u-8	OASH (ODPHP)
42 USC $705	HSA (BCHS)
42 USC $713	HSA (BCHS)
42 USC $1312	HSA (BCHS)
42 USC $1320c-4	HCFA (HSQB)
42 USC $1320c-12	HCFA (HSQB)
42 USC $1320c-20	HCFA (HSQB)
42 USC $139sh	HCFA (Medicare)
42 USC $1395u	HCFA (Medicare)
42 USC s1395kk	HCFA (Medicare)
42 USC ~1395/ /	HCFA (Medicare)
42 USC ~1395rr	HCFA (Medicare)
42 USC $1396a	HCFA (Medicaid)
42 USC 94551	ADAMHA (NIAAA)
42 USC $4821	CDC & HUD

Agencies listed within parentheses are components of the larger HEW agencies listed on their left

Table 3.—List of Implied Authorities and Administering Agencies

U.S. Code citation	Administering agency
15 USC $1337	OASH (OSH)
21 USC $360c	FDA (BMD)
21 USC $360j	FDA (BMD)
21 USC $375	FDA (General)
21 USC S376	FDA (BF)
21 USC $1177	ADAMHA (NIDA)
21 Usc $1191	ADAMHA (NIDA)
21 USC $1192	ADAMHA (NIDA)
25 USC $1653	HSA (IHS)
29 USC %75	CDC (NIOSH) & DOL
30 USC $811	CDC (NIOSH) & DOL
30 USC ~936	CDC (NIOSH)
30 USC $958	CDS (NIOSH)
42 USC $218(c)(2)	ADAMHA (NIMH)
42 USC $j218(d)	ADAMHA (NIAAA)
42 USC $242 note	ADAMHA (NIDA)
42 USC $242m (a)	OASH (NCHS) & (NCHSR)
42 USC $242m(g)	OASH (NCHSR)
42 USC $2420	OASH (General)
42 USC $248	HSA (BMS)
42 USC $254c	HSA (BCHS)
42 USC $254e	HRA (BHM) & HSA (BCHS)
42 USC s254i	HRA (BHM) & HSA (BCHS)
42 USC $262	FDA (BoB)
42 USC $263	FDA (BRH)
42 USC $280b	NIH (NLM)
42 USC $280b-5	NIH (NLM)
42 USC $280b-9	NIH (NLM)
42 USC $284	NIH (NCI)
42 USC ~287b	NIH (NHLBI
42 USC $287g	NIH (NHLBI
42 USC S288C	NIH (NIDR)
42 USC ~289a(a)	NIH (NIAMDD) & (NINCDS)
42 USC ~289a(b)	NIH (General)
42 USC ~289c	NIH (General)
42 USC ~289c-3a	NIH (NIAMDD)
42 USC ~289c-6	NIH (NIAMDD)
42 USC s289d	NIH (NICHD)
42 USC $289e	NIH (NIEHS)
42 USC $289i	NIH (NEI)
42 USC $289k-1	ADAMHA (NIMH)
42 USC $289k-4	NIH (NIA)
42 USC ~300a-3	HSA (BCHS)
42 USC ~300d-9	HSA (BMS)
42 USC $3001-2	OASH (NCHS' & HRA (BHP)
42 USC ~300m-1	OASH (NCHS & HRA (BHP)
42 USC $300m-2	HRA (BHP)
42 USC *$300m-3*	HRA (BHP)
42 USC $300n-2	HRA (BHP)
42 USC ~300u	OASH (ODPHP) & CDC
42 USC ~300u-l(a)	OASH (ODPHP) & CDC
42 USC $300u-3	OASH (ODPHP) & CDC
42 Usc $300U-4	OASH (ODPHP)
42 USC $300u-5	OASH (ODPHP)
42 USC $300u-8	OASH (ODPHP)
42 USC ~712 ,	HSA (BCHS)
42 USC ~1306	HCFA (Medicare), (Medicaid), (HSQB)
42 USC $1320c-5	HCFA (HSQB)
42 USC $1395b-1	HCFA (OPPR)
42 Usc 51395X note 1	HCFA (OPPR)
42 USC ~1320x note 2	HSA (BCHS)
42 USC $1396b	HCFA (Medicaid)
42 USC ~1396g	HCFA (Medicaid)
42 USC s2689q	ADAMHA (NIMI)-
42 USC &4551 '. ... ,	ADAMHA (NIAAA)
42 USC $4552	ADAMHA (NIAAA)
42 USC $7454	NIH (NCI) & (NIEHS) & EPA

Agencies Iisted within parentheses are components of the larger HEW agencies Iisted on their left

FINDINGS

The degree to which legislative authorities create problems in Federal health data collection activities is examined broadly in terms of six issue areas. Findings in each of the six areas are discussed briefly below. Stated as questions, the six issues are:

1. Does legislation mandate or simply allow data collection?
2. How are legislative authorities delegated to agencies within HEW?
3. Are there overlapping legislative requirements for the collection of health data?
4. What is the intent of Congress in requiring specific data collections?
5. Does legislation contain requirements for coordinating data collection?
6. Does legislation consider the extent of reporting burden on respondents?

Mandatory or Discretionary Data Collection

OTA analyzed the legislative language to determine the degree to which data collection is allowed or required. Based on the specificity of the language supporting agencies' data collection, the 169 statutes listed in this directory are classified as specific, general, or implied authorities to collect certain data (see definitions above). The language also was examined to determine whether a statute states that data "shall, " rather than "may," be collected. Language in a specific authority stating that data "shall" be collected was regarded as mandating data acquisition.

The largest number of authorities are either general or implied and allow, rather than require, data collection. There are *75* general and 67 implied authorities cited in this directory. Every Federal agency administers at least one general or one implied authority and, therefore, has some statutory basis for justifying its data collection activities.

Many of these statutes begin with the word "shall," but do not identify a data collection system or mandate the collection of a particular type of health data. Most general and implied authorities are mandatory only with respect to functions other than data collection, such as research. Consequently, causal relationships between these legislative authorities and the data systems described in Part I are, at best, weak. The existence of a general or implied authority to collect data does not necessarily lead to the creation, or signify the existence, of a data collection system. Conversely, agencies may use these authorities to generate large and complex data systems. For example, the Medicare Program in the Health Care Financing Administration (HCFA) operates an extensive statistical program that uses a single general authority, 42 U.S. C. $139511, as its legislative mandate. An agency's resources and internal priorities, rather than legislative directive, often determine the existence and scope of its data collection activities.

OTA determined that 60 sections, or 36 percent, of the 169 authorities listed in this directory are specific. The majority of authorities classified as specific state that data "shall" or "must" be collected and are, therefore, considered mandatory. The legislative mandate to establish an end stage renal disease medical information system (ESRD MIS) is an example of such a specific authority (42 U. S.C. $1395rr). It states that the Secretary

shall submit an annual report to Congress on the end stage renal disease program that includes, for example, data on the number of patients on dialysis, the number and use of facilities providing dialysis, the number of patients awaiting kidney transplants, patient mortality and morbidity rates, the costs of kidney acquisition, and the number of facilities providing transplants.

Legislation specifying the kinds and types of data to be collected is a relatively new phenomenon in Congress. Only nine of the specific authorities listed in this directory originated in legislation passed before 1970. Conversely, almost every law with data requirements passed in this decade enumerates the class of data required.

Twenty-eight agencies within HEW have responsibilities for fulfilling the requirements of the 60 specific sections. Thirteen of these sections are jointly administered by at least two agencies within HEW; responsibility for seven more sections is shared with several other departments and agencies, such as the Departments of Labor and Interior and the EPA.

Delegated Authorities

Congress occasionally indicates which agency within HEW is responsible for collecting data required by legislation. However, broad mandates usually are given to the Secretary or, in some instances, to the Surgeon General, either of whom delegates responsibility to the administrative unit deemed appropriate. Forty-two of the 169 statutes authorize particular agencies to collect health data. The Occupational Safety and Health Act of 1970, for example, specifically directs the National Institute for Occupational Safety and Health (NIOSH) to conduct industrywide studies on the effects of chronic exposures to certain industrial materials (29 U.S. C. $669 and *671).* In contrast, 51 statutory sections direct recipients of Federal funds, such as grantees, contractors, State agencies, and advisory councils, rather than particular agencies, to collect data. For example, migrant health centers (42 U.S. C. 247d), community health centers (42 U.S. C. $254c), and health maintenance organizations (42 U.S. C. $300e) are all required by statute to develop effective recordkeeping procedures for reporting program-related information to the Secretary of HEW.

The majority of legislative authorities are delegated by the Secretary of HEW, who is guided by the recommendations of the Assistant Secretary for Management and Budget (ASMB), an HEW staff office. The Secretary enjoys a great deal of latitude in delegating data collection authorities, and no policy precludes separating data collection responsibilities from other program responsibilities. However, the Secretary usually delegates data authorities to agencies responsible for program administration, and only **29** of the *169* statutory authorities relating to health data collection are jointly delegated by the Secretary to two agencies within HEW. Hence, the *role* legislation plays in determining the agency responsible for and the method of administering data collection authorities is relatively minor.

Overlapping Legislative Requirements

Using statutory authorities to determine the extent of overlap in the data collection projects of various agencies is difficult because the required data elements are not usually itemized in the legislation, even in specific authority sections. This directory illustrates the diversity of legislative language authorizin, data collections; legislation requiring research to be conducted, questions to be answered, or, more infrequently, recordkeeping systems to be established may justify creating new health data systems. The texts of

authorizing legislation are often too imprecise to determine whether such authorities result in duplicative data collection activities.

OTA reviewed this directory for statutory authorities that are obviously duplicative. Although several such instances were found, multiple sections authorizing precisely the same data requirements are rare. An example of such exact duplication are the two legislative sections authorizing the collection of information relating to the causes of sudden infant death syndrome (SIDS). One section is delegated to the National Institute of Child Health and Human Development (NICHD) (42 U.S.C. ~289d) and the other, to the Bureau of Community Health Services (BCHS) (42 U.S.C. $300c-11). However, considerable leeway exists in the interpretation and implementation of statutory requirements. Even in cases where statutes mimic one another, the information obtained by agencies may be quite different. This diversity reflects different agency needs and responsibilities.

Comparing legislative authorities can serve as the starting point for grouping potentially overlapping data activities. Each agency's statutory requirements for data collection can then be evaluated systematically in terms of existing data projects. OTA used a category of data, health effects of the environment, to illustrate this approach to identifying potential overlap in data collection activities. Because broad terminology is used in legislative language, a class of information like environmental data is a good basis for analysis. Environmental data include a range of subjects and are parallel to data categories such as health manpower or health status.

Environmental data were chosen, moreover, because they are collected primarily by agencies outside HEW. However, OTA did identify **20** HEW statutory authorities that reference either the term "environmental data" or data primarily considered part of the environment category. A summary of the legislative authorities for HEW agencies is shown in table 4.

By focusing on classes of data, rather than specific data elements, it appears that a number of these authorities contain overlapping data mandates. The Center for Disease Control (CDC) and the National Institute for Environmental Health Sciences (NIEHS) both have responsibilities with respect to lead-based paint poisoning *(42* U.S.C. **~4821** and *42* U.S. C. $247a note, respectively). FDA and the National Institutes of Health (NIH) are both directed to study the effects of ionizing radiation. The broader language employed in the majority of statutes also could lead to overlapping agency authorities. Comparison of the data systems of these agencies is outside the scope of this report. Such analysis would reveal duplication, if it exists, as well as identify opportunities for coordinating statistical activities.

Congressional Intent

Understanding why Congress mandates the collection of health data helps to explain the proliferation of data authorities. Part of this proliferation can be attributed to the increasing number of Federal programs in the health area; data collection is a necessar$_{y}$ corollary to most program activities. Another reason for the growth in data authorities is the increased reliance on data by Congress to identify and define issues or problems and to develop legislation designed to address them.

To examine the issue of congressional intent in greater detail, OTA categorized specific authorities listed in the directory according to their purpose: program management, evaluation, regulation, needs assessment, research, monitoring and surveillance, or policymaking. Congressional intent for collecting data usually is not explicitly stated in statute; consequently, the following analysis is largely subjective. Many specific

Table 4.—Authorities for the Collection of Environmental Health Data

U.S. Code citation	Administering agency (ies)	Data mandate
42 USC $242b(a)	OASH (NCHCT, NCHS, NCHSR)	Study the impact of the environment on individual health and health care.
42 USC $242b(e)	OASH (NCHS)	Study the present and projected future health care costs of pollution and other environmental conditions.
42 USC ~242k	OASH (NCHS)	Collect statistics on environmental health hazards and on the effects of the environment on health.
42 USC $300u-3	OASH (ODPHP) & CDC	Disseminate information about environmental health.
42 USC ~4821	CDC & HUD	Research the nature and extent of lead-based paint poisoning.
29 USC $$657, 669,675	CDC (NIOSH)	Collect data concerning exposure of employees to toxic substances.
30 USC f$811, 813	CDC (NIOSH)	Collect data concerning exposure of miners to toxic substances.
42 USC ~$263e, 263/	FDA (BRH) & EPA	Collect data on the health hazards from electronic product radiation and other types of ionizing radiation and the incidence of resultant health problems.
42 USC ~300L2	HRA (BHP) & OASH (NCHS)	Collect data concerning environmental and occupational exposure factors affecting immediate and long-term health conditions.
42 USC $247d	HSA (BCHS)	Assess problems related to sanitation, pesticide hazards, and other environmental health hazards to which migratory agriculture workers are exposed.
42 USC ~254c	HSA (BCHS)	Assess the needs of the community health centers' population for environmental health services.
42 USC 241(b)	N I H	Research the biological effects of low-level ionizing radiation.
15 Usc $793	NIH (NIEHS) & EPA	Study the health effects of emissions of sulfur oxides to the air.
42 USC §247a note	NIH (NIEHS)	Study long-term effects on child development of various levels of lead in blood.
42 USC ~7454	EPA (in coordination with NIEHS & NCI)	Research the effects of changes in the ozone in the stratosphere upon human health.
42 USC $287b	NIH (NHLBI)	Research the environmental determinants and influences on all aspects of heart, blood vessel, lung, and blood diseases.

Agenc,e. Ilsted wlthm parentheses are components of the larger HEW agenc]es hsted on them left.

authorities appear to have multiple purposes and are, therefore, difficult to classify. However, some general comparisons can be made.

The largest number of specific legislative data requirements apply to recipients of Federal funds, not to Federal agencies. The implied purposes of these requirements are efficient management and uniform recordkeeping by grantees or contractors. Health maintenance organizations, drug abuse treatment centers, community mental health centers, community health centers, migrant health centers, and emergency medical service systems all must meet extensive data requirements. Congress does not stipulate that these data be forwarded to the Federal level, but such data are available for Federal review. Other similar sections provide for uniform reporting by States about public health services and medical facilities. Uniform accounting and reporting systems designed to be used by health care providers are mandated, as are employer-maintained records concerning the health of employees. Finally, health planning agencies and Professional Standards Review Organizations (PSROS) also are expected to meet minimum data requirements.

Some data collection projects are authorized to evaluate Federal programs, including, for example, quality assurance in medical care, health planning, family planning services, emergency medical services, end stage renal disease, and health manpower in medically underserved areas. Other sections enumerate data, necessary for regulatory purposes, that must be included in applications to Federal agencies, including those for new food additives, new drugs, and use of chemical pesticides.

Assessment of need is another purpose implied by a number of sections. The Bureau of Health Manpower (BHM) is authorized to gather extensive data regarding the supply of and demand for health manpower resources. Community health centers and urban Indian organizations must demonstrate need in their respective populations in order to receive Federal funds for health services. State plans for medical facilities are mandated in order to determine the need for new facilities or capital improvements.

Data collections also may be authorized to investigate general problem areas, monitor diseases, or study research questions. CDC, in particular, is mandated to monitor the occurrence of specific diseases, NIOSH, a part of CDC, is responsible both for measuring miners' exposure to toxic materials and conducting research on black lung disease (pneumoconiosis). Other agencies are authorized for research purposes to collect specific data concerning arthritis, alcohol abuse, and cancer.

Congress sometimes requests information about the extent and nature of particular problems. For example, data collections are required for policymaking purposes on the following topics: the adverse health effects of sulfur oxide emissions, the incidence and type of health problems caused by electronic product radiation, the actual incidence of forcible rape, and the extent to which preventive health services are covered under various insurance plans.

Finally, there are some specific authorities, relating to health research and statistics, that are considered general-purpose in nature because they do not relate to particular program needs. These authorities are administered by the National Center for Health Statistics (NCHS), the National Center for Health Services Research (NCHSR), and the National Center for Health Care Technology (NCHCT).

Coordination Requirements

OTA examined the legislative authorities to determine congressional awareness of the need for agency coordination in meeting data requirements. The great majority of au-

thorities in this directory make ***no*** reference to coordinating data collection. Approximately 20 statutory sections do mandate some type of coordination, but usually in programs rather than in agencies. The national end stage renal disease medical information system (ESRD MIS), for example, is required to be coordinated with the data activities of Professional Standard Review Organizations (PSROS) and health systems agencies (HSAS) (42 U.S.C. $1395rr). The legislation governing HSAS specifies that they coordinate their data collection with PSROS **(42** U.S.C. $300/-2). PSROS are directed, in turn, to coordinate with one another and with other public and private agencies having related data activities **(42** U.S.C. $1320c-14).

A major attempt by Congress to orchestrate, by statute, the coordination of data collection is evidenced in legislation originally passed in **1974,** Public Law 93-353, and amended in **1978,** by Public Law **95-623.**

> The Secretary shall coordinate all health services research, evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology undertaken and supported through units of the Department of Health, Education, and Welfare. To the maximum extent feasible such coordination shall be carried out through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology.
>
> The Secretary shall coordinate the health services research, evaluations, and demonstrations, and health statistical and (where appropriate) epidemiological activities, and the research, evaluations, and demonstrations respecting the assessment of health care technology authorized by this Act through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology. (42 U.S.C. $242b)

The establishment of the Cooperative Health Statistics System (CHSS) in **1974** also reflects congressional interest in improving health data collection (42 U.S. C. ~242k). CHSS, as described in Part I of this report, is a cooperative Federal, State, and local system for the collection of comparable and uniform health statistics. Subsequent to its initiation, Congress directed several agencies to either coordinate with CHSS, or, if possible, use CHSS as the primary collector of required data.

The Health Professions Educational Assistance Act, Public Law 94-484, directed the Secretary to coordinate required data collection with NCHS, which administers CHSS (42 U.S. C. $295h-2 and ~295h-4 note); and the Health Planning and Resource Development Act, Public Law 93-641, stipulated that mandated data collection also be coordinated, to the extent possible, with CHSS (42 U.S.C. $300/-2, $300m-1). In the 1977 Medicare-Medicaid Anti-Fraud and Abuse Amendments to the Social Security Act, Public Law 95-142, Congress referenced CHSS, but did not explicitly require that data be collected through the cooperative system (42 U.S. C. $1320a).

The statutes cited above represent recent attempts by Congress to address the issue of coordination in health data activities, The intent of Congress is clear in these examples; coordination of health data activities must be undertaken and that the Secretary of HEW has the greatest responsibility for determining the manner in which that goal is accomplished.

Reporting Burden

One problem directly related to the increased number of data collection activities is the burden placed upon the individuals and public and private organizations that must

supply the requested data. Complaints have grown as the number of reports required by the Federal Government has increased.

Reporting burdens imposed on the public as a result of Federal data requirements are not directly correlated with the number of statutory sections authorizing health data collection, and the impact of data requirements varies widely. The majority of specific legislative data requirements listed in the directory, for example, only apply to defined groups of Federal grantees or contractors. The general public is unaffected, and such recordkeeping requirements are in keeping with efficient management practices and prudent purchase of services.

However, a single statutory requirement may necessitate a number of costly data collection activities involving many respondents and may, therefore, significantly increase reporting burden. If Congress requires information about the extent or incidence of particular problems or hazards, costly special data projects that sample groups nationwide may have to be initiated. For example, PHS'S initial estimate for meeting data requirements relating to health manpower (contained in only a few statutory sections mandated under the Health Professions Educational Assistance Act of 1976, Public Law 94-484) totaled $26.6 million over 3 years and involved 38 discrete data projects (4). Moreover, Congress specifically exempted data projects conducted under these authorities from the reports clearance procedure, the primary administrative review for supervising Federal statistical activities.

Congress usually does not assess the impact of data requirements mandated in legislation. In reviewing HEW legislative authorities, OTA identified only two statutes that require the agencies responsible for implementing the legislation to avoid unreasonable paperwork burden on respondents. These requirements are contained in the Occupational Safety and Health Act of 1970 and the Federal Coal Mine Health and Safety Act of 1969, as amended.

Congressional concern is growing, however, regarding the impact of legislation on statistical and data-gathering activities of Federal agencies and on reporting burden. In February 1977, the Senate amended its own Standing Rules to require that a regulatory impact evaluation accompany each bill reported by a Committee. The rule was enacted primarily to ensure against needless or excessive Government regulation on the public, and requires, among other provisions, a paperwork assessment statement. Such an assessment must include estimates of the cost both to Government and respondents for the gathering and processing of information. The purpose of this rule is to alert Congress to the potential impact of legislation on paperwork and to provide guidance for executive agencies interpreting congressional intent.

A bill introduced in the 95th Congress, H.R. **11253,** would have broadened the information requirements of the Senate Standing Rule for statistical impact statements and would have applied to all proposed legislation that provides Federal authority for the collection of information. An amended version of H.R. 11253, the Federal Statistical Activity Control Act of 1978, which was considered by the House of Representatives, retained a requirement for a computerized catalog of all Federal statistical activities and added requirements for a continuing review and analysis of these activities. However, Congress took no action on this legislation; whether it will be considered in the 96th Congress is unknown.

User's Guide and Methodology

This directory is designed to be used as a planning tool. It lists data collection authorities according to HEW agencies that have been delegated responsibilities for their implementation. Linking the legislation that generates data collection with the HEW offices responsible for implementing their statutory requirements is essential for planning purposes; without this information, coordination is impossible. iPHS agencies appear first, in alphabetical order; offices within HCFA follow, also alphabetically. Each legislative section within the directory is also listed by parallel citation; both Public Law section numbers and United States Code citations are used. These sections are cataloged in ascending numerical order and include the date of original enactment. An index to all statutory sections cited is also provided at the end of the directory and cross-referenced to the appropriate administering agencies and page numbers. Entries in the directory are made according to legislative sections; and subsections are grouped under corresponding sections. The initial number of a provision denotes the ***section;*** this is followed by alternating letters and numbers in parentheses to designate ***subsections.*** For example:

United States Code Title				
42	U.S.C.	301a (section)	(a)(l)	(A)(II)(a)(iii) (subsection)

This citation refers to Title 42 of the United States Code, section 301a, subsection (a)(l) (A)(II)(a)(iii). The subsequent ***section*** would be: **42** U.S.C. 301b, and the subsequent ***subsection*** would be: 42 U.S.C. 301a(a) (l)(A) (II)(a) (iv).

Legislative sections cited here were identified by a two-step process. First, the HEW administrative units assumed to be collecting health data were requested to supply a list of all their statutory authorities. The lists returned by each office were not limited to the data collection function. OTA then examined these lists to determine which sections appeared to directly or indirectly authorize data collection. Each legislative section was then classified by the type of authority—specific, general, or implied. In some cases, sections were classified by more than one type of authority. Each office was contacted again to comment and verify OTA's classifications. Through this process, OTA was able both to link legislative authorities with individual agencies and determine "jointly administered" authorities.

Relying on HEW-supplied statutory authorities was essential in order to determine how these authorities were delegated because most legislation does not designate the administrative office responsible for implementation. Delegation is an internal administrative decision that may or may not be accompanied by formal documents of delegation. Informal delegation grants the Secretary the greatest freedom in determining how best to administer a law; however, it also makes efforts to organize laws by agencies dependent on information supplied by HEW.

One further point should be noted, all offices within PHS could cite section 301(a) of the Public Health Service Act (42 U.S. C. ~241(a)), as authority for data collection activities. This section is a general authorization for the Surgeon General to perform research and collect information relating to the "causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." Section 301(a) is listed only once in the directory under the general authority of the Assistant Secretary for Health. In certain cases, however, the authority of section 301(a), 42 U.S. C. ~241(a), is explicitly incorporated into other statutory sections. In such cases, the section is footnoted with an explanatory note.

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3. U.S. Department of Health, Education, and Welfare, Public Health Service, Health ***Statistics Plan, Fiscal Years*** **2976-2977.** U.S. Government Printing Office. November 1975.
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GLOSSARY OF TERMS

Specific authority—explicitly mandates (1) the initiation of a data collection system and/or (2) the collection of explicitly identified data.

General authority—mandates the performance of a function, such as research or the preparation of a report, that requires the collection of original data. The required data, however, are not identified; only the subject area for which the data are to be gathered is indicated.

Implied authority—mandates a particular function that may require collecting original data if the data necessary to fulfill the function are unavailable. Examples are mandates to establish information clearinghouses, disseminate information about particular topics, or prepare reports summarizing available data.

1. OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Legal citation	Type of authority	Legislative text
A. General Authority Applicable to all Public Health Service Agencies		
a) Public Health Service Act • P.L. 78-410$301 (1944), and amended • *42 USC ~ 241*	General	(a) "The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control and prevention of physical and mental diseases and impairments of man . . . In carrying out the foregoing the Secretary is authorized to— (1) collect and make available through publications and other appropriate means, information as to, the practical application of, such research and other activities . . . *(6)* make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies and surveys in health and medical fields;" Transfer of functions [All functions of the Public Health Service, of the Surgeon General of the Public Health Service, and of all other officers and employees of the Public Health Service, and all functions of all agencies of or in the Public Health Service were transferred to the Secretary of Health, Education, and Welfare by *1966* Reorg. Plan No. 3, 31 F.R. *8855,* as a note under section 202 of title 42 of the United States Code.]
b) Public Health Service Act • P.L. 78-410$310, as added by P.L. 93-353 $107(a) (1974) • 42 USC ~2420	Implied	"From time to time the Secretary shall issue information related to public health, in the form of publications or otherwise, for the use of the public, and shall publish weekly reports of health conditions in the United States and other countries and other pertinent health information for the use of persons and institutions concerned with health services. "

Legal citation	Type of authority	Legislative text
B. Health Maintenance Organizations (HMOs)		
a) Public Health Service Act • P.L. 78-410 ~1301 as added by P.L. 93-222$2 (1973) and amended • **42** USC $300e	Specific	(c) "Each health maintenance organization shall– . . . (11) provide, in accordance with regulations of the Secretary (including safeguards concerning the confidentiality of the doctor-patient relationship), an effective procedure for developing, compiling, evaluating, and reporting to the Secretary, statistics and other information (which the Secretary shall publish and disseminate on an annual basis and which the health maintenance organization shall disclose, in a manner acceptable to the Secretary, to its members and the general public) relating to (A) the cost of its operations, (B) the patterns of utilization of its services, (C) the availability, accessibility, and acceptability of its services, (D) to the extent practical, developments in the health status of its members, and (E) such other matters as the Secretary may require. "
b) Public Health Service Act • P.L. 78-410 ~1315 as added by P.L. 93-222$2 (1973) and amended • **42** USC ~300e-14	General	(a) "The Secretary shall periodically review the programs of assistance authorized by this title and make an annual report to the Congress of a summary of the activities under each program. The Secretary shall include in such summary— . . . (2) The statistics and other information reported in such period to the Secretary in accordance with section Shoe of . . . title *[42];"*
C. Office of Adolescent Pregnancy Programs		
a) Health Services and Centers Amendments of 1978 • P.L. 95-626$606 (1978) • 42 USC ~300a-26	Specific	(a) "An application for a grant under this Act shall be in such form and contain such information as the Secretary may require, and shall include— (1) an identification of the incidence of adolescent pregnancy and related problems; (2) a description of the economic conditions and income levels in the geographic area to be served; (3) a description of existing pregnancy prevention and pregnancy-related services (including family life and sex education), and including where, how, by whom and to whom they are provided, and the extent to which they are coordinated in the geographic area to be served; (4) a description of the major unmet needs for services for adolescents at risk of initial or repeat pregnancies, the number

C. Office of Adolescent Pregnancy Programs—continued

Legal citation	Type of authority	Legislative text
		of adolescents currently served in the area, and the number of adolescents not being served in the area; *(5)* a description of how all of the core services will be provided in the project using funds under this Act or otherwise provided by the grantee, to whom they will be provided, how they will be coordinated, integrated, and linked with other related programs and services and the source or sources of funding of such core services; (6) a description of how adolescents needing services other than those provided directly by the grantee will be identified and how access and appropriate referral to those services (such as medicaid, public assistance, employment services; child care services for adolescent parents; and other city, county, and State programs related to adolescent pregnancy) will be provided including a description of the plan to coordinate such services with activities funded under this Act; (12) assurances that the'applicant shall have a system for maintaining the confidentiality of patient records in accordance with regulations promulgated by the Secretary; (b) Each grantee which participates in the program established by this title shall make such reports concerning its use of Federal funds as the Secretary may require. Reports shall include the impact the project has had on reducing the rate of first and repeat pregnancies among adolescents, and the effect on factors usually associated with welfare dependency. "

D. Office of Disease Prevention and Health Promotion

1. Office of Health Information, Health Promotion, and Physical Fitness, and Sports Medicine

a) Public Health Service Act • P.L. 78-410$1701 as added by P.L. 94-317$102 *(1976),* and amended • *42* USC ~300u	General	(a) "The Secretary shall– . . . (4) undertake and support research and demonstrations respecting health information and health promotion, preventive health services, and education in the appropriate use of health care; . . . (7) foster the exchange of information respecting, and foster cooperation in the conduct of, research, demonstration, and training programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care; . . .

1). Office of Disease Prevention and Health Promotion
1. Office of Health Information, Health Promotion, and Physical Fitness, and Sports Medicine—continued

Legal citation	Type of authority	Legislative text
	Implied	(c) It shall be the duty of the State Council on Physical Fitness to— . . . (2) assess the physical fitness and nutrition status of residents of the State; (3) plan and administer a program of grants-in-aid to support physical fitness projects, research projects, and public information efforts to promote the development of physical fitness for the residents of the State; (4) evaluate and improve the availability and quality of sports medicine and athletic trainer programs in the State. ” [Jointly administered with the Center for Disease Control.]
b) Public Health Service Act • P.L. 78-410 ~1702, as added by P.L. 94-317 ~lo2 (1976)	General	(a) “The Secretary is authorized to conduct and support by grant or contract . . . research in health information and health promotion, preventive health services, and education in the appropriate use of health care. . . . The Secretary shall also— * * *
• 42 USC ~300u-1	Implied	(2) determine the best methods of disseminating information concerning personal health behavior, preventive health services and the appropriate use of health care and of affecting behavior so that such information is applied to maintain and improve health, and prevent disease, reduce its risk, or modify its course or severity; , . .
	General	(4) develop (A) methods by which the cost and effectiveness of activities respecting health information and health’th promotion, preventive health services, and education in the appropriate use of health care, can be measured, including methods for evaluating the effectiveness of various settings for such activities and the various types of persons engaged in such activities, (B) methods for reimbursement or payment for such activities, and (C) models and standards for the conduct of such a$_c$-tivities . . . (5) develop a method for assessing the cost and effectiveness of specific medical services and procedures under various conditions of use, including the assessment of the sensitivity and specificity of screening and diagnostic procedures; and (6) enumerate and assess, using methods developed under paragraph (5), preventive health measures and services with

f). Office of Disease Prevention and Health Promotion
1. Office of Health Information, Health Promotion, and Physical fitness, and Sports Medicine—contiflued

Legal citation	Type of authority	Legislative text
		respect to their cost and effectiveness under various conditions of use.
	Specific	(b) The Secretary shall make a periodic survey of the needs, interest, attitudes, knowledge, and behavior of the American public regarding health and health care. The Secretary shall take into consideration the findings of such surveys and the findings of similiar surveys conducted by national and community health education organizations, and other organizations and agencies for formulating policy respecting health information and health promotion, preventive health services, and education in the appropriate use of health care. ” [Jointly administered with the Center for Disease Control.]
c) Public Health Service Act • P.L. 78-410 ~1704, as added by P.L. 94-317 ~l02 (1976) • *42* USC $300u-3	Implied	“The Secretary is authorized to conduct and support . . . such activities as may be required to make information respecting health information and health promotion, preventive health services, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters. Such activities may include at least the following: (1) The publication of information, pamphlets, and other reports which are specially suited to interest and instruct the health consumer, which information, pamphlets and other reports shall . . . pertain to the individual’s ability to improve and safeguard his own health shall include material, accompanied by suitable illustrations, on child care, family life and human development, disease prevention . . . physical fitness, dental health, environmental health, nutrition, safety and accident prevention, drug abuse and alcoholism, mental health, management of chronic diseases . . . and venereal diseases; * * *
	General	*(6) Assess,* with respect to the effectiveness, safety, cost, and required training for and conditions of use, of new aspects of health care, and new activities, programs, and services designed to improve human health and publish in readily understandable language . . . such assessments . . . “ [Jointly administered with the Center for Disease Control.]

D. *Office* of Disease Prevention and Health Promotion
1. Office of Health Information, Health Promotion, and Physical Fitness, and Sports Medicine—continued

Legal citation	Type of authority	Legislative text
d) Public Health Service Act • P.L. 94-317 ~102 (1976) • 42 USC ~300u-4	Implied	(a) "The Secretary shall, not later than two years after June 23, 1976, and annually thereafter, submit to the President for transmittal to Congress a report on the status of health information and health promotion, preventive health services, and education in the appropriate use of health care. Each such report shall include— (1) a statement of the activities carried out under this subchapter since the last report and the extent to which such activity achieves the purposes of this subchapter; (2) an assessment of the manpower resources needed to carry out programs relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, and a statement describing the activities currently being carried out under this subchapter designed to prepare teachers and other manpower for such programs; (3) the goals and strategy formulated pursuant to section 300u(a)(l) of title *42*. . . *(4)* such recommendations as the Secretary considers appropriate for legislation respecting health information and health promotion, preventive health services, and education in the appropriate use of health care . . .
	Specific	(b) "The Secretary shall conduct a study of health education services and preventive health services to determine the coverage of such services under public and private health insurance programs, including the extent and nature of such coverage and the cost sharing requirements required by such programs for coverage of such services. " [Jointly administered with the Center for Disease Control]
e) Public Health Service Act • P.L. 78-410 ~1706 as added by P.L. 94-317$102 (1976), and amended • 42 USC ~300u-5	Implied	(a) "The Secretary shall establish within the Office of the Assistant Secretary for Health an Office of Health Information and Health Promotion and Physical Fitness and Sports Medicine which shall— (3) establish a national information clearinghouse to facilitate the exchange of information concerning matters relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, to facilitate access to such information, and to assist in the analysis of issues and problems relating to such matters; and (4) support projects, conduct research, and disseminate information in the areas of physical fitness and sports medicine.

D. Office of Disease Prevention and Health Promotion
1. Office of Health Information, Health Promotion, and Physical Fitness, and Sports Medicine—continued

Legal citation	Type of authority	Legislative text
	General	(b) The Office shall also– (1) assist, and foster research, investigations, and model projects on the nature of physical fitness, the development of physical fitness, and the relation of physical fitness to health; (2) assist, and foster research and investigations into the utilization of sports medicine, the development of sports medicine techniques, and the application of sports medicine throughout organized systems of athletic competition and in personal physical fitness development activities at every age and competition level; (3) foster and assist research into the proper role of nutrition in physical fitness programs; (4) promote the coordination of research and model programs conducted by the Office with similar programs conducted by other agencies of the Federal Government and other public and private organizations; (5) communicate the results of the studies in the widest possible manner to the American people and to special groups with particular interests and special needs in the development of physical fitness, such as young children, the handicapped, senior citizens, and workers in occupations which present special risks of physical disability; . . . “
f) Public Health Service Act • P.L. 78-410 ~1709 as added by P.L. 95-626$502 (1978) 42 USC $300u-8	General	(a) “The Office shall establish a program of project grants to conduct research into the problem of athletic injuries with specific concentration on frequency of injuries, seriousness of injuries, the development of training and conditioning techniques and the development of athletic protective equipment to enable participants to avoid injuries to the maximum extent feasible, recovery rates, and problems associated with full recovery from athletic injuries.
	Implied	(b) The Office shall, in cooperation with the President’s Council on Physical Fitness, establish a Clearinghouse on Sports Medicine Research to disseminate the results of that research to practioners in relevant fields of health care and physical fitness. . . . “

Legal citation	Type of authority	Legislative text
E. Office of Smoking and Health		
a) Federal Cigarette Labeling and Advertising Act • P.L. 89-92, $8 (1965), and amended • 15 USC *$1337*	Implied	(a) "The Secretary of Health, Education, and Welfare shall transmit a report to the Congress not later than January 1, 1971, and annually thereafter, concerning (A) current information on the health consequences of smoking, and (B) such recommendations for legislation as he may deem appropriate."
b) Health Services and Centers Amendments of 1978 • P.L. 95-626 ~402 (1978) • 42 USC $247b-2	General	(a) "The Secretary of Health, Education, and Welfare, after consultation with appropriate public and private entities, shall establish a comprehensive program designed to deter smoking and the use of alcoholic beverages among children and adolescents. Such a program shall include— (1) the undertaking or support (through grants or contracts or both) of biomedical and behavioral research designed to increase understanding of the biological and behavioral determinants of smoking and the use of alcoholic beverages among children and adolescents, with special emphasis on children aged twelve or below, . . . " [Jointly administered with National Institute on Alcohol Abuse and Alcoholism (ADAMHA).]
F. Office of Health Research, Statistics, and Technology **1. National Center for Health Care Technology**		
a) Public Health Service Act • P.L. 78-410 ~304, as added by P.L. 93-353$103, **(1974),** and amended • 42 USC $242b	Specific	(a)(l) "The Secretary, acting through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology, 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 (l), the Secretary 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,

F. Office of Health Research, Statistics, and Technology
1. National *Center* for Health Care Technology—continued

Legal citation	Type of authority	Legislative text

(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 health care technologies,

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

(G) the special health problems of low income and minority groups and the elderly to insure that these problems are assessed on a periodic regular basis,

(H) the prevention of illness, disability, and premature deaths in the United States,

(I) health care costs, increases in such costs, and the reasons for such increases, and

(J) the impact of the environment on individual health and on 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 . . . provide technical assistance and advice, make grants, and when appropriate enter into contracts.

(c)(1) The Secretary shall coordinate all health services research, evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology undertaken and supported through units of the Department of Health, Education, and Welfare. To the maximum extent feasible such coordination shall be carried out through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology.

(2) The Secretary shall coordinate the health services research, evaluations, and demonstrations, the health statistical and (where appropriate) epidemiological activities, and the research, evaluations, and demonstrations respecting the assessment of health care technology authorized by this Act through the National Center for HeaIth Services Research, the National Center of Health Statistics, and the National Center for Health Care Technology. ”

[Jointly administered with the National Center for Health

F. Office of Health Research, Statistics, and Technology
1. National Center for Health Care Technology—continued

Legal citation	Type of authority	Legislative text
		Statistics and the National Center for Health Services Research.]
b) Public Health Service Act • P.L. 78-410$309, as added by P.L. 95-623, $6 (1978) • *42* USC ~242n	General	(a) "There is established in the Department of Health, Education, and Welfare the National Center for Health Care 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 Assistant Secretary for Health (or such other officer of the Department as maybe designated by the Secretary as the principal adviser to him for health programs). (b)(l) The Secretary, acting through the Center, shall undertake and support (by grant or contract) assessments of health care technology. Such assessments shall take into account the safety, effectiveness, and cost effectiveness of, and the social, ethical, and economic impact of health care technologies. (2) The Secretary, acting through the Center, shall encourage, undertake, and support (by grant or contract) research, demonstrations, and evaluations respecting— (A) the factors that affect the use of health care technologies in the United States; (B) methods for disseminating information on health care technologies, and (C) the effectiveness, cost effectiveness, and social, ethical, and economic impacts of particular medical technologies. (3) The Secretary, acting through the Center, shall en-.ourage and support (by grant or contract) research, evaluations, and demonstrations respecting the safety and efficacy of particular health care technologies. (4) The Secretary, acting through the Center and in consultation with the National Council on Health Care Technology, shall establish priorities for the activities prescribed by paragraphs (1), (2), and (3). In determining if an activity respecting a particular health care technology should be given priority, emphasis shall be placed on— (A) the actual or potential risks and the actual or potential benefits to patients associated with the use of the technology, (B) the actual or potential cost of the technology, (C) the actual or potential rate of its use, and (D) the stage of development of the technology . . . "

F. Office of Health Research, Statistics, and Technology
2. National Center for Health Service Research

Legal citation	Type of authority	Legislative text

2. National Center for Health Services Research

a) Public Health Service Act • P.L. 78-410$304 and added by P. L.93-353 $103 1974) and amended • *42* USC ~242b	Specific	(a)(l) "The Secretary, acting through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology, 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 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, (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 health care technologies, (F) alternative methods for disseminating knowledge concerning health and health related activities, (G) the special health problems of low income and minority groups and the elderly to insure that these problems are assessed on a periodic regular basis, (H) the prevention of illness, disability, and premature deaths in the United States, (1) health care costs, increases in such costs, and the reasons for such increases, and (J) the impact of the environment on individual health and on 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 . . . provide technical assistance and advice, make grants, and when appropriate enter into contracts. (c)(1) The Secretary shall coordinate all health services

F. Office of Health *Research, Statistics, and Technology*
2. **National Center for Health earch—continued**

Legal citation	Type of authority	Legislative text
		research, evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology undertaken and supported through units of the Department of Health, Education, and Welfare. To the maximum extent feasible such coordination shall be carried out through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology. (2) The Secretary shall coordinate the health services research, evaluations, and demonstrations, the health statistical and (where appropriate) epidemiological activities, and the research, evaluations, and demonstrations respecting the assessment of health care technology authorized by this Act through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology." [Jointly administered with the National Center for Health Statistics and the National Center for Health Care Technology.]
b) Public Health Service Act • P.L. 78-4105305, as added by P.L. 93-353 ~lo4 (1974), and amended • 42 USC $242c	General	(b) "In carrying out section 242b(a) of this title, the Secretary, acting through the Center, shall undertake and support research, evaluation, and 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; (3) the design, utilization, organization, cost of facilities and equipment; and (4) the uses of computer science in health services delivery and medical information systems. "

F. Office of *health~ea/th* Research, *Statistics,* and Technology
2. Nationa/ Center for Health *Service* Research—continued

Legal citation	Type of authority	Legislative text
c) Public Health Service Act • P.L. 78-410$308, as added by P.L. 93-353 $107(a) (1974), and amended	Implied	(a)(l) "Not later than December 1, of each year, the Secretary shall make a report to Congress respecting— (A) the administration of sections 242b, *242c,* 242k, and *2421* and 242n of this title during the preceding fiscal year, and (B) the current state and progress of health services research, health statistics, and health care technology. "
• 42 USC ~242m	Specific	(a)(2) The Secretary, acting through the National Center for Health Services Research and the National Center for Health Statistics, shall assemble and submit to the President and the Congress not later than December 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 242k(b)(l)(G) of this title. (B) A report on health resources. Such report shall include a description and analysis, by geographic area, of the statistics collected under section 242k(b)(l)(E) of this title. (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 24 Zk(b)(l)(F) of this title. (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 242k(b)(l)(A) of this title. " [Jointly administered with the National Center for Health Statistics.]
	Implied	(g)(l) 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, demonstration, and evaluations undertaken and supported under sections 242b and *242c* of this title; (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. . . . "

F. Office of Health Research, Statistics, and Technology
3. National Center *for* Health Statistics

Legal citation	Type of authority	Legislative text

3. National Center for Health Statistics

a) Public Health Service Act • P.L. 78-410 ~304, as added by P.L. 93-353 ~l03 (1974), and amended • 42 USC ~242b	Specific	(a)(l) "The Secretary, acting through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology, 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 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, (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 health care technologies, (F) alternative methods for disseminating knowledge concerning health and health related activities, (G) the special health problems of low income and minority groups and the elderly to insure that these problems are assessed on a periodic regular basis, (H) the prevention of illness, disability, and premature deaths in the United States, (I) health care costs, increases in such costs, and the reasons for such increases, and (J) the impact of the environment on individual health and on 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 . . . provide technical assistance and advice, make grants . . . and when appropriate enter into contracts. . . .

F. Office of Health Research, Statistics, and Technology
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text
		(c)(l) The Secretary shall coordinate all health services research, evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology undertaken and supported through units of the Department of Health, Education, and Welfare. To the maximum extent feasible such coordination shall be carried out through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology. (2) The Secretary shall coordinate the health services research, evaluations, and demonstrations, the health statistical and (where appropriate) epidemiological activities, and the research, evaluations, and demonstrations respecting the assessment of health care technology authorized by this Act through the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology." [Jointly administered with the National Center for Health Services Research and the National Center for Health Care Technology.]
	Specific	(e)(l) The Secretary and the National Academy of Sciences (acting through the Institute of Medicine and other appropriate units) shall, jointly and in cooperation with the Administrator of the Environmental Protection Agency, the Secretary of Labor, the Consumer Product Safety Commission, the Council of Economic Advisers, the Council on Wage and Price Stability, the Council on Environmental Quality, and other entities of the Federal Government which the Secretary determines have the expertise in the subject of the study prescribed by this paragraph, conduct, with funds appropriated under section 308(i)(2) [42 USC S242m], an ongoing study of the present and projected future health costs of pollution and other environmental conditions resulting from human activity (including human activity in any place in the indoor or outdoor environment, including places of employment and residence). In conducting the study, the Secretary and the National Academy of Sciences (hereinafter in this subsection referred to as the 'Academy') shall, to the extent feasible— (A) identify the pollution (and the pollutants responsible for the pollution) and other environmental conditions which are, or may reasonably be anticipated to be, resportsible for causing, contributing to, increasing susceptibility to, or aggravating human diseases and adverse effects on humans;

F. Office of Health Research, Statistics, and Technology
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text

(B) identify each such disease and adverse effect on humans and specifically determine whether cancer, birth defects, genetic damage, emphysema, asthma, bronchitis, and other respiratory diseases, heart disease, stroke, and mental illness and impairment are such a disease or effect;

(C) identify (on a national, regional, or other geographical basis) the source or sources of such pollutants and conditions and estimate the portion of each pollutant and the extent of each condition which can be traced to a specific type of source;

(D) ascertain

(i) the extent to which the pollutants and conditions identified under subparagraph (A) are, or may reasonably be anticipated to be, responsible, individually or collectively, for causing, contributing to, increasing susceptibility to, or aggravating the diseases and effects identified under subparagraph (B), and

(ii) the effect upon the incidence or severity of specific diseases and effects of individual or collective, as appropriate, incremental reductions in the pollutants and changes in such conditions, and

(E) quantify

(i) the present and projected future health costs of the diseases and effects identified under subparagraph (B), and

(ii) the reduction in health costs which would result from each incremental reduction and change referred to in subparagraph (D)(ii).

* * *

(3) The first report on the study prescribed by paragraph (1) shall be made to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives by the Secretary and the Academy not later than eighteen months after the date of the enactment of this subsection. Subsequent reports on the study shall be made by the Secretary and the Academy every two years after the date the first report is submitted. Each report shall

(A) identify deficiencies and limitations in the data on the matters considered in the study and recommend actions which may be taken to eliminate such deficiencies and limitationstions,

(B) include such recommendations for legislation as the Secretary determines appropriate,

(C) include recommendations for facilitating studies of the effects of hazardous substances on humans, and

F. Office of Health Research, Statistics, and Technology
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text
		(D) include a description of any administrative action proposed to be taken by the Secretary, the Administrator of the Environmental Protection Agency, the Secretary of Labor, and the Consumer Product Safety Commission to reduce the costs which have been quantified under paragraph (l)(E)(i). In conducting the study, the Secretary and the Academy shall seek assistance from public and private health financing entities in securing the data needed for the study. (4) For purposes of paragraph (1), the term 'health costs of pollution and other environmental conditions' means the costs of human diseases and other adverse effects on humans which pollution and other environmental conditions are, or may reasonably be anticipated to be, responsible for causing, contributing to, increasing susceptibility to, or aggravating, including the costs of preventing such diseases and effects, the costs of the treatment, cure, convalescence, and rehabilitation of persons afflicted by such diseases, costs reasonably attributable to pain and suffering from such diseases and effects, loss of income and future earnings resulting from such diseases and effects, adverse effects on productivity (and thus increases in production costs and consumer prices) resulting from such diseases and effects, loss of tax revenues resulting from such decreases in earnings and productivity, costs to the welfare and unemployment compensation systems and the programs of health benefits under titles XVIII and XIX of the Social Security Act resulting from such diseases and effects, the overall increases in costs throughout the economy resulting from such diseases and effects, and other related direct and indirect costs. " [National Center for Health Statistics has the lead responsibility, though there is coordination with other Federal agencies.]
b) Public Health Service Act • P.L. 78-410$306, as added by P.L. 93-353$105 (1974), and amended • 42 USC $242k	Specific	(b) "In carrying out section 242b(a) of this title, the Secretary, acting through the Center, shall (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,

F. Office of Health Research, Statistics, and Technology
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text

(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 pay-merit for health care services, and Federal, State and local government expenditures for health care services, and

(H) family formation, growth and dissolution; and . . .

(3) may undertake and support . . . epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1); and

(4) may collect, furnish, tabulate, and analyze statistics, and prepare studies, on matters referred to in paragraph (1) upon request of public and nonprofit private entities under arrangements under which the entities will pay the cost of the service provided. . . .

(e) for the purpose of producing comparable and uniform health information and statistics, there is established the Cooperative Health Statistics System. The Secretary, acting through the Center, shall—

(1) coordinate the activities of Federal agencies involved in the design and implementation of the System;

(2) undertake and support (by grant or contract) research, development, demonstrations, and evaluations respecting the System;

(3) make grants to and enter into contracts with State and local health agencies to assist them in meeting the costs of data collection carried out under the System; and

(4) review the statistical activities of the Department of Health, Education, and Welfare to assure that they are consistent with the System.

States participating in the System shall designate a State agency to administer or be responsible for the administration of the statistical activities within the State under the System. The Secretary, acting through the Center, shall prescribe guidelines to assure that statistical activities within States par-

F. Office of Health Research, Statistics, and Technology
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text

ticipating in the system produce uniform and timely data and assure appropriate access to such data. . . .

(g) To secure uniformity in the registration and collection of mortality, morbidity, and other health data, the Secretary 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. . . .

(j) In carrying out the requirements of this title [42 USC] and paragraph (1) of subsection (e) of this section, the Secretary shall coordinate health statistical and epidemiological activities of the Department of Health, Education, and Welfare by—

(1) establishing standardized means for the collection of health information and statistics under laws administered by the Secretary;

(2) developing, in consultation with the National Committee on Vital and Health Statistics, and maintaining the minimum sets of data needed on a continuing basis to Fulfill the collection requirements of subsection (b)(l) of this section;

(3) after consultation with the National committee on Vital and Health Statistics, establishing standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis;

(4) in the case of proposed health data collections of the Department which are required to be reviewed by the Director of the Office of Management and Budget under section 3509 of title 44, United States Code, reviewing such proposed collections to determine whether they conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3), and if any such proposed collection is found not to be in conformance, by taking such action as may be necessary to assure that it will conform to such sets of data and standards; and

(5) periodically reviewing ongoing health data collections of the Department, subject to review under such section 3509, to determine if the collections are being conducted in accordance with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3) and, if any such

F. Office of Health Research, Statistics, *and* Technology
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text
		collection is found not to be in conformance, by taking such action as may be necessary to assure that the collection will conform to such sets of data and standards not later than the ninetieth day after the date of the completion of the review of the collection. . . . (1)(1) The Secretary, acting through the Center, shall develop a plan for the collection and coordination of statistical and epidemiological data on the effects of the environment on health. Such plan shall include a review of the data now available on health effects, deficiencies in such data, and methods by which existing data deficiencies can be corrected. The Secretary shall submit such plan to the Congress not later than January 1, 1980. (2)(A) The Secretary, acting through the Center, shall establish, not later than two years after November 9, 1978, guidelines for the collection, compilation, analysis, publication, and distribution of statistics and information necessary for determining the effects of conditions of employment and indoor and outdoor environmental conditions on the public health. , . . The guidelines shall be reviewed and, if appropriate, revised at least every three years after the date they are initially established. Guidelines shall take effect on the date of the promulgation of the regulation establishing or revising the guidelines or such later date as may be specified in the guidelines. (B) The guidelines shall be designed– (i) to improve coordination of environmental and health studies, statistics, and information, and to prevent overlap and unnecessary duplication with respect to such studies, statistics, and information; (ii) to assure that such studies, statistics, and information will be available to executive departments responsible for the administration of laws relating to the protection of the public health and safety or the environment; (iii) to encourage the more effective use by executive departments of such studies, statistics, and information; (iv) to improve the statistical validity and reliability of such studies, statistics, and information; and (v) to assure greater responsiveness by the Department of Health, Education, and Welfare and other executive departments in meeting informational and analytical needs for determining the effects of employment and indoor and outdoor environmental conditions on public health.

F. Office of Health Research, Statistics, and Technology
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text
		(C) In establishing and revising guidelines under subparagraph (A), the Secretary shall take into consideration the plan developed pursuant to paragraph (1). (D) The Center shall serve as a clearinghouse for statistics and information with respect to which guidelines have been established under subparagraph (A) and shall assist executive departments in obtaining such statistics and information for purposes of administering laws under their jurisdiction relating to environmental health protection or the safety and health of employees. . . . (F) In carrying out his duties under this paragraph, the Secretary, acting through the Center, shall, insofar as practicable, provide for coordination of his activities with those of other Federal agencies and interagency task forces relating to the collection, analysis, publication, or distribution of statistics and information necessary for determining the effects of conditions of employment and indoor and outdoor environmental conditions on the public health. ”
c) Public Health Service Act • P.L. 78-410$308, as added by P.L. 93-353 ~107a (1974), and amended • *42* USC $242m	Implied Specific	(a)(l) “Not later than December 1, of each year the Secretary shall make a report to Congress respecting— (A) the administration of sections 242b,242c, 242k, 2421 and 242n of this title during the preceding fiscal year, and (B) the current state and progress of health services research, health statistics, and health care technology. (a)(2) The Secretary, acting through the National Center for Health Services Research and the National Center for Health Statistics, shall assemble and submit to the President and the Congress not later than December 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 242k(b)(l)(G) of this title. (B) A report on health resources. Such report shall include a description and analysis, by geographic area, of the statistics collected under section 242k(b)(l)(E) of this title. (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 242k(b)(l)(F) of this title. (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

F. ***Office*** **of Health Research, Statistics, and Technology**
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text
		section 242k(b)(l)(A) of this title. ” [Jointly administered with the National Center for Health Services Research.]
d) Health Services and Centers Amendments of 1978 • P.L. 95-626 ~404 • 42 USC $242p	Specific	(a) “The Secretary, acting through the National Center for Health Statistics, shall submit to Congress on December 1, 1980, and on December 1 of every third year thereafter, a national disease prevention data profile in order to provide a data base for the effective implementation of this Act and to increase public awareness of the prevalence, incidence, and any trends in the preventable causes of death and disability in the United States. Such profile shall include at a minimum— (1) mortality rates for preventable diseases; (2) morbidity rates associated with preventable diseases; (3) the physical determinants of health of the population of the United States and the relationship between these determinants of health and the incidence and prevalence of preventable causes of death and disability; and (4) the behavioral determinants of health of the population of the United States including, but not limited to, smoking, nutritional and dietary habits, exercise, and alcohol consumption, and the relationship between these determinants of health and the incidence and prevalence of preventable causes of death and disability. (b) In preparing the profile required by subsection (a) of this section, the Secretary, acting through the National Center for Health Statistics, shall comply with all relevant provisions of sections **306** and 308 of the Public Health Service Act [42 USC 242k, 242m].
e) Public Health Service Act • P.L. 78-410$708, as added by P.L. 94-484 ~206 (1976) and amended • *42* USC ~292h	Specific	(a) “The Secretary shall establish a program, including a uniform health professions data reporting system, to collect, compile, and analyze data on health professions personnel which shall initially include data respecting all physicians and dentists in the States. The Secretary is authorized to expand the program to include, whenever he determines it necessary, the collection, compilation, and analysis of data respecting pharmacists, optometrists, podiatrists, veterinarians, public health personnel, audiologists, speech pathologists, **health** care administration personnel, nurses, allied health personnel, medical technologists, and any other health personnel in States designated by the Secretary to be included in the programs. Such data shall include data respecting the training, licensure status (including permanent, temporary, partial, limited, or institutional), place or places of practice, professional speciality, practice characteristics, place and date of

F. Office of Health Research, Statistics, and Technology
3. National *Center for Health Statistics—continued*

Legal citation	Type of authority	Legislative text

birth, sex, and socio-economic background of health professions personnel and such other demographic information regarding health professions personnel as the Secretary may require.

(b)(l) In carrying out subsection (a) of this section, the Secretary shall collect available information from appropriate local, State, and Federal agencies and other appropriate sources.

(2) The Secretary shall conduct or enter into contracts for the conduct of analytic and descriptive studies of the health professions, including evaluations and projections of the supply of, and requirements for, the health professions by specialty and geographic locations.

(3) The secretary is authorized to make grants and to enter into contracts with States (or an appropriate nonprofit private entity in any State) for the purpose of participating in the program established under subsection (a) of this section. . . . To be eligible for a grant or contract under this paragraph a State or entity shall submit an application in such form and manner and containing such information as the Secretary may require. Such application shall include reasonable assurances, satisfactory to the Secretary, that—

(A) such State (or nonprofit entity within a State) will establish a program of mandatory annual registration of the health professions personnel described in subsection (a) of this section who reside in or practice in such State and of health institutions licensed by such State, which registration shall include such information as the Secretary shall determine to be appropriate;

(B) such State or entity shall collect such information and report it to the Secretary in such form and manner as the Secretary shaIl prescribe; and

(C) such State or entity shall comply with the requirements of subsection (e) of this section.

(c) For purposes of providing the Secretary with information under this section, each school which receives financial support under section 295f of . . . title [42] shall annually report to the Secretary information, determined to be appropriate by the Secretary, respecting the students who attend such school. The Secretary may collect such additional data respecting students of the health professions as he determines to be appropriate.

(d) The Secretary shall assemble and submit to the President and Congress a report on the status of health professions personnel in the United States, which report shall include a description and analysis of the data collected pursuant to this

F. Office of Health Research, Statistics, and Technology
3. National Center *for* Health Statistics—continued

Legal citation	Type of authority	Legislative text
		section. Such report may be included as part of the report made under section 242m (a)(2)(C) of this title. Such report shall be submitted biennially, and the first such report shall be due not later than October 1, 1979. . . . (f) In carrying out his responsibilities under this section, the Secretary shall not be subject to the provisions of Chapter 35 of Title 44 [providing for exemption from the Federal Reports Clearance Act.] [Jointly administered with the Bureau of Health Manpower (HRA).]
f) Public Health Service Act • P.L. 78-410$793, as added by P.L. *94-484,* $701(a) (1976) • 42 USC $295h-2	Specific	(a) "The Secretary shall, in coordination with the National Center for Health Statistics . . . continuously develop, publish, and disseminate on a nationwide basis statistics and other information respecting public and community health personnel, including— (1) detailed descriptions of the various types of activities in which public and community health personnel are engaged, (2) the current and anticipated needs for the various types of public and community health personnel, and (3) the number, employment, geographic locations, salaries, and surpluses and shortages of public and community health personnel, the educational and licensure requirements for the various types of such personnel, and the cost of training such personnel. . . . (c) The Secretary shall submit biennially to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on— (1) the statistics and other information developed pursuant to subsection (a) of this section, and (2) the activities conducted under this subpart, including an evaluation of such activities. " [Jointly administered with the Bureau of Health Manpower (HRA).]
g) Public Health Service Act • P.L. 78-410 ~795 note, as added by P. L.94-484 $702 (1976) • 42 USC 295h-4 note	Specific	(b) " . . . The Secretary shall, in coordination with the National Center for Health Statistics (established under section 306 of the Public Health Service Act) (section 242k of Title *42),* develop, publish, and disseminate on a nationwide basis a report containing statistics and other information respecting allied health personnel, including— (1) detailed descriptions of the various types of such personnel and the activities in which such personnel are engaged, (2) the current and anticipated needs for the various types of such health personnel,

F. Office of Health Research, Statistics, and Technology
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text
		(3) the number, employment, geographic locations, salaries, and surpluses and shortages of such personnel ." [Jointly administered with the Bureau of Health Manpower (HRA).]
h) Public Health Service Act • P.L. 78-410 ~1513 as added by P.L. 93-641$3 (1975) and amended • 42 USC ~300/-2	Specific	(b) "In providing health planning and resources development for its health service area, a health system agency shall perform the following functions: (1) The agency shall assemble and analyze data concerning— (A) the status (and its determinants) of the health of the residents of its health service area, (B) the status of the health care delivery system in the area and the use of that system by residents of the area, (C) the effect the area's health **care** delivery system has on the health of the residents of the area, (D) the number, type, and location of the area's health resources, including health services, manpower, and facilities, (E) the patterns of utilization of the area's health resources, and (F) the environmental and occupational exposure factors affecting immediate and Iongterm health conditions. . . . In carrying out this paragraph, the agency shall to the maximum extent practicable use existing data (including data developed under Federal health programs) and coordinate its activities with the cooperative system provided for under section 242k(e) of . . . tide [42]. (2) The agency shall, after appropriate consideration of the recommended national guidelines for health planning policy issued by the Secretary under section 300k-1 of . . . title [42], the priorities set forth in section 300k-2 of . . . title *[42],* and the data developed pursuant to paragraph (l), establish, annually review, and amend as necessary a health systems plan (hereinafter in this subchapter referred to as the "HSP") . . .
	Implied	(c) A health systems agency shall implement its HSP and AIP, and in implementing the plans it shall perform at least the following functions: (2) The agency may provide, in accordance with the priorities established in the AIP, technical assistance . . . for the development of projects and programs which the agency determines are necessary to achieve the health systems described in the HSP, . . .

F. Office of Health Research, Statistics, and Technology
3. National Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text
		(d) Each health systems agency shall coordinate its activities with—
		(1) each Professional Standards Review Organization (designated under section 1320c-1 of . . . title [42],
		(2) entities referred to in paragraphs (1) and (2) of section 3334(a) of this title and regional and local entities the views of which are required to be considered under regulations prescribed . . . to carry out section 4231(b) of this title.
		(3) other appropriate general or special purpose regional planning or administrative agencies, and
	General	(4) any other appropriate entity, in the health systems agency's health service area. The agency shall, as appropriate, secure data from them for use in the agency's planning and development activities, . . .
	Implied	(g)(l) Except as provided in paragraph (2), each health systems agency shall review on a periodic basis (but at least every five years) all institutional health services offered in the health service area of the agency and shall make recommendations to the State health planning and development agency . . . respecting the appropriateness in the area of such services,
		(2) A health systems agency shall complete its initial review of existing institutional health services within three years after the date of the agency's designation under section *300 Z-4(C)* of this title."
		[Jointly administered with the Bureau of Health Planning (HRA).]
i) Public Health Service Act	General	(a) "A State administrative program (hereinafter in this section referred to as the "State Program") is a program for the performance within the State by its State Agency of the functions prescribed by section 300m-2 of this title [42]. . . .
• P.L. 78-410$1522, as added by P.L. 93-641~3 (1975)		(b) The State Program of a State must—
		* * *
• *42* USC ~300m-1		(7)(A) provide for the coordination . . . with the cooperative system provided for under section 242k(e) of . . . title [42] of the activities of the State Agency for the collection, retrieval, analysis, reporting and publication of statistical and other information related to health and health care, and
		(B) require providers of health care doing business in the State to make statistical and other reports of such information to the State Agency; . . .
	Implied	(8) provide, in accordance with methods and procedures prescribed or approved by the Secretary, for the evaluation,

F. Office of Health Research, Statistics, and Technology
3. Nationa/ Center for Health Statistics—continued

Legal citation	Type of authority	Legislative text
		at least annually, of the performance by the State Agency of its functions and of their economic effectiveness, (9) provide that the State Agency wilI from time to time, and in any event not less often than annually, review the State Program and submit to the Secretary required modifications; (10) require the State Agency to make such reports, in such form and containing such information, concerning its structure, operations, performance of functions, and other matters as the Secretary may from time to time require, and keep such records and afford such access thereto as the Secretary may find necessary to verify such records; . . .“ [Jointly administered with the Bureau of Health Planning (HRA).]
	General	
j) Social Security Act • P.L. 74-241$1121 as added by P.L. 95-142 ~19(a) (1977) • 42 USC $1320a	Specific	(a) “For the purposes of reporting the cost of services provided by, of planning, and of measuring and comparing the efficiency of an effective use of services in hospitals, skiI1ed nursing facilities, intermediate care facilities, home health agencies, health maintenance organizations, and other types of health services facilities and organizations to which payment may be made under this Act, the Secretary shall establish by regulation, for each such type of health services facility or organization a uniform system for the reporting by a facility or organization of that type of the following information: (1) The aggregate cost of operation and the aggregate volume of services. (2) The costs and volume of services for various functional accounts and sub-accounts. (3) Rate, by category of patient and class of purchaser. (4) Capital assets, as defined by the Secretary, including (as appropriate) capital funds, debt services, lease agreements used in lieu of capital funds, and the value of land, facilities, and equipment. (5) Discharge and bill data. The uniform reporting system for a type of health services facility or organization shall provide for appropriate variation in the application of the system to different classes of facilities or organizations within that type and shall be established, to the extent practicable, consistent with the cooperative system for producing comparable and uniform health information and statistics described in section 306(e)(l) of the Public Health Service Act. In reporting under such a system hospitals shall employ such chart of accounts, definitions, principles, and statistics as the Secretary may prescribe in order to reach

F. Office of **Health Research, Statistics, and** *Technology*
3. National Center for Health Statistics—continued

Legal citation	'Type of authority	Legislative text
		a uniform reconciliation of financial and statistical data for specified uniform reports to be provided to the Secretary, (b) The Secretary shall– (1) monitor the operation of the systems established under subsection (a); (2) assist with and support demonstrations and evaluations of the effectiveness and cost of the operation of such systems and encourage State adoption of such systems; and (3) periodically revise such systems to improve their effectiveness and diminish their cost. (c) The Secretary shall provide information obtained through use of the uniform reporting systems described in subsection (a) in a useful manner and format to appropriate agencies and organizations, including health systems agencies (designated under section 1515 of the Public Health Service Act) and State health planning and development agencies (designated under section 1521 of such Act), as may be necessary to carry out such agencies' and organizations' functions. " [Delegation is to the Health Care Financing Administration, and HCFA is directed to ***coordinate*** with the National Center for Health Statistics in carrying out portions of its duties under the above-cited authority.]

II. ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Legal citation	Type of authority	Legislative text
A. National Institute on Alcohol Abuse and Alcoholism		
a) Public Health Service Act • P.L. 78-410 ~217, as added by P.L. 91-616 $401(a) (1970) and amended • 42 USC $218	Implied	(d) "The National Advisory Council on Alcohol Abuse and Alcoholism shall advise, consult with, and make recommendations to, the Secretary . . . in the field of alcohol abuse and alcoholism . . . The Council is authorized . . . *(2)* to collect information as to studies being carried on in the field of alcohol abuse and alcoholism, and with the approval of the Secretary, make available such information through appropriate publications for the benefit of health and welfare agencies or organizations . . . or physicians or any other scientists, and for the information of the general public . . . "
b) Health Services and Centers Amendments of 1978 • P.L. 95-626 ~402 (1978) • 42 USC ~247b-2	General	(a) "The Secretary of Health, Education, and Welfare, after consultation with appropriate public and private entities, shall establish a comprehensive program designed to deter smoking and the use of alcoholic beverages among children and adolescents. Such a program shall include— (1) the undertaking or support (through grants or contracts or both) of biomedical and behavioral research designed to increase understanding of the biological and behavioral determinants of smoking and the use of alcoholic beverages among children and adolescents, with special emphasis on children aged twelve or below; . . . " [Jointly administered with the Office of Smoking and Health (OASH).]
c) Comprehensive AlcoholAbuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 • P.L. 91-616$101 (1970), and amended • 42 USC $4551	Implied General	(a) "There is established the National Institute on Alcohol Abuse and Alcoholism . . . ***to*** administer the programs and authorities assigned to the Secretary of Health, Education, and Welfare . . . by this chapter and part C of the Community Mental Health Centers Act (42 USC 2688e et seq.). The Secretary, acting through the Institute, shall, in carrying out the purposes of section 241 and 242a of . . . title [42] with respect to alcohol abuse and alcoholism, develop and conduct comprehensive health, . . . research, and planning programs for the prevention and treatment of alcohol abuse and alcoholism and for the rehabilitation of alcohol abusers and alcoholics. The Secretary shall carry out through the Institute the . . . policy development and planning, evaluation, and public information functions which are required for the implementation of such programs and authorities."*

● **Section 301 of the** Public Health Service Act, **42 USC ~241, is the general data collection authority** for the Secretary of HEW.

A. National Institute on Alcohol Abuse and Alcoholism—continued

Legal citation	Type of authority	Legislative text
d) Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 • P.L. 91-616 ~102 (1970), and amended • 42 USC $4552	Implied	"The Secretary shall— . . . (2) submit to Congress on or before the expiration of the one-year period beginning December 31, 1970 and every three years thereafter, a report (A) containing current information on the health consequences of using alcoholic beverages . . . "
e) Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 • P.L. 91-616 ~501, as added by P.L. 94-371 ~7 (1976), and amended • 42 USC &1585	Specific	(a) "The Secretary, acting through the Institute, shall carry out a program of research, investigations, experiments, demonstrations, and studies, directly and by grant or contract, into— (1) the behavioral and biomedical etiology of, *(2)* treatment of, (3) mental and physical health consequences of, (4) social and economic consequences of, and (5) the impact on families of, alcohol abuse and alcoholism. (b) In carrying out the program described in subsection (a) of this section, the Secretary, acting through the Institute, is authorized to— (1) collect and make available through publications and other appropriate means, information as to, and the practical application of, the research and other activities under the program, . . . "

B. National Institute on Drug Abuse

a) Drug Abuse Officeand Treatment Act of 1972 • P.L. *92-255 ~304,* (1972) and amended • *21* USC $1164	General	"To facilitate the preparation of the strategy, the [Strategy] Council shall (2) at the request of any member, require departments and agencies engaged in Federal drug abuse prevention functions and drug traffic prevention functions to submit such studies and surveys as are necessary to carry out the purposes of this subchapter, and the departments and agencies shall submit to the Council and to the requesting member the information, reports, studies, and surveys so required, . . . "

B. National Institute on Drug Abuse—continued

Legal citation	Type of authority	Legislative text
b) Drug Abuse Office and Treatment Act of 1972 • P.L. 92-255$405, (1972) and amended • 21 USC $1172	General	(b) "The Secretary shall submit to the President and the Congress with respect to each fiscal year on— (1) the health consequences and extent of drug abuse in the United States, (2) a description and evaluation of the effectiveness of the drug abuse prevention functions carried out through any entity of the Department of Health, Education, and Welfare in the fiscal year for which the report is made, (3) a description of the manner in which such functions were carried out, a description of the amount of funds expended in carrying out such functions, and a description and evaluation of the coordination within the Department of Health, Education, and Welfare in carrying out such functions, (4) a description and evaluation of the effectiveness of experimental methods and programs implemented in carrying out such functions, recommendations for implementation of such methods and programs by others in carrying out their drug abuse prevention functions, and a description and **evaluation** of the effectiveness of the means used to disseminate information respecting such methods and programs, and (5) proposals for changes in the drug abuse prevention functions carried out through the Department of Health, Education, and Welfare (including recommendations for legislation). The report required by this subsection shall be transmitted not later than January 15 of each year . . . "
c) Drug Abuse Office and Treatment Act of 1972 • P.L. 92-255$406 (1972) • 21 USC $1173	Specific	**(a) "The** Secretary shall– (1) operate an information center for the collection, preparation, and dissemination of all information relating to drug abuse prevention functions, including information concerning State and local drug abuse treatment plans, and the availability of treatment resources, training and educational programs, statistics, research, and other pertinent data and information; (2) investigate and publish information concerning uniform methodology and technology for determining the extent and kind of drug use by individuals and effects which individuals are likely to experience from such use; (3) gather and publish statistics pertaining to drug abuse and promulgate regulations specifying uniform statistics to be furnished, records to be maintained, and reports to be submitted, on a voluntary basis by public and private entities and individuals respecting drug abuse; . . .

B. National Institute on Drug Abuse—continued

Legal citation	Type of authority	Legislative text
		(b) After December 31, 1974, the Secretary shall carry out his functions under subsection (a) of this section through the National Institute on Drug Abuse. ”
d) Drug Abuse Office and Treatment Act of 1972 • P.L. 92-255 ~409 (1972), and amended • 21 USC ~1176	Specific	(e) “Any State desiring to receive a grant under subsection (b)(2) or (b)(3) of this section shall submit t. th$_e$ Secretary . . . a State plan for . . . the development of more effective drug abuse prevention functions in the State and for evaluating the conduct of such functions . . . Each State plan shall . . . (5)(A) set forth, in accordance with criteria established by the Secretary, a detailed survey of the local and State needs for prevention and treatment of drug abuse and drug dependence, including a survey of the health facilities needed to provide services for drug abuse and drug dependence, and a plan for the development and distribution of such facilities and programs throughout the State in accordance with such needs; (B) include in the the survey conducted pursuant to subparagraph (A) an identification of the need for prevention and treatment of drug abuse and drug dependence by women and by individuals under the age of eighteen and provide assurance that prevention and treatment programs within the State will be designed to meet such need;
	General	(9) provide that the State ~g~ncy will make such reports, in such form and containing such information as the Secretary may from time to time reasonably require, and will keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness and verification of such reports; . . . “
e) Drug Abuse Office and Treatment Act of 1972 • P.L, 92-255 $410 (1972) and amended • 21 USC $1177	Implied	**(a)** “The Secretary, acting through the National Institute on Drug Abuse, shall * * * (3) make grants . . . and enter into contracts with public and private agencies, organizations, institutions, and individuals to establish, conduct, and evaluate drug abuse prevention, treatment, and rehabilitation programs within State and local criminal justice systems; (4) make grants to or contracts with groups composed of individuals representing a broad cross-section of medical, scientific or social disciplines for the purpose of determining the causes of drug abuses in a particular area, prescribing methods for dealing with drug abuse in such an area, or con-

B. National Institute on Drug Abuse—continued

Legal citation	Type of authority	Legislative text
		ducting programs for dealing with drug abuse in such an area; . . . (5) make research grants . . . and enter into contracts with public and private agencies, organizations, and institutions, and individuals for improved drug maintenance techniques or programs, and (6) make grants . . . and enter into contracts with public and private agencies, organizations, institutions, and individuals to establish, conduct, and evaluate drug abuse prevention and treatment programs. . . . "
f) Drug Abuse Office and Treatment Act of 1972 • P.L. 92-255$501 (1972), and amended • 21 USC $1191	Implied	"There is established the National Institute on Drug Abuse . . . to administer the programs and authorities of the Secretary of Health, Education, and Welfare . . . with respect to drug abuse prevention functions. The Secretary, acting through the Institute, shall in carrying out the purposes of sections 301, 302, and 303 [42 USC ~$241, 242, 242a] of the Public Health Service Act with respect to drug abuse, develop and conduct comprehensive health, education, training, research, and planning programs for the prevention and treatment of drug abuse and for the rehabilitation of drug abusers. The Secretary shall carry out through the Institute the administrative and financial management, policy development and planning, evaluation, and public information functions which are required for the implementation of such programs and authorities. *
g) Drug Abuse Office and Treatment Act of 1972 • P.L. 92-255 ~502, as added by P.L. 94-237 $12(b)(l) (1976) • 21 USC $1192	Implied	**(a)** "The Director shall– * * * (2) provide for a central clearinghouse for Federal, State, and local governments, public and private agencies, and individuals seeking drug abuse information and assistance from the Federal Government. (b) In carrying out his functions under this section, the Director may— (1) provide technical assistance . . . to analyze and identify State and local drug abuse problems and assist in the development of plans and programs to meet the problems so identified; . . . "

'Section 301 of the **Public Health Service Act, 42, USC ~241, is the genera] data** collection authority for the Secretary of HEW.

B. National Institute on Drug Abuse—continued

Legal citation	Type of authority	Legislative text
h) Public Health Service Act • P.L. 78-410 S217(e) **as** added by P.L. 92-255 ~502(a) (1972) • 42 USC ~218	General	(e)(2) "The [National Advisory Council on Drug Abuse] . . . shall advise, consult with and make recommendations to the Secretary (A) concerning matters relating to the activities and functions of the Secretary in the field of drug abuse, including, but not limited to, the development of new programs and priorities, the efficient administration of programs, and the supplying of needed scientific and statistical data and program information to professionals, paraprofessionals, and the general public; . . . "
i) Public Health Service Act • P.L. 78-410$302 (1944), and amended • 42 USC **~242**	General	(a) "In carrying out the purposes of section 241 of . . . title [42] with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Act ."* [Jointly administered with the Bureau of Drugs (FDA), and the Drug Enforcement Administration.]
j) Marihuana *and* Health Reporting Act • P.L. 91-296, ~502 (1970), and amended • **42** USC **~242** note	Implied	"The Secretary of Health, Education, and Welfare, after consultation with the Surgeon General and other appropriate individuals, shall transmit a report to the Congress on or before January 31, 1971 and biennially thereafter (1) containing current information on the health consequences of using marihuana, and (2) containing such recommendations for legislative and administrative action , as he may deem appropriate. A preliminary report shall be transmitted to the Congress by the Secretary concerning current information on the health consequences of using

● Section 301 of the Public Health Service Act, *42* USC $241, is the general data collection authority for the Secretary of HEW.

B. Nationai institute on Drug Abuse—continued

Legal citation	Type of authority	Legislative text
		marihuana not later than ninety (90) days after the date of enactment of this title. ”
k) Public Health Service Act • P.L. 78-410 ~303, as added by P.L. 79-787 ~7(c) (1946) and amended • 42 USC ~242a	General	(a) “In carrying out the purposes of section 241 of . . . title [42] with respect to mental health, the Surgeon General is authorized— * * * (2) to make grants . . . for investigations, experiments, demonstration, studies, and research projects with respect to the development of improved methods of diagnosing mental illness [such as research on the use and effect of alcohol and other psychoactive drugs], and of care, treatment, and rehabilitation of the mentally ill . . . “* [Jointly administered with the National Institute of Mental Health, and the Food and Drug Administration, FDA authority extends to regulation of protection of research subjects and confidentiality.]

C. National Institute of Mental Health

a) Public Health Service Act • P.L. 78-410$217, (1944) and amended • 42 USC ~218	Implied	(c)(2) “The National Advisory Mental Health Council . . . is authorized . . . (2) to collect information as to studies being carried on in the field of mental health and, with the approval of the Surgeon General, make available such information through the appropriate publications for the benefit of health and welfare agencies or organizations (public and private), physicians, or any other scientists, and for the information of the general public . . . “
b) Public Health Service Act P.L. 78-410 ~303, as added by P.L. 79-487 $7(c) (1946) and amended • 42 USC ~242a	General	(a) “In carrying out the purposes of section 241 of . . . title [42] with respect to mental health, the Surgeon General is authorized— * * (2) to make grants . . for investigations, experiments, demonstrations, studies, and research projects with respect to the development of improved methods of diagnosing mental illness, (such as research on the use and effect of alcohol and other psychoactive drugs), and of care, treatment, and rehabilitation of the mentally ill . . . “* [Jointly administered with the National Institute on Drug Abuse, and the Food and Drug Administration; FDA authority extends to regulation of protection of research subjects and confidentiality.]

● Section 301 of the Public Health Service Act, *42* USC S241, is the general data collection authority for the Secretary of HEW.

C. National Institute of Mental Health—continued

Legal citation	Type of authority	Legislative text
c) Public Health Service Act • P.L. 78-410$314 (1944), as added by P.L. 95-622 ~109 (1978) • 42 USC §246	Specific	(g)(2) "NO grant may be made [to State mental health authorities to assist them in meeting the costs of providing mental health services] . . . unless an application . . . has been submitted . . . in such form and manner and shall contain such information as the Secretary may require, and shall contain or be supported by assurances satisfactory to the Secretary that— . . . **(C) the** State mental health authority will– (ii) from time to time, but not less often than annually, report to the Secretary (through a uniform national reporting system and by such categories as the Secretary may prescribe) a description of the mental health services provided in the State in the fiscal year for which the grant applied for is made . . . ; and (iii) make such reports (in such form and containing such information as the Secretary may prescribe) as the Secretary may reasonably require, and keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness of, and to verify, such reports, . . . "
d) Public Health Service Act • P.L. 78-410 ~455, as added by P.L. 93-282 §202 (1974) • 42 USC §289k-1	Implied	(a) "There is established the National Institute of Mental Health . . . to administer the programs and authorities of the Secretary with respect to mental health. The Secretary, acting through the Institute, shall . . . with respect to mental illness, develop and conduct comprehensive health, education, training, research, and planning programs for the prevention and treatment of mental illness and for the rehabilitation of the mentally ill. The Secretary shall carry out through the Institute the administrative and financial management, policy development and planning, evaluation, and public information functions which are required for the implementation of such programs and authorities. . . . "
e) Mental Retardation Facilities and Community Mental Health Centers Construction Act • P.L. 88-164 §201, as added by P.L. 94-635303 (1975), and amended • 42 USC §2689	Specific	(d) "A [community mental health] center shall have established, in accordance with regulations prescribed by the Secretary, . . . (2) an integrated medical records system (including a drug use profile) which, in accordance with applicable Federal and State laws respecting confidentiality, is designed to provide access to all past and current information regarding the health status of each patient and to maintain safeguards to preserve confidentiality and to protect the rights of the patient . . . "

C. National Institute of Mental Health—continued

Legal citation	Type of authority	Legislative text
f) Mental Retardation Facilities and Community Mental Health Centers Construction Act • P.L. 88-164 §206 as added by P.L. 94-63 §303 (1975), and amended • 42 USC §2689e	Specific	(c)(l) "An application for a [community mental health center] grant under this part shall be submitted in such form and manner as the Secretary shall prescribe and shall contain such information **as** the Secretary may require . . . An application for a grant under . . . this title shall contain . . . assurances . . . that (A) the community mental health center for which the application is submitted will provide . . . (ii) an effective procedure for developing, compiling, evaluating, and reporting to the Secretary statistics and other information (which the Secretary shall publish and disseminate on a periodic basis and which the center shall disclose at least annually to the general public) relating to (I) the cost of the center's operation, (II) the patterns of use of its services, (III) the availability, accessibility and acceptability of its services, (IV) the impact of its services upon the mental health of the residents of its catchment area, and, (V) such other matters as the Secretary may require; . . . "
g) Mental Retardation Facilities and Community Mental Health Centers Construction Act • P.L. 88-164$231 as added by P.L. 94-63$303 (1975), and amended • 42 USC §2689q	Specific	(a) "The Secretary shall establish within the National Institute of Mental Health . . . the National Center for the Prevention and Control of Rape (hereinafter in this section referred to as the "Center"). (b)(l) The Secretary, acting through the Center, may, directly or by grant, carry out the following: (A) A continuing study of rape, including a study and investigation of— (i) the effectiveness of existing Federal, State, and local laws dealing with rape; (ii) the relationship, if any, between traditional legal and social attitudes toward sexual roles, the act of rape, and the formulation of laws dealing with rape; (iii) the treatment of the victims of rape by law enforcement agencies, hospitals or other medical institutions, prosecutors, and the courts; (iv) the causes of rape, identifying to the degree possible— (1) social conditions which encourage sexual attacks, and (II) the motives of offenders; and (v) the impact of rape on the victim and the family of the victim;

C. National Institute of Mental Health—continued

Legal citation	Type of authority	Legislative text
		(vi) sexual assaults in correctional institutions; (vii) the actual incidence of forcible rape as compared to the reported incidence of forcible rape and the reasons for any difference in such incidence; and (viii) the effectiveness of existing private and local and State government educational, counseling, and other programs designed to prevent and control rape. (B) The compilation, analysis, and publication of summaries of the continuing study conducted under subparagraph (A) and the research and demonstration projects conducted under subparagraph (E). The Secretary shall annually submit to the Congress a summary of such study and projects together with recommendations where appropriate.
	Implied	(C) The development and maintenance of an information clearinghouse with regard to— (i) the prevention and control of rape; (ii) the treatment and counseling of the victims of rape and their families; and (iii) the rehabilitation of offenders. . . . “

III. CENTER FOR DISEASE CONTROL

Legal citation	Type of authority	Legislative text

A. Center for Disease Control—Generally

a) Public Health Service Act • P.L. 78-410$307 formerly 308, as added by P.L. 86-610 §3 (1960) renumbered and amended • 42 USC §242/	General	(a) "For the purpose of advancing the status of the health sciences in the United States (and thereby the health of the American people), the Secretary may participate with other countries in cooperative endeavors in biomedical research and the health services research and statistical activities authorized by sections 242b, 242c, and 242k of this title. "
b) Public Health Service Act • P.L. 78-410$314 as added by P.L. 94-63$102 (1975) and amended • 42 USC §246	Specific	(d)(l) . . . "The Secretary shall make grants to State health authorities . . . to assist in meeting the costs of providing comprehensive public health services. (2) No grant may be made under paragraph (1) to the State health authority of any State unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and shall contain such information as the Secretary may require, and shall contain or be supported by assurances satisfactory to the Secretary that— (A) the comprehensive public health services which will be provided within the State with funds under a grant under paragraph (1) will be provided in accordance with the State health plan in effect under section 1524(c); . . . (ii) from time to time as prescribed by the Secretary, report to the Secretary (through a uniform national reporting system and by such categories as the Secretary may prescribe) a description of the comprehensive public health services provided in the State in the fiscal year for which the grant applied for is made and the amount and source of funds expended in that fiscal year and in the preceding fiscal year for the provision of each such category of services; and (iii) make such other reports (in such form and containing such information as the Secretary may prescribe) as the Secretary may reasonably require, and keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness of, and to verify, such reports; . . .
	Implied	(4)(A) . . . In determining the amount of a grant to a State health authority under subclause (I), the Secretary shall

A. Center for Disease Control-WinUed

Legal citation	Type of authority	Legislative text
		take into account the financial need of such State and the level of State and local expenditures for comprehensive public health services [as defined in subparagraph (C)]. In determining the financial need of a State, the Secretary shall consider, as major factors, the proportion of the State's population whose income level is below the poverty income level established by the Secretary and the proportion of its population which is living in medical underserved areas. " [Jointly administered with the Bureau of Community Health Services (HSA).]
c) Public Health Service Act • P.L. 78-410 §317, as added by P.L. 87-868 ~2 (1962), and amended c 42 USC §247b	General	(a) "The Secretary may make grants— (1) to State health authorities to assist them in meeting the costs of establishing and maintaining preventive health service programs for screening for, the detection, diagnosis, prevention, and referral for treatment of, and follow-up on compliance with treatment prescribed for hypertension; and (2) to States and, . . . to political subdivisions of States and to other public entities to assist them in meeting the costs of establishing and maintaining preventive health service programs (other than programs described in paragraph (1)). (b) No grant may be made under section (a) unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be in such form and be submitted in such manner as the Secretary shall by regulation prescribe and shall provide— (1) a complete description of the type and extent of the program for which the applicant is seeking a grant under subsection (a); (2) with respect to each such program, . . . (B) a description of the services provided by the applicant in such program in such period . . . and, (D) if the applicant proposes changes in the provision of the services in such program, the priorities of such proposed changes, reasons for such changes, and the amount of Federal funds needed by the applicant to make such changes; . , . (s) assurances satisfactory to the Secretary that the applicant will provide for periodic evaluation of its program or programs; (6) assurances satisfactory to the Secretary that the applicant will make such reports (in such form and containing such information as the Secretary may by regulation prescribe) as the Secretary may reasonably require and keep such records and afford such access thereto as the Secretary may find

A. Center for Disease Control—Generally—continued

Legal citation	Type of authority	Legislative text
		necessary to assure the correctness of, and to verify, such reports; . . . (h) The Secretary shall include, as part of the report required by section 1705 [42 USC $300u-4] a report on the extent of the problems presented by the diseases and conditions referred to in subsection (j) [concerning preventive health service programs to immunize children against immunizable diseases, and influenza], . . . and on the effectiveness of the activities assisted under grants under subsection (a) in controlling such diseases and conditions. [Center for Disease Control administers all but the authority concerning hypertension; the Bureau of Community Health Services (HSA), administers the hypertension program.]
d) Public Health Service Act s P.L. 78-410$318, as added by P.L. 92-499 ~203 (1972), and amended • 42 USC §247c	Specific	(b) "The Secretary is authorized to make grants . . . for the conduct of research . . . [and] public information . . . for the prevention and control of venereal disease. (c) The Secretary is also authorized to make project grants . . . for— (1) venereal disease surveillance activities, including the reporting, screening, and followup of diagnostic tests for, and diagnosed cases of, venereal disease; (2) casefinding and case followup activities respecting venereal disease, including contact tracing of infectious cases of venereal disease and routine testing, including laboratory tests and followup systems; (3) interstate epidemiologic referral and followup activities respecting venereal disease; (4) professional (incIuding appropriate allied health personnel) venereal disease education training and clinical skills improvement activities; and (5) such special studies or demonstrations to evaluate or test venereal disease prevention and control strategies and activities as may be prescribed by the Secretary. "
e) Public Health Service Act • P.L. 78-410$353, as added by P.L. 90-174 $5(a) (1967) • 42 USC §263a	General	(d)(l) "A license shall not be issued in the case of any clinical laboratory unless (A) the application therefor contains or is accompanied by such information as the Secretary finds necessary, and (B) the applicant agrees and the Secretary determines that such laboratory will be operated in accordance with standards found necessary by the Secretary to carry out the purposes of this section. Such standards shall be designed to assure consistent performance by the laboratories of accurate laboratory procedures and services, and shall include among others, standards to assure—

A. Center for Disease Control—Generally—conthwed

Legal citation	Type of authority	Legislative text
		(i) maintenance of a quality control program adequate and appropriate for accuracy of the laboratory procedures and services; (ii) maintenance of records, equipment, and facilities necessary to proper and effective operation of the laboratory; (iii) qualifications of the director of the laboratory and other supervisory professional personnel necessary for adequate and effective professional supervision of the operation of the laboratory (which shall include criteria relating to the extent to which training and experience shall be substituted for education); and (iv) participation in a proficiency testing program established by the Secretary. " [Jointly administered with the Health Standards and Quality Bureau (HCFA).]
f) Public Health Service Act • P.L. 78-410$365 (1944), and amended • 42 USC **§268**	General	(a) "Any consular or medical officer of the United States, designated for such purpose by the Secretary, shall make reports to the Surgeon General, on such forms and at such intervals as the Surgeon General may prescribe, of the health conditions at the port or place at which such officer is stationed. "
g) Public Health Service Act • P.L. 78-410$1107, as added by P.L. 95-626, §205 (1978) • 42 USC $300 b-6	Specific	"The Secretary, acting through an identifiable administrative unit, shall— (1) conduct epidemiological assessments and surveillance of genetic diseases to define the scope and extent of such diseases and the need for programs for the diagnosis, treatment, and control of such diseases, screening for such diseases, and the counseling of persons with such diseases; (2) on the basis of the assessments and surveillance described in paragraph (1), develop for use by the States programs which combine in an effective manner diagnosis, treatment, and control of such diseases, screening for such diseases, and counseling of persons with such diseases; . . . " [Jointly administered with the Bureau of Community Health Services (HSA).]

A. Center for Disease Control—General/y— continued

Legal citation	Type of authority	Legislative text
h) Public Health Service Act • P.L. 78-410 §1701, as added by P.L. 94-317 §lo2 (1976), and amended • 42 USC §300u	General	(a) "The Secretary shall– (4) undertake and support research and demonstrations respecting health information and health promotion, preventive health services, and education in the appropriate use of health care. (7) foster the exchange of information respecting, and foster cooperation in the conduct of, research, demonstration, and training programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care. * * *
	Implied	(c) It shall be the duty of the State Council on Physical Fitness to— (2) assess the physical fitness and nutrition status of residents of the State; (3) plan and administer a program of grants-in-aid to support physical fitness projects, research projects, and publIc information efforts to promote the development of physical fitness for the residents of the State; (4) evaluate and improve the availability and quality of sport medicine and athletic trainer programs in the State. " [Jointly administered with the Office of the Disease Prevention and Health Promotion (OASH).]
i) Public Health Service Act • P.L. 78-410 §1702, as added by P.L. 94-317$102 (1976)	General	(a) "The Secretary is authorized to conduct and support by grant or contract . . . research in health information and health promotion, preventive health services, and education in the appropriate use of health care. . . . The Secretary shall also— * * *
• 42 USC $300u-1	Implied	(2) determine the best methods of disseminating information concerning personal health behavior, preventive health services and the appropriate use of health care and of affecting behavior so that such information is applied to maintain and improve health, and prevent disease, reduce its risk, or modify its course or severity,
	General	(4) develop (A) methods by which the cost and effectiveness of activities respecting health information and health promotion, preventive health services, and education in the appropriate use of health care, can be measured, including methods for

A. Center for Disease Control—Generally—continued

Legal citation	Type of authority	Legislative text
		evaluating the effectiveness of various settings for such activities, and the various types of persons engaged in such activities, (B) methods for reimbursement or payment for such activities, and (C) models and standards for the conduct of such activities . . . (5) develop a method for assessing the cost and effectiveness of specific medical services and procedures under various conditions of use, including the assessment of the sensitivity and specificity of screening and diagnostic procedures; and (6) enumerate and assess, using methods developed under paragraph (5), preventive health measures and services with respect to their cost and effectiveness under various conditions of use.
	Specific	b) The Secretary shall make a periodic survey of the needs, interest, attitudes, knowledge, and behavior of the American public regarding health and health care. The Secretary shall take into consideration the findings of such surveys and the findings of similar surveys conducted by national and community health education organizations, and other organizations and agencies for formulating policy respecting health information and health promotion, preventive health services, and education in the appropriate use of health care. " [Jointly administered with the Office of Disease Prevention and Health Promotion (OASH).]
j) Public Health Service Act • P.L. 78-410$1704 as added by P.L. 94-317$102 (1976) • 42 USC §300u-3	Implied	"The Secretary is authorized to conduct and support . . . such activities as may be required to make information respecting health information and health promotion, preventive health services, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters. Such activities may include at least the following: (1) The publication of information, pamphlets, and other reports which are specially suited to interest and instruct the health consumer, which information, pamphlets and other reports shall . . . pertain to the individual's ability to improve and safeguard his own health; shall include material, accompanied by suitable illustrations, on child care, family life and human development, disease prevention . . . physical fitness, dental health, environmental health, nutrition, safety and accident prevention, drug abuse and alcoholism, mental health,

A. Center for Disease Control- Generally —continued

Legal citation	Type of authority	Legislative text
		management of chronic diseases . . . and venereal diseases; . . .
	General	(6) Assess, with respect to the effectiveness, safety, cost, and required training for and conditions of use, of new aspects of health care, and new activities, programs, and services designed to improve human health and publish in readily understandable language . . . such assessments . . . “ [Jointly administered with the Office of Disease Prevention and Health Promotion (OASH).]
k) Public Health Service Act • P.L. 78-410$1705, as added by P.L. 94-317 §102 (1976) • 42 USC §300u-4	Implied	(a) “The Secretary shall, not later than two years after June 23, 1976, and annually thereafter, submit to the President for transmittal to Congress a report on the status of health information and health promotion, preventive health services, and education in the appropriate use of health care. Each such report shall include— (1) a statement of the activities carried out under this subchapter since the last report and the extent to which such activity achieves the purposes of this subchapter; (2) an assessment of the manpower resources needed to carry out programs relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, and a statement describing the activities currently being carried out under this subchapter designed to prepare teachers and other manpower for such programs; (3) the goals and strategy formulated pursuant to section 300u(a)(l) of title 42. . . the models and standards developed under this subchapter, and the results of the study required by subsection (b) of this section; and (4) such recommendations as the Secretary considers appropriate for legislation respecting health information and health promotion, preventive health services, and education in the appropriate use of health care . . .
	Specific	(b) “The Secretary shall conduct a study of health education services and preventive health services to determine the coverage of such services under public and private health insurance programs, including the extent and nature of such coverage and the cost sharing requirements required by such programs for coverage of such services. ” [Jointly administered with the Office of Disease Prevention and Health Promotion (OASH).]

A. *Center for* **Disease Control—GenerallY—continued**

Legal citation	Type of authority	Legislative text
1) Lead-Based Paint Poisoning Prevention Act • P.L. 91-695 §301 (1971), and amended . 42 USC $4821	General	(a) "The Secretary of Housing and Urban Development, in consultation with the Secretary of Health, Education, and Welfare, shall develop and carry out a demonstration and research program to determine the nature and extent of the problem of lead based paint poisoning in the United States, particularly in urban areas, including the methods by which the lead based paint hazard can most effectively be removed from interior surfaces, porches, and exterior surfaces of residential housing to which children maybe exposed." [Jointly administered with the Department of Housing and Urban Development.]

B. National Institute for Occupational Safety and Health

a) Occupational Safety and Health Act • P.L. 91-596$8 (1970) • 29 USC ~657	Specific	(c)(l) "Each employer shall make, keep and preserve, and make available to the Secretary of Health, Education, and Welfare, such records regarding his activities relating to this chapter as the Secretary [of Labor], in cooperation with the Secretary of Health, Education, and Welfare, may prescribe by regulation as necessary or appropriate for the enforcement of this chapter or for developing information regarding the causes and prevention of occupational accidents and illnesses. . . . (2) The Secretary [of Labor], in cooperation with the Secretary of Health, Education, and Welfare, shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job. (3) The Secretary [of Labor], in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 655 of . . . title [29]. Such regulations shall provide employees or their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof. Such regulations shall also make appropriate provision for each employee or former employee to have access to such records as will indicate his

B. National Institute for Occupational Safety and Health—continued

Legal citation	Type of authority	Legislative text
		own exposure to toxic materials or harmful physical agents. . . . (d) Any information obtained by . . . the Secretary of Health, Education, and Welfare, or a State agency under this chapter shall be obtained with a minimum burden upon employers, especially those operating small businesses. Unnecessary duplication of efforts in obtaining information shall be reduced to the maximum extent feasible. . . . (g)(l) The Secretary [of Labor] and Secretary of Health, Education, and Welfare are authorized to compile, analyze, and publish, either in summary or detailed form, all reports or information obtained under this section. " [Jointly administered with the Secretary of Labor.]
b) Occupational Safety and Health Act • P.L. 91-596$20 (1970) • 29 USC $669	General	(a)(l) "The Secretary of Health, Education, and Welfare, after consultation with the Secretary [of Labor] and with other appropriate Federal departments or agencies, shall conduct . . . research, experiments, and demonstrations relating to occupational safety and health, including studies of psychological factors involved, and relating to innovative methods, techniques, and approaches for dealing with occupa~tional safety and health problems. (2) The Secretary of Health, Education, and Welfare shall from time to time consult with the Secretary [of Labor] in order to develop specific plans for such research, demonstrations, and experiments as are necessary to produce criteria, including criteria identifying toxic substances, enabling the Secretary [of Labor] to meet his responsibility for the formulation of safety and health standards under this chapter; and the Secretary of Health, Education, and Welfare, on the basis of such research, demonstrations, and experiments and any other information available to him, shall develop and publish at least annually such criteria as will effectuate the purposes of this chapter. (3) The Secretary of Health, Education, and Welfare, on the basis of such research, demonstrations, and experiments, and any other information available to him, shall develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience. (4) The Secretary of Health, Education, and Welfare shall also conduct special research, experiments, and demonstra-

B. National Institute for Occupational Safety and health—continued

Legal citation	Type of authority	Legislative text
		tions relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health, which may require ameliorative action beyond that which is otherwise provided for in the operating provisions of this chapter. The Secretary of Health, Education, and Welfare shall also conduct research into the motivational and behavioral factors relating to the field of occupational safety and health.
	Specific	(5) The Secretary of Health, Education, and Welfare, in order to comply with his responsibilities under paragraph (2), and in order to develop needed information regarding potentially toxic substances or harmful physical agents, may prescribe regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents which the Secretary of Health, Education, and Welfare reasonably believes may endanger the health or safety of employees. The Secretary of Health, Education, and Welfare also is authorized to establish such programs of medical examinations and tests as may be necessary for determining the incidence of occupational illnesses and the susceptibility of employees to such illnesses. . . . (7) Within two years of December 29, 1970, and annually thereafter the Secretary of Health, Education, and Welfare shall conduct and publish industrywide studies of the effect of chronic or low-level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in aging adults. . . . (d) Information obtained by the Secretary [of Labor] and the Secretary of Health, Education, and Welfare under this section shall be disseminated by the Secretary to employers and employees and organizations thereof. (e) The functions of the Secretary of Health, Education, and Welfare under this chapter shall, to the extent feasible, be delegated to the Director of the National Institute for Occupational Safety and Health established by section 671 of this title." [Jointly administered with the Secretary of Labor.]

B. Nationa/ Institute for Occupational Safety and Health—continued

Legal citation	Type of authority	Legislative text
c) Occupational Safety and Health Act • P.L. 91-596 §21 (1970) • 29 USC $671	General	(b) "There is hereby established in the Department of Health, Education, and Welfare a National Institute for Occupational Safety and Health. The Institute shall be headed by a Director who shall be appointed by the Secretary of Health, Education, and Welfare, . . . (c) The Institute is authorized to– (1) develop and establish recommended occupational safety and health standards; and (2) perform all functions of the Secretary of Health, Education, and Welfare under sections 669 and 670 of . . . title [29]. (d) Upon his ***own*** initiative, or upon the request of the Secretary [of Labor] or the Secretary of Health, Education, and Welfare, the Director is authorized (1) to conduct such research and experimental programs as he determines are necessary for the development of criteria for new and improved occupational safety and health standards . . . "
d) Occupational Safety and Health Act • P.L. 91-596$24 (1970) • 29 USC ~673	Specific	(a) "In order to further the purposes of this chapter, the Secretary [of Labor], in consultation with the Secretary of Health, Education, and Welfare, shall develop and maintain an effective program of collection, compilation, and analysis of occupational safety and health statistics. Such program may cover all employments whether or not subject to any other provisions of this chapter but shall not cover employments excluded by section 653 of this title. The Secretary [of Labor] shall compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job . . . " [NOTE: The Secretary of Labor, not the Secretary of Health, Education, and Welfare, has primary authority for administration of this section.]
e) Occupational Safety and Health Act • P.L. 91-596$26 (1970) • 29 USC $675	Implied	"Within one hundred and twenty days following the convening of each regular session of each Congress, the Secretary [of Labor] and the Secretary of Health, Education, and Welfare shall each prepare and submit to the President for transmittal to the Congress a report upon the subject matter of this chapter, the progress toward achievement of the purpose of this chapter, the needs and requirements in the field of occupational safety and health, and any other relevant information. Such reports shall include information regarding occupa-

B. National Institute for Occupational Safety and Health—continued

Legal citation	Type of authority	Legislative text
		tional safety and health standards, and criteria for such standards, developed during the preceding year; evaluation of standards and criteria previously developed under this chapter, defining areas of emphasis for new criteria and standards; an evaluation of the degree of observance of applicable occupational safety and health standards, and a summary of inspection and enforcement activity undertaken; analysis and evaluation of research activities for which results have been obtained under governmental and nongovernmental sponsorship; an analysis of major occupational diseases, evaluation of available control and measurement technology for hazards for which standards or criteria have been developed during the preceding year; description of cooperative efforts undertaken between Government agencies and other interested parties in the implementation of this chapter during the preceding year; a progress report on the development of an adequate supply of trained manpower in the field of occupational safety and health, including estimates of future needs and the efforts being made by Government and others to meet those needs; listing of all toxic substances in industrial usage for which labeling requirements, criteria, or standards have not yet been established; and such recommendations for additional legislation as are deemed necessary to protect the safety and health of the worker and improve the administration of this chapter." [Jointly administered with the Secretary of Labor.]
f) Federal Coal Mine Health and Safety Act • P.L. 91-173$101 (1969), and amended • 30 USC §811	Implied	**(a)** "The Secretary [of Labor] shall by rule . . . develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal or other mines. (1) Whenever the Secretary, [of Labor], upon the basis of information submitted to him in writing by . . . the Secretary of Health, Education, and Welfare, the National Institute for Occupational Safety and Health . . . determines that a rule should be promulgated in order to serve the objectives of this Act, the Secretary [of Labor] may request the recommendation of an advisory committee. . . . The Secretary [of Labor] shall provide such an advisory committee with . . . all pertinent factual information developed by the Secretary [of Labor] or the Secretary of Health, Education, and Welfare, or otherwise available, including the results of research, demonstrations, and experiments. . . . (6)(A) The Secretary [of Labor], in promulgating mandatory standards dealing with toxic materials or harmful

B. National Institute for Occupational Safety and *Health—continued*

Legal citation	Type of authority	Legislative text
		physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life. Development of mandatory standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws . . . (B) The Secretary of Health, Education, and Welfare, as soon as possible after the date of enactment of the Federal Mine Safety and Health Amendments Act of 1977 but in no event later than 18 months after such date and on a continuing basis thereafter, shall, for each toxic material or harmful physical agent which is used or found in a mine, determine whether such material or agent is potentially toxic at the concentrations in which it is used or found in a mine. The Secretary of Health, Education, and Welfare shall submit such determinations with respect to such toxic substances or harmful physical agents to the Secretary [of Labor]. Thereafter, the Secretary of Health, Education, and Welfare shall submit to the Secretary [of Labor] all pertinent criteria regarding and such substances determined to be toxic or any such harmful agents as such criteria are developed. . . . (7) . . . Where appropriate, such mandatory standard [promulgated under this subsection]. . . . shall provide for monitoring or measuring miner exposure at such locations and intervals, and in such manner so as to assure the maximum protection of miners. In addition, where appropriate, any such mandatory standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the operator at his cost, to miners exposed to such hazards in order to most effectively determine whether the health of such miners is adversely affected by such exposure. . . . In the event such medical examinations are in the nature of research, as determined by the Secretary of Health, Education, and Welfare, such examinations may be furnished at the expense of the Secretary of Health, Education, and Welfare. The results of examinations or tests made pursuant to the preceding sentence shall be furnished only to the Secretary [of Labor] or the Secretary of Health, Education,

6. National Institute for Occupational Safety and Health—continued

Legal citation	Type of authority	Legislative text
		and Welfare, and, at the request of the miner, to his designated physican." [Jointly administered with the Secretary of Labor.]
g) Federal Coal Mine Health and Safety Act • P.L. 91-173 §~103 (1969), and amended • 30 USC $813	Specific	(a) "Authorized representatives of the Secretary [of Labor] or the Secretary of Health, Education, and Welfare shall make frequent inspections and investigations in coal or other mines each year for the purpose of (1) obtaining, utilizing, and disseminating information relating to health and safety conditions, the causes of accidents, and the causes of diseases and physical impairments originating in such mines, (2) gathering information with respect to mandatory health or safety standards, (3) determining whether an imminent danger exists, and (4) determining whether there is compliance with the mandatory health or safety standards . . . (c) The Secretary [of Labor], in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under this Act. . . . (e) Any information obtained by the Secretary [of Labor] or by the Secretary of Health, Education, and Welfare under this Act shall be obtained in such a manner as not to impose an unreasonable burden upon operators, especially those operating small businesses, consistent with the underlying purposes of this Act. Unnecessary duplication of effort in obtaining information shall be reduced to the maximum extent feasible. . . .
	General	(h) In addition to such records as are specifically required by this Act, every operator of a coal or other mine shall establish and maintain such records, make such reports, and provide such information, as the Secretary [of Labor] or the Secretary of Health, Education, and Welfare may reasonably require from time to time to enable him to perform his functions under this Act. The Secretary [of Labor] or the Secretary of Health, Education, and Welfare is authorized to compile, analyze, and publish, either in summary or detailed form, such reports or information so obtained. Except to the extent otherwise specifically provided by this Act, all records, information, reports, findings, citations, notices, orders, or decisions required or issued pursuant to or under this Act may be published from time to time, maybe released to any interested person, and shall be made available for public inspection. " [Jointly administered with the Secretary of Labor.]

B. National Institute for Occupation/ Safety and Health—continued

Legal citation	Type of authority	Legislative text
h) Federal Coal Mine Health and Safety Act • P.L. 91-173$203 (1969) • **30** USC §843	Specific	(a) "The operator of a coal mine shall cooperate with the Secretary of Health, Education, and Welfare in making available to each miner working in a coal mine the opportunity to have a chest roentgenogram. . . . Each worker who begins work in a coal mine for the first time shall be given, as soon as possible after commencement of his employment, and again three years later if he is still engaged in coal mining, a chest roentgenogram; . . . All chest roentgenograms shall be given in accordance with specifications prescribed by the Secretary of Health, Education, and Welfare and shall be supplemented by such other tests as the Secretary of Health, Education, and Welfare deems necessary. The films shall be read and classified in a manner to be prescribed by the Secretary of Health, Education, and Welfare, and the results of each reading on each such person and of such test shall be submitted to the Secretary [of Labor] and to the Secretary of Health, Education, and Welfare, and, at the request of the miner, to his physician. The Secretary [of Labor] shall also submit such results to such miner and advise him of his rights under this chapter related thereto. Such specifications, readings, classifications, and tests shall, to the greatest degree possible, be uniform for all coal mines and miners in such mines." [Jointly administered with the Secretary of Labor. I
i) Federal Coal Mine Health and Safety Act • P.L. 91-173$426 (1969) and amended • 30 USC $936	Implied	(b) "Within 120 days following the convening of each session of Congress the Secretary of Health, Education, and Welfare shall submit to the Congress an annual report upon the subject matter of part B of this subchapter . . . "
j) Federal Coal Mine Health and Safety Act • P.L. 91-173$501 (1969) and amended • 30 Usc ~951	Specific	(a) "The Secretary [of the Interior] and the Secretary of Health, Education, and Welfare, as appropriate, shalI conduct such studies, research, experiments, and demonstrations as may be appropriate— . . . (5) to develop epidemiological information to (A) identify and define positive factors involved in occupational diseases of miners, (B) provide information on the incidence and prevalence of pneumoconiosis and other respiratory ailments of miners, and (C) improve mandatory health standards; . . . (7) to evaluate the effect on bodily impairment and occupational disability of miners afflicted with an occupational disease;

B. **National Institute for Occupational** *Safety and Health—continued*

Legal citation	Type of authority	Legislative text
		(8) to prepare and publish from time to time, reports on all significant aspects of occupational diseases of miners as well as on the medical aspects of injuries, other than diseases which are revealed by the research carried on pursuant to this subsection; (9) to study the relationship between coal or other mine environments and occupational diseases of miners, and . . . (11) for such other purposes as they deem necessary to carry out the purposes of this chapter. (b) Activities under this section in the field of coal or other mine health shall be carried out by the Secretary of Health, Education, and Welfare, through the National Institute for Occupational Safety and Health. . . . (d) The Secretary of Health, Education, and Welfare shall also conduct studies and research into matters involving the protection of life and the prevention of diseases in connection with persons, who although not miners, work with, or around the products of, coal or other mines in areas outside of such mines and under conditions which may adversely affect the health and well-being of such persons." [Jointly administered with the Secretary of Interior.]
k) Federal Coal Mine Health and Safety Act • P.L. 91-173$511 (1969), and amended • 30 USC $958	Implied	(b) "Within one hundred and twenty days following the convening of each session of Congress, the Secretary of Health, Education, and Welfare shall submit through the President to the Congress and to the Office of Science and Technology an annual report upon the health matters covered by this chapter, . . . the needs and requirements in the field of coal or other mine health, a description and the anticipated cost of each project and program he has undertaken under sections 861(b) and 951 of . . . title [30], and any other relevant information, including any recommendations he deems appropriate. The first such report shall include the recommendations of the Secretary of Health, Education, and Welfare as to necessary mandatory health standards, including his recommendations as to the maximum permissible individual exposure to miners from respirable dust during a shift ."

IV. FOOD AND DRUG ADMINISTRATION

Legal citation	Type of authority	Legislative text
A. General Authority Applicable to all FDA Bureaus		
a) Federal Food, Drug and Cosmetic Act • P.L. 75-517$705 (1938) as amended • 21 Usc $375	Implied	(b) "The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department. "
B. Bureau of Biologics		
a) Public Health Service Act • P.L. 78-410$351 (1944) • 42 USC $262	Implied	(d) "Licenses for the maintenance of establishments for the propagation ***or*** manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards . . ."
C. Bureau of Drugs		
a) Federal Food, Drug and Cosmetic Act • P.L. 75-717$505 (1938) and amended • 21 Usc $355	Specific	(b) "Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.
	General	(i) The Secretary shall 'promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regula-

C. Bureau of Drugs—continued

Legal citation	Type of authority	Legislative text
		tions may, within the discretion of the Secretary . . . provide for conditioning such exemption upon— (1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing; (2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigators or to clinics, for administration to human beings; and (3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section. (j)(l) In the case of my Lr~g*fm which **an** approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may . . . prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine . . . whether there is or may be grounds for invoking subsection (e) of this section . . .“
b) Federal Food, Drug and Cosmetic Act ● P.L. 75-717$507, as added by Act of July 6,1945,$3, and amended ● 21 Usc ~357	General	(d) “The Secretary shall promulgate regulations exempting from any requirement of this section and of section 352(]) of this title, (1) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured . . .; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by

C. Bureau of Drugs—continued

Legal citation	Type of authority	Legislative text
		scientific training and experience to investigate the safety and efficacy of drugs. Such regulations may, within the discretion of the Secretary . . . provide for conditioning the exemption under clause (3) of this subsection upon— (1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing; * * * (3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application for certification or release pursuant to subsection (a) of this section. * * * (g)(l) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect ***to*** such drug, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be, amended or repealed . . .“
c) Public Health Service Act • P.L. 78-410$302, (1944) • 42 USC $242	General	(a) “In carrying out the purposes of section 241 of . . . title [42] with respect to drugs, the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives and preparation, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to

C. Bureau of Drugs—continued

Legal citation	Type of authority	Legislative text
		supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts". * [Jointly administered with the National Institute on Drug Abuse (ADAMHA), and the Drug Enforcement Administration.]
d) Public Health Service Act ● P.L. 78-910$303, as added by P.L. 79-487 §7(c) (1946) and amended ● 42 USC §242a	General	(a) "In carrying out the purposes of section 241 of . . . title [42] with respect to mental health, the Surgeon General is authorized—. . . (2) to make grants . . . for investigations, experiments, demonstrations, studies, and research projects with respect to the development of improved methods of diagnosing mental illness (such as research on the use and effect of alcohol and other psychoactive drugs), and of care, treatment, and rehabilitation of the mentally ill. . . ."* [Jointly administered with the National Institute on Drug Abuse, and the National Institute of Mental Health, (ADAMHA); FDA authority extends to regulations of protection of research subjects and confidentiality.]

D. Bureau of Foods

a) Federal Food, Drug and Cosmetic Act ● P.L. 75-717 §408 **as** added by Act of July 22,1954,$3 (1954) and amended ● 21 USC §346a	Specific	(d)(l) "Any person who has registered, or who has submitted an application for the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Administrator, a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of, such pesticide, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

'Section **301** of the Public Health Service Act, **42 USC $241,** is the general data collection authority for the Secretary of HEW.

D. Bureau of Foods—continued

Legal citation	Type of authority	Legislative text
		(A) the name, chemical identity, and composition of the pesticide chemical; (B) the amount, frequency, and time of application of the pesticide chemical; (C) full reports of investigation made with respect to the safety of the pesticide chemical; (D) the results of tests on the amount of residue remaining, including a description of the analytical methods used; (E) practicable methods for removing residue which exceeds any proposed tolerance; (F) proposed tolerances for the pesticide chemical if tolerances are proposed; and (G) reasonable grounds in support of the petition. Samples of the pesticide chemical shall be furnished to the Administrator upon request. . . . Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed, " [This authority was transferred to the Environmental Protection Agency (EPA) under Reorganization Plan No. 3, 1970. FDA enforces tolerances established by EPA through FDA's food inspection program.]
b) Federal Food, Drug and Cosmetic Act w P.L. 75-717$409, as added by P.L. 85-929 §4 (1958), and amended ● 21 USC §348	Specific	(b)(l) "Any person may, with respect to any intended use of a food additive, file with the Secretary **a** petition proposing the issuance of a regulation prescribing the conditions under which such additive **may** be **safely** used. (2) Such petition shall, in addition to any explanatory or supporting data, contain— (A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition; (B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling; (C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect; (D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and (E) full reports of investigations made with respect to the safety for use of such additive, including full information

0. Bureau of Foods—continued

Legal citation	Type of authority	Legislative text
		as to the methods and controls used in conducting such investigations. ”
c) Federal Food, Drug and Cosmetic Act ● P.L. 75-717 ~706, (1938), and amended ● 21 USC §376	Implied	(b)(S)(A) “In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors— (i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive; (ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet; (iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and (iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (11) such additive in or on any article of food, drug or device, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive . . .“

E. Bureau of Medical Devices

a) Federal Food, Drug and Cosmetic Act ● P.L. 75-717$513 as added by P.L. 94-295 §2 (1976) ● 21 USC §360c	Implied	(a)(3)(A) “Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 360d and 360e of this title, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.”

E. Bureau of Medical Devices—continued

Legal citation	Type of authority	Legislative text
b) Federal Food, Drug and Cosmetic Act ● P.L. 75-717 §519, as added by P.L. 94-295 §2 (1976) 21 USC §360i	General	(a) "Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed— . . . (3) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;"
c) Federal Food, Drug and Cosmetic Act ● P.L. 75-717$520, as added by P.L. 94-295$2 (1976) ● 21 USC §360j	General	(g)(2)(A) "The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 360e, 360f, 360i or 376 of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety 'and effectiveness of such devices. (B) The conditions prescribed pursuant to subparagraph (A) shall include the following: (i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify. (ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device. (iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety. . . ."
	Implied	(h)(z) "The Secretary shall promulgate regulations under which each advisory committee established under section 360e (g)(2)(B) of this title shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recom-

E. Bureau of Medical Devices—continued

Legal citation	Type of authority	Legislative text
		mendation to the Secretary made pursuant to Section 360e(g)(2)(A) of this title. A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order. (3) Any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this chapter by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section. . . .“

F. Bureau of Radiological Health

a) Public Health Service Act ● P.L. 78-410 ¦354, as added by P.L. 90-602 §2(3) (1968) ● 42 USC §263b	Implied	“The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation. Thus, it is the purpose of this subpart to provide for the establishment by the Secretary of an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation from electronic products and the undertaking by public and private organizations of research and investigation into the effects and control of such radiation emissions. ”
b) Public Health Service Act ● P.L. 78-410 §356, as added by P.L. 90-602 §2(3) (1968) ● 42 USC §263d	General	(a) “The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of such program, he shall—. . . (2) plan, conduct, coordinate, and support research . . . to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation; . . . (4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields; . . . (b) In carrying out the purposes of subsection (a) of this section, the Secretary is authorized to— (1)(A) collect and make available, through publications and other appropriate means, the results of, and other in-

F. Bureau of Radiological Health—continued

Legal citation	Type of authority	Legislative text
		formation concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation . . . (c)(l) each recipient of assistance under this subpart . . . shall keep such records as the Secretary shall prescribe . . ."
c) Public Health Service Act ● P.L. 78-410$357 as added by P.L. 90-602 §2(3), (1968) ● 42 USC §263e	Specific	(a) "The Secretary shall conduct the foIlowing studies, and shall make a report or reports of the results of such studies to Congress on or before January 1, 1970, and from time to time thereafter as he may find necessary, together with such recommendations for legislation as he may deem appropriate: (1) A study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include, but not be limited to— (A) control of health hazards from radioactive materials other than material regulated under the Atomic Energy Act of 1954; (B) any gaps and inconsistencies in present controls; **(C) the** need for controlling the sale of certain used electronic products, particularly antiquated X-ray equipment, without upgrading such products to meet the standards for new products or separate standards for used products; (D) measures to assure consistent and effective control of the aforementioned health hazards; (E) measures to strengthen radiological health programs of State governments; and (F) the feasibility of authorizing the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation; (2) A study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes; and (3) A study of the development of practicable procedures for the detection and measurement of electronic product radiation which may be emitted from the electronic products manufactured or imported prior to the effective date of any applicable standards established pursuant to this subpart. . . . (c) The Secretary or his designee shall organize the studies and the participation of the invited participants as he deems best. Any dissent from the findings and recommendations of

F. Bureau of Radiological Health—continued

Legal citation	Type of authority	Legislative text
		the Secretary shall be included in the report if so requested by the dissenter. "
d) Public Health Service Act • P.L. 78-410 §360A, as added by P.L. 90-602 §2(3) (1968) • 42 USC §263i	General	(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to this subpart. (c) Every manufacturer of electronic products shall provide to the Secretary such performance data and other technical data related to safety as may be required to carry out the purposes of this subpart. The Secretary is authorized to require the manufacturer to give such notification of such performance and technical data at the time of original purchase to the ultimate purchaser of the electronic product, as he determines necessary to carry out the purposes of this subpart after consulting with the affected industry. . . . (f) The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 263g of this title, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. . . . If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. . . . "
e) Public Health Service Act • P.L. 78-410 §60D, as added by P.L. 90-602 62(3) (1968) • 42 USC §2631	Specific	(a) "The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this subpart for the preceding calendar year. Such report shall include— (1) a thorough appraisal (including statistical analyses, estimates, and long-term projections) of the incidence of biological injury, and effects, including genetic effects, to the population resulting from exposure to electronic product

F. Bureau of Radiological Health—continued

Legal citation	Type of authority	Legislative text

radiation, with a breakdown, insofar as practicable, among the various sources of such radiation;

(2) a list of Federal electronic product radiation control standards prescribed or in effect in such year, with identification of standards newly prescribed during such year;

(3) an evaluation of the degree of observance of applicable standards, including a list of enforcement actions, court decisions, and compromises of alleged violations by location and company name;

(4) a summary of outstanding problems confronting the administration of this subpart in order of priority;

(5) an analysis and evaluation of research activities completed as a result of Government and private sponsorship, and technological progress for safety achieved during such year;

(6) a list, with a brief statement of the issues, of completed or pending judicial actions under this subpart;

(7) the extent to which technical information was disseminated to the scientific, commercial, and labor community and consumer oriented information was made available to the public; and

(8) the extent of cooperation between Government officials and representatives of industry and other interested parties in the implementation of this subpart including a log or summary of meetings held between Government officials and representatives of industry and other interested parties.

(b) The report required by subsection (a) of this section shall contain such recommendations for additional legislation as the Secretary deems necessary to promote cooperation among the several States in the improvement of electronic product radiation control and to strengthen the national electronic product radiation control program. ”

NOTE: Under 42 USC 263, FDA authority extends to electronic product radiation control. Environmental aspects were transferred to EPA under Reorganization Plan No. 3, 1970.

G. Bureau of *Veterinary Medicine*

Legal citation	Type of authority	Legislative text

G. Bureau of Veterinary Medicine

a) Federal Food, Drug and Cosmetic Act • P.L. 75-717 §512, as added by P.L. 90-399 §Iol(b) **(1968)** and amended • 21 USC ~360b	General	(1)(1) "In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to deiermine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m) (4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary. (m)(5) In case of an animal feed for which an approval of an application filed pursuant to this subsection is in effect— (A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b) of this section, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary . . . to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section or paragraph (4) of this subsection. . . ."

V. HEALTH RESOURCES ADMINISTRATION

Legal citation	Type of authority	Legislative text
A. Bureau of Health Facilities Financing, Compliance, and Conversion		
a) Public Health Service Act • P.L. 78-410$604, as added by P.L. 88-443 $3(a) (1964) and amended • 42 USC §291d	Specific	(a) "Any State desiring to participate in this part [e.g., to obtain grants and loans for construction and modernization of hospitals and other medical facilities] may submit a State plan. Such plan must— . . . (4) set forth, . . . on the basis of a statewide inventory of existing facilities, a survey of need, and . . . community, area or regional plans— (A) the number of general hospital beds and long-term care beds, and the number and types of hospital facilities and facilities for long-term care, needed to provide adequate facilities for inpatient care of people residing in the State, and a plan for the distribution of such beds and facilities in service areas throughout the State; (B) the publIc health centers needed to provide adequate public health services for people residing in the State, and a plan for the distribution of such centers throughout the State; (C) the outpatient facilities needed to provide adequate diagnostic or treatment services to ambulatory patients residing in the State, and a plan for distribution of such facilities throughout the State; (D) the rehabilitation facilities needed to assure adequate rehabilitation services for disabled persons residing in the State, and a plan for distribution of such facilities throughout the State; and (E) . . . the extent to which existing facilities referred to in section 291a(a) or (b) of this title in the State are in need of modernization; . . .
	General	(10) provide that the State agency will make such reports, in such form and containing such information, as the Surgeon General may from ***time*** to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports; . . ."
b) Public Health Service Act • P.L. 78-410 ~1603, as added by P.L. 93-641 §4 (1975) • 42 USC 3000-2	Specific	(a) "Before an application for assistance . . . for a medical facility project described in section 3000 of . . . title [42] may be approved, the State Agency of the State in which such project is located must have submitted to the Secretary and had approved by him a State medical facilities plan. To be approved by the Secretary a State medical facilities plan for a State must— * * * (4) set forth, in accordance with criteria established in regulations prescribed under section 3000-l(a) of . . . title

A. Bureau of Health Facilities Financing, Compliance, and Conversion—continued

Legal citation	Type of authority	Legislative text
		[42] and on the basis of a statewide inventory of existing medical facilities, a survey of need, and the plans of health systems agencies within the State— (A) the number and type of medical facility beds and medical facilities needed to provide adequate inpatient care to people residing in the State, and a plan for the distribution of such beds and facilities in health services areas throughout the State, (B) the number and type of outpatient and other medical facilities needed to provide adequate public health services and outpatient care to people residing in the State, and a plan for the distribution of such facilities in health services areas throughout the State, and (C) the extent to which existing medical facilities in the State are in need of modernization or conversion to new uses;. . . "

B. Bureau of Health Manpower

a) Public Health Service Act ● P.L. 78-410 §~332, as added by P.L. 94-484 $407(b)(3), (1976) ● 42 USC ~254e	Implied	(b) "The Secretary shall establish by regulation, promulgated not later than May 1, 1977, criteria for the designation of areas, population groups, medical facilities, and other public facilities, in the States, as health manpower shortage areas. In establishing such criteria, the Secretary shall take into consideration the following: (1) The ratio of available health manpower to the number of individuals in an area or population group, or served by a medical facility or other public facility under consideration for designation. (2) Indicators of a need, notwithstanding the supply of health manpower, for health services for the individuals in an area or population group or served by a medical facility or other public facility under consideration for designation, with special consideration to indicators of— (A) infant mortality, (B) access to health services, and (C) health status. (3) The percentage of physicians serving an area, population group, medical facility, or other public facility under consideration for designation who are employed by hospitals and who are graduates of foreign medical schools. . . . (d) In accordance with the criteria established under subsection (b) of this section and the considerations listed in subsec-

B. Bureau of Health Manpower—continued

Legal citation	Type of authority	Legislative text
		tion (c) of this section, the Secretary shall designate, not later than November 1, 1977, health manpower shortage areas in the States, publish a descriptive list of the areas, population groups, medical facilities, and other public facilities so designated, and at least annually review and, as necessary, revise such designations. . . .“ [Jointly administered with the National Health Service Corps (HSA).]
b) Public Health Service Act • P.L. 78-410 §333, as added by P.L. 94-484 $407(b)(3), (1976) • 42 USC §254f	Specific	(g) ‘The Secretary shall conduct, or enter into contracts for the conduct of, studies of the methods of assignments of Corps members to health manpower shortage areas. Such studies shall include studies of— (1) the characteristics of physicians, dentists, and other health professionals who are more likely to remain in practice in health manpower shortage areas; (2) the characteristics, including utilization and reimbursement patterns, of areas which have been able to retain health manpower personnel; and (3) the appropriate conditions for the assignment and use of nurse practitioners, physician assistants, and expanded function dental auxiliaries in health manpower shortage areas. ” [Jointly administered with the National Health Service Corps (HSA).]
c) Public Health Service Act • P.L. 78-410$336, as added by P.L. 94-484 §407(b)(3) (1976) • 42 USC §254i	Implied	“The Secretary shall submit an annual report to Congress on May 1 of each year, and shall include in such report with respect to the previous calendar year— (1) the number, identity, and priority of all health manpower shortage areas designated in such year and the number of health manpower shortage areas which the Secretary estimates will be designated in the subsequent year; (2) the number of applications filed under section 254f of . . . title [42] in such year for assignment of Corps members and the action taken on each such application; (3) the number and types of Corps members assigned in such year to health manpower shortage areas, the number and types of additional Corps members which the Secretary estimates will be assigned to such areas in the subsequent year, and the need for additional members for the Corps; (4) the recruitment efforts engaged in for the Corps in such year and the number of qualified individuals who applied for service in the Corps in such year;
	Specific	(5) the number of patients seen and the number of patient visits recorded during such year with respect to each health

B. Bureau of Health Manpower—continued

Legal citation	Type of authority	Legislative text
		manpower shortage area to which a Corps member was assigned during such year; (6) the number of Corps members who elected, and the number of Corps members who did not elect, to continue to provide health services in health manpower shortage areas after termination of their service in the Corps and the reasons (as reported to the Secretary) of members who did not elect for not making such election; (7) the results of evaluations and determinations made under section 254 f(a)(l)(D) of this title during such Year; and (8) the amount charged during such year for health services provided by Corps members, the amount which was collected in such year by entities in accordance with agreements under section 254g of this title, and the amount which was paid to the Secretary in such year under such agreements. ” [Jointly administered with the National Health Service Corps (HSA
d) Public Health Service Act ● P.L. 78-410 §708, as added by P.L. 94-484$206 (1976) and amended ● 42 USC §292h	Specific	(a) “The Secretary shall establish a program, including a uniform health professions data reporting system, to collect, compile, and analyze data on health professions personnel which shall initially include data respecting all physicians and dentists in the United States. . . . The Secretary is authorized to expand the program to include, whenever he determines it necessary the collection, compilation, and analysis of data respecting pharmacists, optometrists, podiatrists, veterinarians, public health personnel, audiologists, speech pathologists, health care administration personnel, nurses, allied health personnel, medical technologists, and any other health personnel in States designated by the Secretary to be included in the program. Such data shall include data respecting the training, Iicensure status (including permanent, temporary, partial, limited, or institutional), place or places of practice, professional specialty, practice characteristics, place and date of birth, sex, and socio-economic background of health professions personnel and such other demographic information regarding health professions personnel as the Secretary may require. (b)(l) In carrying out subsection (a) of this section, the Secretary shall collect available information from appropriate local, State and Federal agencies and other appropriate sources. (2) The Secretary shall conduct or enter into contracts for the conduct of analytic and descriptive studies of the health professions, including evaluations and projections of the sup-

B. Bureau of Health Manpower—continued

Legal citation	Type of authority	Legislative text
		ply of, and requirements for, the health professions by specialty and geographic location. (3) The Secretary is authorized to make grants and to enter into contracts with States (or an appropriate nonprofit private entity in any State) for the purpose of participating in the program established under subsection (a) of this section. . . . To be eIigible for a grant or contract under this paragraph a State or entity shall submit an application in such form and manner and containing such information as the Secretary shall require. Such application shall include reasonable assurances, satisfactory to the Secretary, that— (A) such State (or nonprofit entity within a State) will establish a program of mandatory annual registration of the health professions personnel described in subsection (a) of this section who reside or practice in such State and of health institutions licensed by such State, which registration shall include such information as the Secretary shall determine to be appropriate; (B) such State or entity shall collect such information and report it to the Secretary in such form and manner as the Secretary shall prescribe; and (C) such State or entity shall comply with the requirements of subsection (e) of this section. (c) for purposes of providing the Secretary with information under this section, each school which receives financial support under section 295f of . . . title [42] shall annually report to the Secretary information, determined to be appropriate by the Secretary, respecting the students who attend such school. The Secretary may collect such additional data respecting students of the health professions as he determines to be appropriate. (d) The Secretary shall assemble and submit to the President and Congress . . . a report on the status of health professions personnel in the United States, which report shall include a description and analysis of the data collected pursuant to this section. Such report may be included as part of the report made under section 242m(a)(2)(C) of this title. Such report shaII be submitted biennially, and the first such report shall be due not later than October 1, 1979. . . . (f) In carrying out his responsibilities under this section, the Secretary shall not be subject to the provisions of chapter 35 of title 44. " [providing for exemption from the Federal Reports Clearance Act.] [Jointly administered with the National Center for Health Statistics (OASH).]

B. Bureau of Health Manpower—continued

Legal citation	Type of authority	Legislative text
e) Public Health Service Act • P.L. 78-410 §781, as added by P.L. 94-484 §801(a) (1976) • 42 USC §295g-1	General	(d)(2) "Each area health education center shall– (B) assess the health manpower needs of the area served by the center and assist in the planning and development of training programs to meet such needs; . . ."
f) Public Health Service Act • P.L. 48-410$793, as added by P.L. 94-484, $701(a) (1976) • 42 USC y~295h-2	Specific	(a) "The Secretary shall, in coordination with the National Center for Health Statistics . . . continuously develop, publish, and disseminate on a nationwide basis statistics and other information respecting public and community health personnel, including— 1) detailed descriptions of the various types of activities in which public and community health personnel are engaged, (2) the current and anticipated needs for the various types of public and community health personnel, and (3) the number, employment, geographic locations, salaries, and surpluses and shortages of public and community health personnel, the educational and licensure requirements for the various types of such personnel, and the cost of training such personnel. . . . (c) The Secretary shall submit annually to the Committee on Interstate and Foreign Commerce of the House of Representatives and to the Committee on Labor and Public Welfare of the Senate a report on— (1) the statistics and other information developed pursuant to subsection (a) of this section, and (2) the activities conducted under this subpart, including an evaluation of such activities. . . ." [Jointly administered with the National Center for Health Statistics (OASH).]
g) Public Health Service Act • P.L. 78-410 §795 note, as added by P.L. 94-484$702 (1976) • 42 USC §295h-4 note	Specific	(b) . . . "The Secretary shall, in coordination with the National Center for Health Statistics [established under section 306 of the Public Health Service Act (section 242k of . . . title 42)], develop, publish, and disseminate on a nationwide basis a report containing statistics and other information respecting allied health personnel, including— (1) detailed descriptions of the various types of such personnel and the activities in which such personnel are engaged, (2) the current and anticipated needs for the various types of such health personnel, and

B. Bureau of Health Manpower—continued

Legal citation	Type of authority	Legislative text
		(3) the number, employment, geographic locations, salaries, and surpluses and shortages of such personnel. ” [Jointly administered with the National Center for Health Statistics (OASH).]
h) Special Health Revenue Sharing Act of 1975 • P.L. 94-63, Title Ix, $951 (1975) • 42 USC §296 note	Specific	(a)(l) Using procedures developed in accordance with paragraph (3), the Secretary of Health, Education, and Welfare (hereinafter in this section referred to as the ‘Secretary’) shall determine on a continuing basis— (A) the supply (both current and projected and within the United States and within each State) of registered nurses, licensed practical and vocational nurses, nurse’s aides, registered nurses with advanced training or graduate degrees, and nurse practitioners; (B) the distribution, within the United States and within each State, of such nurses so as to determine (i) those areas of the United States which are oversupplied, or which are undersupplied, or which have an adequate supply of such nurses in relation to the population of the area, and (ii) the demand for the services which such nurses provide; and (C) the current and future requirements for such nurses, nationally and within each State. (2) The Secretary shall survey and gather data, on a continuing basis, on— (A) the number and distribution of nurses, by type of employment and location of practice; (B) the number of nurses who are practicing full time and those who are employed part time, within the United States and within each State; (C) the average rates of compensation for nurses, by type of practice and location of practice; (D) the activity status of the total number of registered nurses within each State; (E) the number of nurses with advanced training or graduate degrees in nursing by specialty, including nurse practitioners, nurse clinicians, nurse researchers, nurse educators, and nurse supervisors and administrators; and (F) the number of registered nurses entering the United States annually from other nations, by country of nurse training and by immigrant status. (3) within six months of the date of the enactment of this Act [July 29, 1975], the Secretary shall develop procedures for determining (on both a current and projected basis) the supply

B. Bureau of Health Manpower—continued

Legal citation	Type of authority	Legislative text
		and distribution of and requirements for nurses within the United States and within each State. (b) Not later than October 1, 1979, and October 1 of each odd-numbered year thereafter, the Secretary shall report to the Congress— (1) his determinations under subsection (a)(l) and the data gathered under subsection **(a)(2);** **(2)** an analysis of such determination and data; and (3) recommendations for such legislation as the Secretary determines, based on such determinations and data, will achieve (A) an equitable distribution of nurses within the United States and within each State, and (B) adequate supplies of nurses within the United States and within each State . . ."

C. Bureau of Health Planning

a) Public Health Service Act • P.L. 78-410$1513, as added by P.L. 93-641$3 (1975), and amended • 42 USC $300/-2	Specific	(b) "In providing health planning and resources development for its health service area, a health systems agency shall perform the following functions: (1) The agency shall assemble and analyze data concerning — (A) the status (and its determinants) of the health of the residents of its health service area, (B) the status of the health care delivery system in the area and the use of that system by the residents of the area, (C) the effect the area's health care delivery system has on the health of the residents of that area, (D) the number, type, and location of the area's health resources, including health services, manpower, and facilities, (E) the patterns of utilization of the area's health resources, and (F) the environmental and occupational exposure factors affecting immediate and longterm health conditions. * * * In carrying out this paragraph, the agency shall to the maximum extent practicable use existing data (including data developed under Federal health programs) and coordinate its activities with the cooperative system provided for under section 242k(e) of . . . title [42 of the United States Code]. (2) The agency shall, after appropriate consideration of the recommended national guidelines for health planning

C. Bureau of Health Planning—continued

Legal citation	Type of authority	Legislative text
		policy issued by the Secretary under section 300k-1 of . . . title [42] the priorities set forth in section 300k-2 of . . . title [42], and the data developed pursuant to paragraph (1), establish, annually review, and amend as necessary a health systems plan (hereinafter in this subchapter referred to as the "HSP") . . .
	Implied	(c) A health systems agency shall implement its HSP and AIP, and in implementing the plans it shall perform at least the following functions: . . . (2) The agency may provide, in accordance with the priorities established in the AIP, technical assistance . . . for the development of projects and programs which the agency determines are necessary to achieve the health systems described in the HSP, . . . (d) Each health systems agency shall coordinate its activities with— (1) each Professional Standards Review Organization (designated under section 1320c-1 of . . . title [42]), (2) entities referred to in paragraphs (1) and (2) of section 3334(a) of this title and regional and local entities the views of which are required to be considered under regulations prescribed . . . to carry out section 4231(b) of this title, (3) other appropriate general or special purpose regional planning or administrative agencies, and
	General	(4) any other appropriate entity, in the health system agency's health service area. The agency shall, as appropriate, secure data from them for use in the agency's planning and development activities, . . .
	Implied	(g)(l) Except as provided in paragraph (2), each health systems agency shall review on a periodic basis (but at least every five years) all institutional health services offered in the health service area of the agency and shall make recommendations to the State health planning and development agency . . . respecting the appropriateness in the area of such services. (2) A health systems agency shall complete its initial review of existing institutional health services within three years after the date of the agency's designation under section 300 l-4(c) of this title. [Jointly administered with the National Center for Health Statistics (OASH).]

C. Bureau of Health Planning—continued

Legal citation	Type of authority	Legislative text
b) Public Health Service Act ● P.L. 78-410$1522, as added by P.L. 93-641 §3 (1975) ● 42 USC §300m-1	General	(a) "A State administrative program (hereinafter in this section referred to as the "State Program") is a program for the performance within the State by its State Agency of the functions prescribed by section 300m-2 of . . . title [42]. . . . (b) The State Program of a State must– (7)(A) provide for the coordination . . . with the cooperative system provided for under section 242k(e) . . . title [42] of the activities of the State Agency for the collection, retrieval, analysis, reporting and publication of statistical and other information related to health and health care, and (B) require providers of health care doing business in the State to make statistical and other reports of such information to the State Agency;
	Implied	(8) provide, in accordance with methods and procedures prescribed or approved by the Secretary, for the evaluation, at least annually, of the performance by the State Agency of its functions and of their economic effectiveness; (9) provide that the State Agency will from time to time, and in any event not less often than annually, review the State Program and submit to the Secretary required modifications;
	General	(10) require the State Agency to make such reports, in such form and containing such information, concerning . . ., performance of functions, and other matters as the Secretary may from time to time require, and keep such records . . . as the Secretary may find necessary to verify such reports;" [Jointly administered with the National Center for Health Statistics (OASH).]
c) Public Health Service Act ● P.L. 78-410$1523 as added by P.L. 93-641 §3 (1975) ● 42 USC §300m-2	Implied	(a) "Each State Agency Of a State designated under section 300m(b)(3) of . . . title [42] shall, except as authorized under subsection (b) of this section, perform within the State the following functions; . . . (3) Assist the Statewide Health Coordinating Council of the State in the review of the State medical facilities plan required under section 3000-2 of . . . title [42] . . . (4) . . . (B) administer a State certificate of need program which applies to new institutional health services proposed to be offered or developed within the State and which is satisfactory to the Secretary. Such program shall provide for review and determination of need prior to the time such services, facilities, and organizations are offered or developed or substantial expenditures are undertaken in preparation for such offering or development, and provide that only those services,

C. Bureau of Health Planning—continued

Legal citation	Type of authority	Legislative text
		facilities, and organizations found to be needed shall be offered or developed in the State . . . (6) Review on a periodic basis (but not less often than every five years) all institutional health services being offered in the State and, after consideration of recommendations submitted by health systems agencies under section 3001-2(g) of . . . title [42] respecting the appropriateness of such services, make public its findings. . . ."
d) Public Health Service Act • P.L. 78-410$1524, as added by P.L. 93-641$3 (1975) • 42 USC §300m-3	Implied	(c) "A SHCC [Statewide Health Coordinating Council] shall perform the following functions: . . . (2)(A) Prepare and review and revise as necessary (but at least annually) a State health plan which shall be made up of the HSP'S of the health systems agencies within the States. . . . (B) In the preparation and revision of the State health plan, the SHCC shall review and consider the preliminary State health plan submitted by the State agency under section 300m-2(a)(2) . . ."
e) Public Health Service Act • P.L. 78-410 ~1533, as added by P.L. 93-641$3 (1975) • 42 USC §300n-2	Specific	(b)(l) "The Secretary shall include in the materials provided under subsection (a) of this section [e.g., technical assistance by the Secretary of HEW to the designated health service agencies] the following: (A) Specification of the minimum data needed to determine the health status of the residents of a health service area and the determinants of such status. (B) Specification of the minimum data needed to determine the status of the health resources and services of a health service area. (C) Specification of the minimum data needed to describe the use of health resources and services within a health service area. (2) Planning approaches, methodologies, policies, and standards . . .
	Implied	(c) In order to facilitate the exchange of information concerning health services, health resources, and health planning and resources development practice and methodology, the Secretary shall establish a national health planning information center to support the health planning and resources development programs of health systems agencies, State Agencies, and other entities concerned with health planning and resources development; to provide access to current information on health planning and resources development; and to provide information for use in the analysis of issues and

C. Bureau of Health Planning—continued

Legal citation	Type of authority	Legislative text
		problems related to health planning and resource development."
f) Public Health Service Act • P.L. 78-410 §1535, as added by P.L. 93-641$3 (1975) • 42 USC §300n-4	Specific	(b) "The Secretary shall prescribe performance standards covering the structure, operation, and performance of the functions of each designated health systems agency and State Agency, and he shall establish a reporting system based on the performance standards that allows for continuous review of the . . . functions of such agencies. (c) The Secretary shall review in detail at least every three years the structure, operation and performance of the functions of each designated health systems agency to determine— (1) the adequacy of the HSP of the agency for meeting the needs of the residents of the area for a healthful environment and for accessible, acceptable and continuous quality health care at reasonable costs, and the effectiveness of the AIP in achieving the system described in the HSP; * * * (5) the appropriateness of the data assembled pursuant to section 3002-2 (b)(l) of this title and the quality of the analyses of such data; . . . (7) the extent to which it may be demonstrated that– (A) the health of the residents in the agency's health service area has been improved; (B) the accessibility, acceptability, continuity, and quality of health care in such area has been improved; and (C) increases in costs of the provision of health care have been restrained. (d) The Secretary shall review in detail at least every three years the structure, operation and performance of the functions of each designated State Agency to determine— (1) the adequacy of the State health plan of the Statewide Health Coordinating Council prepared under section 300m-3(c)(2) of this title in meeting the needs of the residents of the State for a healthful environment and for accessible, acceptable, and continuous quality health care at reasonable costs; . . . (6) the extent to which it may be demonstrated that– (A) the health of the residents of the State has been improved; (B) the accessibility, acceptability, continuity, and quality of health care in the State has been improved; and (C) increases in costs of the provision of health care have been restrained."

V1. HEALTH SERVICES ADMINISTRATION

Legal Citation	Type of authority	Legislative text

A. Bureau of Community Health Service

1. Community Health Centers

a) Public Health Service Act • P.L. 78-410$330, as added by P.L. 94-63 $501(a), (1975) and amended • 42 USC §254c	Implied	(c)(1) "The Secretary may make grants to public and nonprofit private entities for projects to plan and develop community health centers which will serve medically underserved populations. A project for which a grant may be made under this subsection . . . shall include— (A) an assessment of the need that the population proposed to be served by the community health center for which the project is undertaken has for primary health services, supplemental health services, and environmental health services; . . . (e)(2) h application for a grant [for the operating costs of community health centers serving medically underserved areas] . . . shall include— (A) a description of the need in the center's catchment area . . .
	Specific	(e)(3) Except as provided in subsection (d)(l)(B) Of this section, the Secretary may not approve an application for a grant under subsection (d) of this section [e.g., for costs of operation of public and nonprofit private community health centers which serve medically underserved populations] unless the Secretary determines . . . that— . . . (H) the center has developed, . . . (ii) an effective procedure for compiling and reporting to the Secretary such statistics and other information as the Secretary may require relating to (I) the costs of its operations, (11) the patterns of use of its services, (III) the availability, accessibility, and acceptability of its services, (IV) such other matters relating to operations of the applicant as the Secretary may, by regulation, require, and (V) expenditures made from any amount the center was permitted to retain under subsection (d)(4) (B)."

A. Bureau of Community Health Service
2. Fam/ly Planning

Legal citation	Type of authority	Legislative text
2. Family Planning		
a) Public Health Service Act • P.L. 78-41051004, **as** added by P.L. 91-572 §6(c), (1970), and amended • 42 USC §300a-2	General	(a) "The Secretary may— (1) conduct, and (2) make grants . . . and enter into contracts . . . for projects for research in biomedical, contraceptive develop-'merit, behavioral, and program implementatio~ fields related to family planning and population . . . " [Jointly administered with the National Institute of Child Health and Human Development (NIH).]
b) Public Health Service Act • P.L. 78-410$1005, as added by P.L. 91-572 §6(c), (1970), and amended Q 42 USC §300a-3	Implied	(a) "The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts . . . to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials). . . . "
c) Public Health Service Act P.L. 78-420 1009y§09, as added by P.L. 94-63 §203(a), (1975) . 42 USC §300a-6a	Specific	(a) "Not later than seven months after the close of each fiscal year, the Secretary shall make a report to the Congress setting forth a plan to be carried out over the next five fiscal years for— (1) extension of family planning services to all persons desiring such services, (2) family planning and population research programs, (3) training of necessary manpower for the programs authorized by this subchapter and other Federal laws for which the Secretary has responsibility and which pertain to family planning, and (4) carrying out the other purposes set forth in this subchapter and the Family Planning Services and Population Research Act of 1970. (b) Such a plan shall, at a minimum, indicate on a phased basis— (1) the number of individuals to be served by family planning programs under this subchapter and other Federal laws for which the Secretary has responsibility, the types of family planning and population growth information and educational materials to be developed under such laws and how they will

A. Bureau of Community Health Service
2. Family P/arming—continued

Legal citation	Type of authority	Legislative text
		be made available, the research goals to be reached under such laws, and the manpower to be trained under such laws; (2) an estimate of the costs and personnel requirements needed to meet the purposes of this subchapter and other Federal laws for which the Secretary has responsibility and which pertain to family planning programs; and (3) the steps to be taken to maintain a systematic reporting system capable of yielding comprehensive data on which service figures and program evaluations for the Department of Health, Education, and Welfare shall be based. (c) "Each report submitted under subsection (a) of this section shall— (1) compare results achieved during the preceding fiscal year with the objectives established for such year under the plan contained in the previous such report; (2) indicate steps being taken to achieve the objectives during the fiscal years covered by the plan contained in such report and any revisions to plans in previous reports necessary to meet these objectives; and (3) make recommendations with respect to any additional legislative or administrative action necessary or desirable in carrying out the plan contained in such report. "

3. Genetic Diseases, Hemophilia, and Sudden Infant Death Syndrome (SIDS)

a) Public Health Service Act ● P.L. 78-410$1101, as added by P.L. 94-278$403, (1976) ● 42 USC §300b	General	***(a)(2) "The Secretary*** shall ***carry*** **out,** through **art** identifiable administrative unit within the Department of Health, Education, and Welfare, a program to develop information and educational materials relating to genetic diseases and to disseminate such information and materials to persons providing health care, to teachers and students, and to the public generally in order to most rapidly make available the latest advances in the testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. . . . "
b) Public Health Service Act ● P.L. 78-410$1102, as added by P.L. 94-278 $403(a), (1976) ● 42 USC §300b-1	General	"In carrying out section 241 of . . . title [42] the Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, . . . In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or

A. Bureau of **Community Health Service**
3. *Genetic Diseases, Hemophilia, and Sudden InfanttnfantNFANT/nfant Death Syndrome (SIDs)—continued*

Legal citation	Type of authority	Legislative text
		contracts which are submitted for research on sickle cell anemia and research on Cooley's anemia."* [Jointly administered with the National Institute of General Medical Sciences (NIH).]
c) Public Health Service Act • P.L. 78-410 § 1107, as added by P.L. 95-626 §205 (1978) • 42 USC §300b-6	Specific	"The Secretary, acting through an identifiable administrative unit, shall— (1) conduct epidemiological assessments and surveillance of genetic diseases to define the scope and extent of such diseases and the need for programs for the diagnosis, treatment, and control of such diseases, screening for such diseases, and the counseling of persons with such diseases; (2) On the basis of the assessments and surveillance described in paragraph (1), develop for use by the States programs which combine in an effective manner diagnosis, treatment, and control of such diseases, screening for such diseases, and counseling of persons with such diseases, . . . " [Jointly administered with the Center for Disease Control.]
d) Public Health Service Act c P.L. 78-410$1121, as added by P.L. 93-270 $3(a) (1974) and amended • 42 USC §300c-11	General	(a) "The Secretary, through the Assistant Secretary for Health, shall carry out **a** program to develop public information and professional educational materials relating to sudden infant death syndrome and to disseminate such information and materials to persons providing health care, to public safety officials, and to the public generally. (b)(l) The Secretary may make grants to public and nonprofit private entities, and enter into contracts with public and private entities, for projects which include both— (A) the collection, analysis, and furnishing of information (derived from post mortem examinations and other means) relating to the causes of sudden infant death syndrome; and (B) the provision of information and counseling to families affected by sudden infant death syndrome. . . . (b)(2) No grant maybe made or contract entered into under this subsection unless an application therefor has been submitted to and approved by the Secretary. . . . Each application shall— (D) provide for making such reports in such form and containing such information as the Secretary may reasonably require.

*Section 301 of the Public Health Service Act, **42** USC **$241,** is the general data collection authority for the Secretary of HEW,

A. Bureau of Community Health Service
3. Genetic Diseases, Hemophilia, and Sudden Infant Death Syndrome (SIDs)—continued

Legal citation	Type of authority	Legislative text
		(c) The Secretary shall submit, not later than January 1, 1976, a comprehensive report to [Congress] respecting the administration of this section and the results obtained from the programs authorized by it. "

4. Health Underserved Rural Areas

a) Public Health Service Act • P.L. 78-410 §340, as added by P.L. 95-626$115 (1978) • 42 USC §256	General	(a) "The Secretary may make grants to, and enter into contracts with, public and private entities which provide health services— (1) to demonstrate new and innovative methods for the provision of primary health services and dental health services, or (2) to conduct research on such methods or on existing methods for the provision of primary health services and dental health services, to medical underserved populations ***or to*** such other populations as the Secretary determines are necessary to demonstrate or conduct research on particular methods. (b) Grants and contracts may be made under subsection (a) to demonstrate and conduct research on— (1) methods of attracting and retaining primary care physicians, dentists, physician assistants, nurse practitioners, and other health professionals, both individually and as teams, to train and practice among medical underserved populations; (2) differing types of organizational models and relationships, including federations of health service centers, designed to meet unique primary health and dental health service needs; (3) management and technological improvements (including new or improved methods for biomedical communication and medical and financial recordkeeping and billing systems) to increase the productivity, effectiveness, efficiency, and financial stability of primary health and dental health service providers; (4) methods of providing health promotion, disease prevention, and health education programs, including school health programs; (5) methods of identifying, coordinating, and integrating existing primary health and dental health service programs with mental health and social service programs to maximize

A. Bureau of Community Health Service
4. Health Underserved Rural Areas—continued

Legal citation	Type of authority	Legislative text
		use of available resources, avoid duplication of effort, and ensure a coordinated, comprehensive care system; (6) specific services or mixtures of services appropriate for a given area, including ambulatory care, home health care, environmental health services (described in section **330(a)(4)),** community outreach activities, transportation services, and other supplemental health services (as defined in section 330(b)(2)); (7) the effect of availability of primary health and home health services in terms of reduction of emergency room visits, hospitalizations, and institutionalization in long-term care facilities; (8) the use of mobile health screening clinics to provide preventive health care services to meet the needs of medical underserved populations; and (9) such other projects as the Secretary determines to be necessary to further the purposes of this section. (c)(2) The Secretary shall,to the extent feasible, coordinate demonstration and research projects carried out under this section with any demonstration and research projects carried out under the Social Security Act for the reimbursement of services which are the subject of projects under this section. (d)(l) No grant may be made under this section unless an application therefor is submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner and shall contain such information as the Secretary shall prescribe. . . .
b) Social Security Act • P.L. 74-241 §1112, as added by P.L. 86-778$705, (1960) and amended • 42 USC §1312	General	"In order to assist the States to extend the scope and content, and improve the quality, of medical care and medical services for which payments are made to or on behalf of needy and low-income individuals under this chapter and in order to promote better public understanding about medical care and medical assistance for needy and low-income individuals, the Secretary shall develop and revise from time to time guides or recommended standards as to the level, content, and quality of medical care and medical services for the use of the States in evaluating and improving their public assistance medical care programs and their programs of medical assistance, shall secure periodic reports from the States on items included in, and the quantity of, medical care and medical services for which expenditures under such programs are made; and shall from

A. Bureau of Community Health Service
4. Health Underserved Rural Areas—continued

Legal citation	Type of authority	Legislative text
		time to time publish data secured from these reports and other information necessary to carry out the purposes of this section. "

5. Maternal and Child Health

a) Social Security Act • P.L. 74-241$505, as added by P.L. 90-248 §~301, 304(a), (1968), and amended • 42 USC §705	General	(a) "In order to be entitled to payments from allotments under section 702 of . . . title [42], a State must have a State plan for maternal and child health services and services for crippled children which— . . . (4) provides that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions **as** he may from time to time find necessary to assure the correctness verification of such reports; . . . " (7) provides, with respect to the portion of the plan relating to services for crippled children, for early identification of children in need of health care and services, and for health care and treatment needed to correct or ameliorate defects or chronic conditions discovered thereby, through provision of such periodic screening and diagnostic services, . . . "
b) Social Security Act • P.L. 74-241 §512, as added by P.L. 90-248 §301, (1968) • 42 USC §712	Implied	"From the sums available under . . . section 702 of . . . title [42], the Secretary is authorized to make grants to or jointly financed cooperative arrangements with public or other nonprofit institutions of higher learning, and public or nonprofit private agencies and organizations engaged in research or in maternal and child health or crippled children's programs, and contracts with public or nonprofit private agencies and organizations engaged in research or in such programs, for research projects relating to maternal and chiId health services or crippled children's services which show promise of substantial contribution to the advancement thereof. Effective with respect to grants made and arrangements entered into after June 30, 1968, (1) special emphasis shall be accorded to projects which will help in studying the need for, and the feasibility, costs, and effectiveness of, comprehensive health care programs in which maximum use is made of health personnel with varying levels of training, and in study methods of training for such progams, . . . "

A. Bureau of **Community Health Service**
5. *Maternal and Child Health*

Legal citation	Type of authority	Legislative text
c) Social Security Act • P.L. 74-241 §513, as added by P.L. 90-248 §301, (1968) • 42 USC §713	General	(a) "The Secretary of Health, Education, and Welfare shall make such studies and investigations as will promote the efficient administration of this subchapter. "

6. Migrant Health

a) Public Health Service Act • P.L. 78-410 y§319 formerly §310 as added by P.L. 94-63 §401(a) (1976), and amended • 42 USC §247d	General	(c)(l)(A) "The Secretary may, in accordance with the priorities assigned under subsection (b)(l) of this section, make grants to public and non-profit private entities for projects to plan and develop migrant health centers which will serve migratory agricultural workers, seasonal agricultural workers, and the members of the families of such migratory and seasonal workers, in high impact areas. A project for which a grant may be made under this subparagraph . . . shall include— (i) an assessment of the need that the workers (and the members of the families of such workers) proposed to be served by the migrant health center for which the project is undertaken have for primary health services, supplemental health services, and environmental health services; . . . (e) "The Secretary may enter into contracts with public and private entities to— * * * (2) conduct projects and studies to assist the several States and entities which have received grants or contracts under this section in the assessment of problems related to camp and field sanitation, pesticide hazards, and other environmental health hazards to which migratory agricultural workers, seasonal agricultural workers, and members of their families are exposed. . . .
	Specific	(f)(2) The Secretary may not approve an application for a grant under subsection (d)(l)(A) of this section [e.g. for the costs of operation of public and nonprofit private migrant health centers in certain cases] unless the Secretary determines that— . . .

A. Bureau of Community Health Service
6. Migrant Health—continued

Legal citation	Type of authority	Legislative text
		(H) the Center has developed (ii) an effective procedure for compiling and reporting to the Secretary such statistics and other information as the Secretary may require relating to (I) the costs of its operations, (II) the patterns of use of its services, (III) the availability, accessibility, and acceptability of its services, and (IV) such other matters relating to operations of the applicant as the Secretary may, by regulation require; . . . "

7. National Health Service Corps

a) Public Health Service Act • P.L. 78-410$332, as added by P.L. 94-484, **§407(b)(3)** (1976) • 42 USC §254e	Implied	(b) "The Secretary shall establish by regulation promulgated not later than May 1, 1977, criteria for the designation of areas, population, groups, medical facilities, and other public facilities, in the States, as health manpower shortage areas. In establishing such criteria, the Secretary shall take into consideration the following: (1) The ratio of available health manpower to the number of individuals in an area or population group, or served by a medical facility or other public facility under consideration for designation. (2) Indicators of a need, notwithstanding the supply of health manpower, for health services for the individuals in an area or population group or served by a medical facility or other public facility with special consideration to indicators of— (A) infant mortality, (B) access to health services, and (C) health status. (3) The percentage of physicians serving an area, population group, medical facility, or other public facility under consideration for designation who are employed by hospitals and who are graduates of foreign medical schools. . . . (d) In accordance with the criteria established under subsection (b) of this section and the considerations listed in subsection (c) of this section, the Secretary shall designate, not later than November 1, 1977, health manpower shortage areas in the States, publish a descriptive list of the areas, population groups, medical facilities, and other public facilities so designated, and at least annually review and, as necessary, revise such designations. . . . "

A. Bureau of Community Health Service
7. National Health Service Corps—continued

Legal citation	Type of authority	Legislative text
		[Jointly administered with the Bureau of Health Manpower (HRA).]
b) Public Health Service Act • P.L. 78-4105333, as added by P.L. 94-484 $407(b)(3), (1976) 42 USC 254f	Specific	(g) "The Secretary shall conduct, or enter into contracts for the conduct of, studies of the methods of assignments of Corps members to health manpower shortage areas. Such studies shall include studies of— (1) the characteristics of physicians, dentists, and other health professionals who are more likely to remain in practice in health manpower shortage areas; (2) the characteristics, including utilization and reimbursement patterns, of areas which have been able to retain health manpower personnel, and (3) the appropriate conditions for the assignment and use of nurse practitioners, physician assistants, and expanded function dental auxiliaries in health manpower shortage areas. " [Jointly administered with the Bureau of Health Manpower (HRA).]
c) Public Health Service Act • P.L. 78-410$336, as added by P.L. 94-484 &107 (b)(3), (1976) • 42 USC ¦254i	Implied	The Secretary shall submit an annual report to Congress on May 1 of each year, and shall include in such report with respect to the previous calendar year— (1) the number, identity, and priority of all health manpower shortage areas designated in such year and the number of health manpower shortage areas which the Secretary estimates will be designated in the subsequent year; (2) the number of applications filed under section 254f . . . title [42] in such year for assignment of Corps members and the action take on each application; (3) the number and types of Corps members assigned in such year to health manpower shortage areas, the number and types of additional Corps members which the Secretary estimates will be assigned to such areas in the subsequent year, and the need for additional members for the Corps; (4) the recruitment efforts engaged in for the Corps in such year and the number of qualified individuals who applied for service in the Corps in such year;
	Specific	(s) the number of patients seen and the number of patient visits recorded during such year with respect to each health manpower shortage area to which a Corps member was assigned during such year; (6) the number of Corps members who elected, and the number of Corps members who did not elect, to continue to provide health services in health manpower shortage areas

A. Bureau of Community Health Service
7. National Heallth Service Corps—continued

Legal citation	Type of authority	Legislative text
		after termination of their service in the Corps and the reasons (as reported to the Secretary) of members who did not elect for not making such election; (7) the results of evaluations and determinations made under section 254 f(a)(l)(D) of this title during such year; and (8) the amount charged during such year for health services provided by Corps members, the amount which was collected in such year by entities in accordance with agreements under section 254g of this title, and the amount which was paid to the Secretary in such year under such agreements. " [Jointly administered with the Bureau of Health Manpower (HRA).]

8. Office of State Program Coordination: Grants to States

a) Public Health Service Act P.L. 78-410 §314, as added by P.L. 94-63 §102, (1975) and amended • 42 USC §246	Specific	(d)(l) "The Secretary shall make grants to State health authorities to assist in meeting the costs of providing comprehensive public health services. (2) No grant may be made under paragraph (1) to the State health authority of any State unless an application therefore has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and shall contain such information as the Secretary may require, and shall contain or be supported by assurances satisfactory to the Secretary that— (A) the comprehensive public health services which will be provided within the State with funds under a grant under paragraph (1) will be provided in accordance with the State health plan in effect under section 1524(c); * * * (C)(ii) from time to time, as prescribed by the Secretary, report to the Secretary (through a uniform national reporting system and by such categories as the Secretary may prescribe) a description of the comprehensive public health services provided in the State in the fiscal year for which the grant applied for is made and the amount and source of funds expended in that fiscal year and in the preceding fiscal year for the provision of each such category of services; and (iii) make such other reports (in such form and containing such information as the Secretary may prescribe) as the Secretary may reasonably require and keep such records and afford such access thereto as the Secretary may find

A. Bureau of Community Health Service
8. Office of State Program Coordination: Grants to States—continued

Legal citation	Type of authority	Legislative text
		necessary to assure the correctness of, and to verify, such reports; * * *
	Implied	(4)(A) . . . In determining the amount of a grant to a State health authority under subclause (I), the Secretary shall take into account the financial need of such State and the level of State and local expenditures for comprehensive public health services (as defined in subparagraph (C)). In determining the financial need of a State, the Secretary shall consider, as major factors, the proportion of the State's population whose income level is below the poverty income level established by the Secretary and the proportion of its population which is living in medical underserved areas. " [Jointly administered with the Center for Disease Control.]
b) Public Health Service Act • P.L. 78-410$317, as added by P.L. 87-868 §2 (1962), and amended • 42 USC $247b	General	(a) "The Secretary may make grants— (1) to State health authorities to assist them in meeting the costs of establishing and maintaining preventive health service programs for screening for, the detection, diagnosis, prevention, and referral for treatment of, and follow-up on compliance with treatment prescribed for hypertension; and (2) to States and, . . . to political subdivisions of States and to other public entities to assist them in meeting the costs of establishing and maintaining preventive health service programs (other than programs described in paragraph (1)). (b) No grant may be made under section (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and be submitted in such manner as the Secretary shall by regulation prescribe and shall provide— (1) a complete description of the type and extent of the program for which the applicant is seeking a grant under subsection (a); (2) with respect to each such program, . . . (B) **a** description of the services provided by the applicant in such program in such period, . . . and, (D) if the applicant proposes changes in the provision of the services in such program, the priorities of such proposed changes, reasons for such changes, and the amount of Federal funds needed by the applicant to make such changes; * * * (5) assurances satisfactory to the Secretary that the applicant will provide for periodic evaluation of its program or programs;

A. Bureau of Community Health Service
8. Office of State Program Coordination: Grants to States—continued

Legal citation	Type of authority	Legislative text
		(6) assurances satisfactory to the Secretary that the applicant will make such reports (in such form and containing such information **as** the Secretary may by regulation prescribe) as the Secretary may reasonably require and keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness of, and to verify, such reports; . . . (h) The Secretary shall include, as part of the report required by section 1705 [42 USC 300u-4], a report on the extent of the problems presented by the diseases and conditions referred to in subsection (j) [concerning preventive health service programs to immunize children against immunizable diseases, and influenza]; . . . and on the effectiveness of the activities assisted under grants under subsection (a) in controlling such diseases and conditions. [Center for Disease Control administers all but the authority concerning hypertension; the Bureau of Community Health Services (HSA) administers the hypertension program.]
c) Social Security Act ● P.L. 74-241$1861 note, as added by P.L. 94-63$602 (1975), and amended ● 42 USC §1395x note 2	Implied	(a)(1) "For the purpose of demonstrating the establishment and initial operation of public and nonprofit private agencies . . . which will provide home health services . . . in areas in which such services are not otherwise avaiIable, the Secretary of Health, Education, and Welfare may . . . make grants to meet the initial costs of establishing and operating such agencies and expanding the services available through existing agencies, and to meet the costs of compensating professional and paraprofessional personnel during the initial operation of such agencies or the expansion of services of existing agencies. (2) In making grants under this subsection, the Secretary shall consider the relative needs of the several States for home health services and preference shall be given to areas within a state in which a high percentage of the population proposed to be served is composed of individuals who are elderly, medically indigent, or both. (3) Application for grants under this subsection shall be in such form and contain such information as the Secretary shall prescribe by regulation. . . . "

Legal citation	Type of authority	Legislative text

B. Bureau of Medical Services
1. Emergency Medical Services

a) Public Health Service Act ● P.L. 78-410 §1205 as added by P.L. 93-154 §2(a) (1973), and amended ● 42 USC §300d-4	General	**(a)** "The Secretary may make grants . . . and enter into contracts . . . for the support of research in emergency medical techniques, methods, devices, and delivery. The Secretary shall give special consideration to applications for grants or contracts for research relating to the delivery of emergency medical services in rural areas and especially research which emphasizes the identification and utilization of techniques and methods to apply the results of such research to improve the delivery of emergency medical services in such areas. * * * (c) The recipient of a grant or contract under this section shall make such reports to the Secretary as the Secretary may require. Such reports shall contain recommendations and a plan of action for applying the results of the research assisted by such grantor contract to improve the delivery of emergency medical services. "
b) Public Health Service Act ● P.L. 78-410 §1206, added by P.L. 93-154, §2(a), (1973), and amended ● 42 USC §300d-5	Specific	(b)(4)(C) "An emergency medical services system shall— . . . (xi) provide for a coordinated patient recordkeeping system meeting appropriate standards established by the Secretary, which records shall cover the treatment of the patient from initial entry into the system through his discharge from it, and shall be consistent with ensuing patient records used in follow-up care and rehabilitation of the patient; . . . (xiii) provide the Secretary with such information as he may require to conduct periodic, comprehensive, and independent reviews and evaluations of the extent and quality of the emergency health care services provided in the system's service area, and submit to the Secretary the results of any review or evaluation which may be conducted by such system of the extent and quality of the emergency health care services provided in the system's service area;"

B. Bureau of Medical Services
1. Emergency Medical Services—continued

Legal citation	Type of authority	Legislative text
c) Public Health Service Act • P.L. 78-410$1208, as added by P.L. 93-154 §2(a), (1973) and amended • 42 USC §300d-7	Specific	(a) The Secretary shall administer the program of grants and contracts . . . authorized by this part through an identifiable administrative unit specializing in emergency medical services within the Department of Health, Education and Welfare. (b) Such administrative unit shall– (1) be responsible for collecting, analyzing, cataloging, and disseminating all data . . . derived from reviews and evaluations of emergency medical services systems assisted under sections 300d-1, 300d-2, and 300d-3 of . . . title [42]; (2) publish suggested criteria for collecting necessary information for the evaluation of projects and programs funded under this subchapter; . . . (7) provide for periodic, independent evaluations of the effectiveness of, and coordination between, the programs carried out under this part and the programs carried out under section 295g-9 of . . . title [42]. (c) In addition, such administrative unit shall, through the Interagency Committee on Emergency Medical Services (established under section 300d-8 of this title)– (1) study on a continuing basis (including evaluating the adequacy, technical soundness, and redundancy of) the roles, resources, and responsibilities of all Federal programs and activities relating to emergency medical services. Such unit shall report to the Congress the results of studies made under paragraph (1). The . . . reports shall be made ***not*** later than February 1 of each year after 1978. ”
d) Public Health Service Act • P.L. 78-410$1210, as added by P.L. 93-15462 (1973) • 42 USC §300d-9	Implied	The Secretary shall prepare and submit annually to the Congress a report on the administration of this subchapter. Each report shall include an evaluation of the adequacy of the provision of emergency medical services in the United States during the period covered by the report, and evaluation of the extent to which the needs for such services are being adequately met through assistance provided under this subchapter . . . “

B. Bureau of Medical Services
1. Emergency Medical Services—continued

Legal citation	Type of authority	Legislative text
e) Public Health Service Act • P.L. 78-410$1221 as added by P.L. 94-573 $14(3), (1976) and amended • 42 USC §300d-21	General	(a)(l) "The Secretary may make grants to, and enter into contracts with, public or private non-profit entities for the support of, and may conduct programs for the establishment, operation, and improvement of activities to (A) demonstrate the effectiveness of different methods for the treatment and rehabilitation of individuals injured by burns, (B) conduct research in the treatment and rehabilitation of such individuals . . . (2) The Secretary may enter into contracts . . . for the support of research in the treatment and rehabilitation of individuals injured by burns." [Jointly administered with the National Institute of General Medical Sciences (NIH).]

2. Public Health Service Hospitals

a) Public Health Service Act • P.L. 78-410$321 (1944) and amended • 42 USC §248	Implied	"The Surgeon General, pursuant to regulations, shall— (a) Control, manage, and operate all institutions, hospitals and stations of the service, . . . and provide for the care, treatment, and hospitalization of patients . . . "

C. Indian Health Service

a) Indian Health Care Improvement Act Q P.L. 94-437 §503 (1976) • 25 USC §1653	Specific	(a) "The Secretary, acting through the Service, shall place such conditions as he deems necessary to effect the purpose of . . . title [25] in any contract which he makes with any urban Indian organization pursuant to this title. Such conditions shall include, but are not limited to, requirements that the organization successfully undertake the following activities: (1) determine the population of urban Indians which are or could be recipients of health referral or care services; (2) identify all public and private health service resources within the urban center in which the organization is.situated which are or may be available to urban Indians; * * * (7) identify gaps between unmet health needs of urban Indians and the resources available to meet such needs;

C. Indian Health Service—continued

Legal citation	Type of authority	Legislative text
		(8) make recommendations to the Secretary and Federal, State, local, and other resource agencies on methods of improving health service programs to meet the needs of urban Indians; . . .
	Implied	(b) The Secretary, acting through the Service, shall by regulation prescribe the criteria for selecting urban Indian organizations with which to contract pursuant to this title. Such criteria shall, among other factors, take into consideration: (1) the extent of the unmet health care needs of urban Indians in the urban center involved; (2) the size of the urban Indian population which is to receive assistance; (3) the relative accessibility which such population has to health care services in such urban center; . . . "
b) Indian Health Care Improvement Act • P.L. 94-437$505 (1976) • 25 USC §1655	General	"For each fiscal year during which an urban Indian organization receives or expends funds pursuant to a contract under . . . title [25], such organization shall submit to the Secretary a report including information gathered pursuant to section 503(a)(7) and (8) [25 USC §1653(a)(7), (8)] . . . and such other information as the Secretary may request. . . . "

V11. NATIONAL INSTITUTES OF HEALTH

Legal citation	Type of authority	Legislative text
A. General Authority Applicable to all NIH Institutes		
a) Public Health Service Act • P.L. 78-410 §301 (1944), as amended by P.L. 95-622 §262 (1978) • 42 USC §241	General	(b)(2)(A) "The secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts. (B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation. (3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatmentof disease and on the maintenance a-rid promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity. . . . "
b) Public Health Service Act • P.L. 78-410$431, as added by P.L. 81-692 §2(b) (1950) • 42 USC §289a	Implied	(b) "The Surgeon General is authorized with the approval of the Secretary to establish in the Public Health Service one or more additional institutes to conduct and support scientific research and professional training relating to the cause, prevention, and methods of diagnosis and treatment of other particular diseases or groups of diseases . . . whenever the Surgeon General determines that such action is necessary to effectuate fully the purposes of section 241 of . . . title [42] with respect to such disease or diseases . . . "*

*Section 301 of the Public Health Service Act, 42 USC $241, is the general data collection authority for the Secretary of HEW.

A. **General** *Authority Applicable to All NIH Institutes—continued*

Legal citation	Type of authority	Legislative text
c) Public Health Service Act • P.L. 78-410$433, as added by P.L. 81-692 §2(b) (195o), and amended • 42 USC §289c	Implied	(a) "Where an institute has been established under this part, the Surgeon General shall carry out the purposes of se&ion 241 of . . . title [42] with respect to the conduct and support of research relating to the disease or diseases to which the activities of the institute are directed, through such institute and in cooperation with the national advisory council or committee established or expanded by reason of the establishment of such institute. The provisions of this subsection shall also be applicable to any institute established by any other provision of this chapter to the extent that such institute does not already have the authority conferred by this subsection."*

B. Fogarty International Center

a) International Health Research Act • P.L. 86-610$5 (1960), and amended • 22 USC §2103	General	(b) "To carry out the purposes of section 2101 of . . . title [22], the President, in cooperation with participating foreign countries, is authorized to encourage, support, and promote the planning and conduct of, , . . research investigations, experiments, and studies in the United States and in participating foreign countries relating to the causes, diagnosis, treatment, control and prevention of diseases and impairments of mankind (including nutritional and other health deficiencies) ***or*** to the rehabilitation of the handicapped. * * * (f) The President may delegate any authority vested in him by this section to the Secretary of Health, Education, and Welfare. (h) The President shall transmit to the Congress at the beginning of each regular session, a report summarizing activities under this section and making such recommendations as he may deem appropriate. "

● Section 301 of the Public Health Service Act, **42** USC **§241, is the general data collection authority** for the Secretary of HEW.

C. National Cancer Institute

Legal citation	Type of authority	Legislative text

C. National Cancer Institute

a) Public Health Service Act ● P.L. 78-410 ~301 (1944), as amended by P.L. 95-622 $262 (1978) ● 42 USC §241	General	(b)(l) "The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.
	Specific	(4) The Secretary shall' publish an annual report which contains— (A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed; (B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances; (C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and (D) a description of (i) each request received during the year involved– (1) from a Federal agency outside the Department of Health, Education, and Welfare for the Secretary, or (II) from an entity within the Department of Health, Education, and Welfare to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and

C. National Cancer institute—continued

Legal citation	Type of authority	Legislative text
		(ii) how the Secretary and each such other entity, . respectively, have responded to each such request.
b) Public Health Service Act • P.L. *78-410$401, (1944)* formerly §402, renumbered and amended by P.L. 95-622, §241 (1978) • 42 USC §282	General	(a) "In carrying out the purposes of section 301 [42 USC y$241] with respect to cancer, the Secretary, through the Institute and in cooperation with the National Cancer Advisory Board, shall– (1) conduct, assist, and foster research, investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of cancer; . . . "*
c) Public Health Service Act • P.L. 78-410, §403 formerly y§409, renumbered and amended by P.L. 95-622 (1978) • 42 USC §284	Implied	"The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include— (1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting the detection, diagnosis, prevention, and treatment of cancer and rehabilitation and counseling respecting cancer to physicians and other health professionals who provide care to individuals who have cancer; . . .
d) Public Health Service Act • P.L. 78-410$404, as added by P.L. 92-218, $3(a), (1971), formerly §407, renumbered and amended and amended by P.L. 95-622 §241 (1978) • 42 USC §285	Specific	(a) "The Director of the Institute in carrying out the National Cancer Program shall— (1) collect analyze, and disseminate information (including information~mation respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country; . . . "

*Section **301** of the Public Health Service Act, 42 USC **§241,** is the general data collection authority for the Secretary of HEW.

C. National Cancer Institute—continued

Legal citation	Type of authority	Legislative text
e) Clean Air Act • P.L. 88-206 §154, as added by P.L. 95-95, §125 (1977) • 42 USC §7454	Implied	(e) "The Secretary of Health, Education, and Welfare shall encourage and support continuing research programs that will increase scientific knowledge of the effects of changes in the ozone in the stratosphere upon human health. Such Secretary shall transmit reports by January 1, 1978, and biennially thereafter, to the Administrator and the Congress on the results of such programs, together with any appropriate recommendations for legislation or regulation (or both). " [Environmental Protection Agency has primary responsibility for this authority, but EPA coordinates with the National Cancer Institute and the National Institute of Environmental Health Sciences.]

D. National Eye Institute

a) Public Health Service Act • P.L. 78-410 §451 as added by P.L. 90-489 §1 (1968) • 42 USC §289i	Implied	"The Secretary is authorized to establish in the Public Health Service an institute for the conduct and support of research for new treatment and cures and training relating to blinding eye diseases and visual disorders, including research and training in the special health problems and requirements of the blind and in the basic and clinical sciences relating to the mechanism of the visual function and preservation of sight. The Secretary is also authorized to plan for research and training, especially against the main causes of blindness and loss of visual function. "
b) Public Health Service Act • P.L. 78-410 §453 as added by P.L. 90-489$1 (1968) and amended 42 USC §289k	General	The Secretary shall, through the National Eye Institute established under this part, carry out the purposes of section 241 of . . . title [42], with respect to the conduct and support of research with respect to blinding eye diseases and visual disorders associated with general health and well-being, including the special health problems and requirements of the blind and the mechanism of sight and visual function, except that the Secretary shall determine the areas in which and the extent to which he will carry out such purposes of section 241 of this title through such Institute or an institute established by or under other provisions of this chapter, or both of them, when both such institutes have functions with respect to the same subject matter. . . . "*

*Section 301 of the Public Health Service Act, 42 USC §241, is the general data collection authority for the Secretary of HEW.

Legal citation	Type of authority	Legislative text

E. National Heart, Lung, and Blood Institute

a) Public Health Service Act • P.L. 78-410 §412 as added by P.L. 80-655 $3(b) (1948), and amended • 42 USC §287a	General	"In carrving out the purposes of section 241 of . . . title [42] with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources the Secretary, through the Institute and in cooperation with the National Heart, Lung, and Blood Advisory Council (hereinafter in this part referred to as the "Council"), shall— (1) conduct, assist, and foster researches, investigations, experiments, and demonstrations relating to the cause, prevention and methods of diagnosis and treatment of heart, blood vessel, lung, and blood diseases and to the use of blood and blood prod~cts and the management of blood resources; . . . (5) establish an information center on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases and on the use of blood and blood products and the management of blood resources, and collect and make available on a timely basis, through publications and other appropriate means, information as to, and the practical application of, research and other activities carried on pursuant to this part; . . . "*
b) Public Health Service Act • P.L. 78-410$413, as added by P.L. 92-423 §3(3) (1972) and amended 42 USC §287b	General	(a) "The Director of the Institute, with the advice of the Council, shall develop a plan for a National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this part referred to as the "Program") to expand, intensify, and coordinate the activities of the Institute respecting heart, blood vessel, lung, and blood diseases and blood resources (including its activities under section 287a of this title) and shall carry out the Program in accordance with such plan. The Program shall . . . provide for— (1) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases; (2) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

● Section 301 of the Public Health Service Act, **42 USC §241,** is the general data collection authority for the Secretary of HEW.

E. National Heart, Lung, and Blood Institute—continued

Legal citation	Type of authority	Legislative text
		(3) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including emergency medical service), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases; . . . (5) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases; (6) studies **and** research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of its resources in this country, including the collection, preservation, fractionalization, and distribution of it and its products; . . . (9) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, and hemolytic and hemophilia diseases) for the development and demonstration of diagnostic, treatment, and preventive approaches to these diseases; and (10) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung or blood diseases, . . .
	Implied	(d) . . . The Director of the Institute, acting through the Assistant Director for Prevention Education, and Control, shall conduct a program to provide on a timely basis the public and the health professions with health information with regard to cardiovascular, blood and pulmonary diseases and blood resources. In the conduct of such program, special emphasis shall be placed upon dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary and blood diseases. ”

E. National Heart, Lung, and Blood institute—continued

Legal citation	Type of authority	Legislative text
c) Public Health Service Act • P.L. 78-410$418, formerly §414, as added by P.L. 80-655 $3(b) (1948), and amended • 42 USC §287g	Implied	(a)(5) "The [National Heart, Lung, and Blood Advisory] Council is authorized to— . . . collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, or methods of diagnosis or treatment of heart, blood vessel, lung and blood diseases and to the use of blood and blood products and the management of blood resources, . . . and . . . make available such information through appropriate publication for the benefit of health and welfare agencies and organizations . . . , physicians, or any other scientists, and for the information of the general public; . . .
d) Public Health Service Act • P.L.78-41O §419A formerly §413, as added by P.L. 80-655 $3(b) (1948), and amended • 42 USC §287h	General	(a) "In carrying out the provisions of section 287a of this title all appropriate provisions of section 241 of . . . title [42] shall be applicable to the authority of the Secretary . . . "*

F. National Institute on Aging

a) Public Health Service Act • P.L. *78-410 §463,* as added by P.L. *93-296, §3 (1974)* • 42 USC §289k-4	General	(a) "The Secretary (1) shall, through the Institute, carry out the purposes of section 241 of . . . title [42] with respect to research investigation, experiments, demonstrations, and studies related to the aging process and the diseases and other special problems and needs of the aged, except that the Secretary shall determine the area in which and the extent to which he will carry out such activities in furtherance of the purposes of section 241 of . . . title [42] through the Institute or another institute established by or under other provisions of this chapter, or both of them, when both such institutes have functions with respect to the same subject matter, . . .
	Specific	(b) The Secretary shall, through the Institute, conduct scientific studies to measure the impact on the biological, medical, and psychological aspects of aging of all programs and activities assisted or conducted by the Department of Health, Education, and Welfare.

***Section 301 of the Public Health** Service Act, **42** USC **§241, is** the general data collection authority for the *Secretary* of HEW.

F. National Instltute on Aging—continued

Legal citation	Type of authority	Legislative text
	Implied	(c) The Secretary, through the Institute, shall carry out public information and education programs designed to disseminate as widely as possible the findings of Institute-sponsored and other relevent aging research and studies and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older."*

G. National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) relies on the general authority of the Secretary of HEW applicable to all Institutes within NIH, specifically 42 USC 289a(b) and 289c(a).

H. National Institute of Arthritis, Metabolism, and Digestive Diseases

a) Public Health Service Act • P.L. 78-410 §431 as added by P.L. 81-692 §2(b) (1950) and amended • *42* USC **Y§289a**	Implied	**"(a) The Surgeon General shall establish** in the Public Health Service an institute for research on arthritis, rheumatism, digestive diseases, and metabolism, and an institute for research on neurological diseases (including epilepsy, cerebral palsy, and multiple sclerosis) and blindness, and he shall also establish a national advisory council or committee for each such institute to advise, consult with, and make recommendations to him with respect to the activities of the institute with which each council or committee is concerned. " [Jointly administered with the National Institute of Neurological and Communicative Disorders and Stroke (NIH).]
b) Public Health Service Act • P.L. 78-410 §434, as added by P.L. 92-305$1 (a) (1972), and amended • 42 USC §289c-1	General	(c) "The Director of the Institute, acting through the Associate Director for Digestive Diseases, shall (1) carry out, at the facilities of the Institute, a program of research in the diagnosis, prevention, and treatment of digestive diseases; and (2) carry out programs of support for research and training . . . in the diagnosis, prevention, and treatment of digestive diseases, including support for . , . epidemiology studies, clinical trials, and interdisciplinary research programs. (d) The Director of the National Institute of Arthritis,

'Section 301 of the Public Health Service Act, 42 USC §241, is the general data collection authority for the Secretary of HEW.

H. National Institute of Arthritis, Metabolism, and Digestive Diseases—continued

Legal citation	Type of authority	Legislative text
		Metabolism, and Digestive Diseases, working through the Associate Director for Diabetes . . . shall— (1) carry out programs of support for research and training in the diagnosis, prevention, and treatment of diabetes mellitus and related endocrine and metabolic diseases, and (2) establish programs of evaluation, planning, and dissemination of knowledge related to research and training in diabetes mellitus and related endocrine and metabolic diseases. ”
b) Public Health Service Act • P.L. 78-410$435, as added by P.L. 93-354 $5(a) (1974) • 42 USC §289c-2	General	(a) “Consistent with applicable recommendations of the National Commission on Diabetes, the Secretary shall provide for the development, or substantial expansion, of centers for research and training in diabetes mellitus and related endocrine and metabolic disorders. Each center developed or expanded under this section shall . . . (2) conduct (A) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic disorders and the complications resulting from such disease or disorders, . . . (C) information programs for physicians and allied health personnel who provide primary care for patients with such disease, disorders, or complications . . . “
d) Public Health Service Act • P.L. 78-410 §436A, as added by P.L. 94-562 §201(a) (1976) • 42 USC §289c-3a	General	(f) “The [National Diabetes Advisory] Board shall– (1) review and evaluate the implementation of the long range plan to combat diabetes mellitus (hereinafter in this section referred to as the “Diabetes Plan”) formulated by the National Commission on Diabetes under section 3(e) of the National Diabetes Mellitus Research and Education Act, . . . (g) The Board may collect such data as it deems advisable and necessary to enable it to perform the functions required by subsection (f) of this section. * * *
	Implied	(j) One year after the date of its establishment and each year thereafter the Board shall submit to the Secretary and to the Congress a report— (2) which describes and evaluates the progress made in such year in diabetes research, . . . “

H. National Institute of Arthritis, Metabolism, and Digestive Diseases—continued

Legal citation	Type of authority	Legislative text
e) Public Health Service Act ● P.L. 78-410$438, as added by P.L. 93-640$4 (1975), and amended ● 42 USC §289c-5	Specific	(c)(1) "As soon as practicable after January 4, 1975, the Secretary, through the Assistant Secretary for Health, shall establish the Arthritis Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with asymptomatic and symptomatic types of arthritis, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis. (2) The Secretary shall provide for standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects under this section and centers assisted under section 289c-6 of this title, and other persons engaged in arthritis programs. "
f) Public Health Service Act P.L. 78-410 §439, as added by P.L. 93-640 §4 (1975) and amended ● 42 USC §289c-6	General	(b) Each [comprehensive arthritis] center assisted under this section shall— . . . (2) conduct– (A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of, arthritis and complications resulting from arthritis, including research into implantable biomaterials and biomechanical and other orthopedic procedures and in the development of other diagnostic and treatment methods; . . . (C) information and continuing education programs for physicians and other health and allied health professional who provide care for patients with arthritis; and (D) programs for the dissemination to the general public of information— (i) on the importance of early detection of arthritis, of seeking prompt treatment, and of following an appropriate regimen; and (ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices. (c) Each center assisted under this section may conduct programs to— (1) develop new and improved methods of screening and early detection, referral, and diagnosis of individuals with a risk of developing arthritis, asymptomatic arthritis,. or symptomatic arthritis, Implied (2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping. . . . "

H. National Institute of Arthritis, Metabolism, and Digestive Diseases—continued

Legal citation	Type of authority	Legislative text
g) Public Health Service Act . P.L. 78-410 §440, as added by P.L. 94-562 §~103(a) (1976) ● 42 USC §289c-7	General	(g) "The [National Arthritis Advisory] Board may collect such data as it deems advisable and necessary to enable it to perform the functions required by subsection (f) of this section. [respecting review and evaluation of the implementation of the Arthritis Plan]"

1. National Institute of Child Health and Human Development

a) Public Health Service Act P.L. 78-410$441, as added by P.L. 87-838$1 (1962) and amended 42 USC §289d	Implied	(a) "The Surgeon General is authorized, with the approval of the Secretary, to establish in the Public Health Service the National Institute of Child Health and Human Development for the conduct and support of research and training relating to maternal health, child health, and human development, ineluding research and training in the special health problems and requirements of mothers and children and in the basic sciences relating to the processes of human growth and development, including prenatal development.
	General	(b) The Secretary shall carry out through the National Institute of Child Health and Human Development the purposes of section 241 of . . . title [42] with respect to the conduct and support of research which specifically relates to sudden infant death syndrome."*
b) Public Health Service Act P.L. 78-410$1004 as added by P.L. 91-572 §6(c), (1970), and amended ● *42* USC §300a-2	General	(a) "The Secretary may– (1) conduct, and (2) make grants . . . and enter into contracts . . . for projects for, research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population . . . " [Jointly administered with Family Planning, Bureau of Community Health Services (HSA).]

***Section 301 of the Public Health Service Act, 42 USC §241, is the general data collection authority for the Secretary of HEW.**

Legal citation	Type of authority	Legislative text

J. National Institute of Dental Research

a) Public Health Service Act • P.L. 78-410 §422, as added by P.L. 80-755 §3(b), (1948), and amended • 42 USC §288a	General	"In carrying out the purposes of section 241 of . . . title [42] with respect to dental diseases and conditions the Surgeon General, through the Institute and in cooperation with the National Advisory Dental Research Council (hereafter in this part referred to as the "Council"), shall— (a) Conduct, assist, and foster researches, [sic], investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of dental diseases and conditions; . . . "*
b) Public Health Service Act • P.L. 78-410$423, as added by P.L. 80-755 §3(b), (1948), and amended • 42 USC §288b	General	(a) "In carrying out the provisions of section 288a of this title all appropriate provisions of section 241 of . . . title [42] shall be applicable to the authority of the Surgeon General, . . . "*
c) Public Health Service Act • P.L. 78-410 §424, as added by P.L. 80-755 §3(b), (1948) • 42 USC §288c	Implied	"The Council is authorized to— * * * (b) Collect information as to studies which are being carried on in the United States or any other country as to the cause, prevention, or methods of diagnosis or treatment of dental diseases and conditions, . . . and with the approval of the Surgeon General make available such information through appropriate publications for the benefit of health agencies and organizations (public or private), physicians, dentists, or any other scientists, and for the information of the general public; . . . "

*Section 301 of the Public Health Service Act, 42 USC §241, is the general data collection authority for the Secretary of HEW.

Legal citation	Type of authority	Legislative text
K. National Institute of Environmental Health Sciences		
a) Energy Supply and Environmental Coordination Act of 1974 • P.L. 93-319$7 (1974) • 15 USC §793	Specific	(b) "In order to determine the health effects of emissions of sulfur oxides to the air resulting from any conversions to burning coal to which section I857c-10 of Title 42 applies, the Department of Health, Education, and Welfare shall, through the National Institute of Environmental Health Sciences and in cooperation with the Environmental Protection Agency, conduct a study of chronic effects among exposed populations. . . . " [Jointly administered with the Environmental Protection Agency (EPA).]
b) Health Services and Centers Amendments of 1978 • P.L. 95-626$209 (1978) • 42 USC §247a note	Specific	"The Secretary of Health, Education, and Welfare shall conduct a study to determine the long-term effect on child development of various levels of lead in blood. The Secretary shall report the results of such study to the Congress together with recommendations for such legislation as the Secretary determines is appropriate."
c) Clean Air Act • P.L. 88-206 §154, as added by P.L. 95-95, §125 (1977) • 42 USC §7454	Implied	(e) "The Secretary of Health, Education, and Welfare shall encourage and support continuing research programs that will increase scientific knowledge of the effects of changes in the ozone in the stratosphere upon human health. Such Secretary shall transmit reports by January 1, 1978, and biennially thereafter, to the Administrator and the Congress on the results of such programs, together with any appropriate recommendations for legislation or regulation (or both). " [Environmental Protection Agency has primary responsibility for this authority, but EPA coordinates with the National Cancer Institute and the National Institute of Environmental Health Sciences (NIH).]

L. **National Institute of General Medical** *Science*

Legal citation	Type of authority	Legislative text
L. National Institute of General Medical Science		
a) Public Health Service Act • P.L. 78-410 §442, as added by P.L. 87-838$1 (1962), and amended • 42 USC §289e	Implied	"The Surgeon General is authorized, with the approval of the Secretary, to establish in the Public Health Service an institute for the conduct and support of research and training in the general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other institutes, or are outside the general area of responsibility of any other institute, established under or by this chapter. "
b) Public Health Service Act • P.L. 78-410$1102, as added by P.L. 94-278 §403(a) (1976) • 42 USC §300b-1	General	"In carrying out section 241 of . . . title [42], the Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, . . . In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia. " * [Jointly administered with the Genetic Disease, Hemophilia and SIDS program, Bureau of Community Health Services (HSA).]
c) Public Health Service Act • P.L. 78-410$1221, as added by P.L. 94-573 §14(3), (1976) • 42 USC §300d-21	General	(a)(l) "The Secretary may make grants to, and enter into contracts with, public or private nonprofit entities for the support of, and may conduct, programs for the establishment, operation, and improvement of activities to (A) demonstrate the effectiveness of different methods for the treatment and rehabilitation of individuals injured by burns, (B) conduct research in the treatment and rehabilitation of such individuals, . . . " [Jointly administered with the Emergency Medical Services Bureau of Medical Services (HSA).]

*Section 301 of the Public Health Service Act, 42 USC§241, is the general data collection authority for the Secretary of HEW.

M. National Institute of Neuroiogical and Communicative Disorders and Stroke

Legal citation	Type of authority	Legislative text

M. National Institute of Neurological and Communicative Disorders and Stroke

a) Public Health Service Act • P.L. 78-410$431 as added by P.L. 81-692 $2(b) (195o) and amended • 42 USC §289a	Implied	(a) "The Surgeon General shall establish in the Public Health Service an institute for research on arthritis, rheumatism, digestive diseases, and metabolism, and an institute for research on neurological diseases (including epilepsy, cerebral palsy, and multiple sclerosis) and blindness, and he shall also establish a national advisory council or committee for each such institute to advise, consult with, and make recommendations to him with respect to the activities of the institute with which each council or committee is concerned. " [Jointly administered with the National Institute of Arthritis, Metabolism and Digestive Diseases (NIH).]

N. National Library of Medicine

a) Public Health Service Act • P.L. 78-410$390, as added by P.L. 89-291 $2(1965), and amended • 42 USC §280b	Implied	(a) "The Congress hereby finds and declares that (1) the unprecedented expansion of knowledge in the health sciences within the past two decades has brought about a massive growth in the quantity, and major changes in the nature of, biomedical information, materials, and publications; (2) there has not been a corresponding growth in the facilities and techniques necessary adequately to co-ordinate and disseminate among health scientists and practitioners the ever-increasing volume of knowledge and information which has been developed in the health science field; (3) much of the value of the ever-increasin$_g$ volume of knowledge and information which has been, and continues to be, developed in the health science field will be lost unless proper measures are taken in the immediate future to develop facilities and techniques necessary to collect, preserve, store, process, retrieve, and facilitate the dissemination and utilization of, such knowledge and information. (b) It is therefore the policy of this part to– (2) assist through grants physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists, in the compilation of existing, and the creation of additional, written matter which will facilitate the distribution and utilization of knowl-

N. National *Library of Medicine—continued*

Legal citation	Type of authority	Legislative text
		edge and information relating to scientific, social, and cultural advancements in sciences related to health; (3) assist in the conduct of research, investigations, and demonstrations in the field of medical library science and related activities, and in the development of new techniques, systems, and equipment for processing, storing, retrieving, and distributing information in the sciences related to health; . . . (5) assist in the development of a national system of regional medical libraries each of which would have facilities of sufficient depth and scope to supplement the services of other medical libraries within the region served by it; . . . "
b) Public Health Service Act • P.L. 78-410 ¦ §394, formerly §395, as added by P.L. 89-291 §2 (1965) and amended • 42 USC §280b-5	Implied	(a) "To carry out the purposes of section 280b(b)(2) of this title, the Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists for the compilation of existing, or writing of original, contributions relating to scientific, social, or cultural, advancements in sciences related to health."
c) Public Health Service Act • P.L. 78-410 §~397, formerly §399, as added by P.L. 89-291 §2 (1965), renumbered §398 and amended • 42 USC §280b-9	Implied	(a) "To carry out the purposes of section 280b(b)(6) of this title, the Secretary, . . . shall make grants to, and enter into appropriate contracts . . . for the purpose of supporting biomedical scientific publications of a non-profit nature and to procure the compilation, writing, editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments. . .

VIII. HEALTH CARE FINANCING ADMINISTRATION

Legal citation	Type of authority	Legislative text

A. Office of the Administrator

1. Office of Policy, Planning, and Research

a) Public Health Service Act ● P.L. 78-410$1533, as added by P.L. 93-641, §3 (1974), and amended ● 42 USC §300n-2	Specific	(d) "The Secretary shall establish the following within one year of January 4, 1975: (1) A uniform system for calculating the aggregate cost of operation and the aggregate volume of services provided by health services institutions as defined by the Secretary in regulations. Such system shall provide for the calculation of the aggregate volume to be based on: (A) The number of patient days; (B) The number of patient admissions; (C) The number of outpatients visits; and (D) Other relevant factors as determined by the Secretary. (2) A uniform system for cost accounting and calculating the volume of services provided by health services institutions. Such system shall: (A) Include the establishment of specific cost centers and, where appropriate, subcost centers. (B) Include the designation of an appropriate volume factor for each cost center. (C) Provide for an appropriate application of such system in the different types 'of institutions (including hospitals, nursing homes, and other types of health services institutions), and different sizes of such types of institutions. (3) A uniform system for calculating rates to be charged to health insurers and other health institutions payers by health service institutions. Such system shall: (A) Be based on all-inclusive rate for various categories of patients (including, but not limited to individuals receiving medical, surgical, pediatric, obstetric, and psychiatric institutional health services). (B) Provide that such rates reflect the true cost of providing services to each such category of patients. The system shall provide that revenues derived from patients in one category shall not be used to support the provision of services to patients in any other category. (C) Provide for an appropriate application of such system in the different types of institutions (incIuding hospitals, nursing homes, and other types of health service institutions) and different sizes of such types of institutions. (D) Provide that differences in rates to various classes of purchasers (including health insurers, direct service payers,

A. *Office of* **the Administrator**
1. *Office of Policy, Planning, and Research—continued*

Legal citation	Type of authority	Legislative text
		and other health institution payers) be based on justified and documented differences in the costs of operation of health service institutions made possible by the actions of such purchasers. (4) A classification system for health services institutions. Such classification system shall quantitatively describe and group health services institutions of the various types. Factors included in such classification system shall include— (A) the number of beds operated by an institution; (B) the geographic location of an institution; (C) the operation of a postgraduate physician training program by an institution; and (D) the complexity of services provided by an institution. (5) A uniform system for the reporting by health services institutions of— (A) the aggregate cost of operation and the aggregate volume of services, as calculated in accordance with the system established by the Secretary under paragraph (l); (B) the costs and volume of services at various cost centers, and subcost centers, as calculated in accordance with the system established by the Secretary under paragraph (2); and (C) rates, by **category** of patient and class of purchaser, as calculated in accordance with the system established by the Secretary under paragraph (3). Such system shall provide for an appropriate application of such system in the different types of institutions (including hospitals, nursing homes, and other types of health services institutions) and different sizes of such institutions. ”
b) Social Security Act • P.L. 74-241, §1121, as added by P.L. 95-142, $19(a) (1977) • 42 USC §1320a	Specific	(a) “For the purposes of reporting the cost of services provided by, of planning, and of measuring and comparing the efficiency of and effective use of services in hospitals, skilled nursing facilities, intermediate care facilities, home health agencies, health maintenance organizations, and other types of health services facilities and organizations to which payment may be made under this Act, the Secretary shall establish by regulation, for each such type of health services facility or organization, a uniform system for the reporting by a facility or organization of that type of the following information: (I) The aggregate cost of operation and the aggregate volume of services.

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1. *Office of Policy, Planning, and Research—continued*

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(2) The costs and volume of services for various functional accounts and subaccounts.

(3) Rates, by category of patient and class of purchaser.

(4) Capital assets, as defined by the Secretary, including (as appropriate) capital funds, debt service, lease agreements used in lieu of capital funds, and the value of land, facilities, and equipment.

(5) Discharge and bill data.

The uniform reporting system for a type of health services facility or organization shall provide for appropriate variation in the application of the system to different classes of facilities or organizations within that type and shall be established, to the extent practicable, consistent with the cooperative system for producing comparable and uniform health information and statistics described in section 306(e)(l) of the Public Health Service Act. In reporting under such a system, hospitals shall employ such chart of accounts, definitions, principles, and statistics as the Secretary may prescribe in order to reach a uniform reconciliation of financial and statistical data for specific uniform reports to be provided to the Secretary.

(b) The Secretary shall–

(1) monitor the operation of the systems established under subsection (a);

(2) assist with and support demonstration and evaluations of the effectiveness and cost of the operation of such systems and encourage State adoption of *such system;* ***and***

(3) periodically revise such systems to improve their effectiveness and diminish their cost.

(c) The Secretary shall provide information obtained through use of the uniform reporting systems described in subsection (a) in a useful manner and format to appropriate agencies and organizations, including health systems agencies (designated under section I515 of the Public Health Service Act) and State health planning and development agencies (designated under section 1521 of such Act), as may be necessary to carry out such agencies' and organizations' functions. "

[This authority is delegated to the Health Care Financing Administration, and HCFA is directed to coordinate with the ***Na***tional Center for Health Statistics (OASH).]

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Legal citation	Type of authority	Legislative text
c) Social Security Act Amendments of 1967 • P.L. 90-248, $402(a), (1967) and amended • 42 USC §1395b-1	Implied	(a)(l) "The Secretary of Health, Education, and Welfare is authorized, either directly or through grants . . . or contracts . . . to develop and engage in experiments and demonstration projects for the following purposes: (A) to determine whether, and if so which, changes in methods of payment or reimbursement (other than those dealt with in section 222 (a) of the Social Security Amendments of 1972) for health care and services under health programs established by this chapter, including a change to methods based on negotiated rates, would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services; (B) to determine whether payments for services other than those for which payment may be made under such programs (and which are incidental to services for which payment may be made under such programs) would, in the judgment of the Secretary, result in more economical provision and more effective utilization of services for which payment may be made under such program, where such services are furnished by organizations and institutions which have the capability of providing— (i) comprehensive health care services, (ii) mental health care services (as defined by section 2691(c) of this title), (iii) ambulatory health care services (includes surgical services provided on an outpatient basis), or (iv) institutional services which may substitute, at lower cost, for hospital care; (C) to determine whether the rates of payment or reimbursement for health care services, approved by a State for purposes of the administration of one or more of its laws, when utilized to determine the amount to be paid for services furnished in such State under the health programs established by this chapter, would have the effect of reducing the costs of such programs without adversely affecting the quality of such services; (D) to determine whether payments under such programs based on a single combined rate of reimbursement or charge for the teaching activities and patient care which residents, interns, and supervising physicians render in connection with a graduate medical education program in a pa-

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1. *Office of Policy, Planning, and Research—continued*

Legal citation	Type of authority	Legislative text

tient facility would result in more equitable and economical patient care arrangements without adversely affecting the quality of such care;

(E) to determine whether coverage of intermediate care facility services and homemaker services would provide suitable alternatives to posthospital benefits presently provided under subchapter XVIII of this chapter; such experiment and demonstration projects may include:

(i) counting each day of care in an intermediate care facility as one day of care in a skilled nursing facility, if such care was for a condition for which the individual was hospitalized,

(ii) covering the services of homemakers for a maximum of 21 days, if institutional services are not medically appropriate,

(iii) determining whether such coverage would reduce long-range costs by reducing the lengths of stay in hospitals and skilled nursing facilities, and

(iv) establishing alternative eligibility requirements and determining the probable cost of applying each alternative, if the project suggests that such extension of coverage would be desirable;

(F) to determine whether, and if so which types of, fixed price or performance incentive contract would have the effect of inducing to the greatest degree effective, efficient, and economical performance of agencies and organizations making payment under agreements or contracts with the Secretary for health care and services under health programs established by this chapter;

(G) to determine under what circumstances payment for services would be appropriate and the most appropriate, equitable, and noninflationary methods and amounts of reimbursement under health care programs established by this chapter for services, which are performed independently by an assistant to a physician including a nurse practitioner (whether or not performed in the office of or at a place at which such physician is physically present), and—

(i) which such assistant is legally authorized to perform by the State or political subdivision wherein such ***serv***-ices are performed, and

(ii) for which such physician assumes full legal and ethical responsibility as to the necessity, propriety, and quality thereof;

(H) to establish an experimental program to provide day-care services, which consist of such personal care, super-

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1. *Office of Policy, Planning, and Research—continued*

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		vision, and services as the Secretary shall by regulation prescribe, for individuals eligible to enroll in the supplemental medical insurance program established under part B of this subchapter and subchapter XIX of this chapter, in day-care centers which meet such standards as the Secretary shall by regulation establish; and (I) to determine whether the services of clinical psychologists may be made more generally available to persons eligible for services under this subchapter and subchapter XIX of this chapter in a manner consistent with quality of care and equitable and efficient administration. . . . "
d) Social Security Act ● P.L. 74-241, 51861(v)(1)(F), as added by P.L. 95-142, §19(b) (1977) ● 42 USC §1395 X	Specific	(v)(l)(F) "Such regulations [e.g. to determine the definition of reasonable costs for health service facilities] shall require each provider of services . . . to make reports to the Secretary of information described in section l121(a) [42 USC §1320a] in accordance with the uniform reporting system (established under such section) for that type of provider. "
e) Social Security Act Amendments of 1972 ● P.L. 92-603 §245 (a)(c) (1972), and amended ● 42 USC $1395x note 1	Implied	(a) "The Secretary is authorized to conduct reimbursement experiments designed to eliminate unreasonable expenses resulting from prolonged rentals of durable medical equipment described in section 1861(s)(6) of the Social Security Act [subsec. (s)(6) of this section]. (c) The Secretary is authorized, at such time as he deems appropriate, to implement on a nationwide basis any such reimbursement procedures which he finds to be workable, desirable and economical and which are consistent with the purposes of this section. "

Legal citation	Type of authority	Legislative text
B. Health Standards and Quality Bureau		
a) Public Health Service Act ● P.L. 78-410, §353, as added by P.L. 90-174, $5(a), (1967) ● 42 USC §263a	General	(d)(l) "A license shall not be issued in the case of any clinical laboratory unless (A) the application therefore contains or is accompanied by such information as the Secretary finds necessary, and (B) the applicant agrees and the Secretary determines that such laboratory will be operated in accordance with standards found necessary by the Secretary to carry out the purposes of this section. Such standards shall be designed to assure consistent performance by the laboratories of accurate laboratory procedures and services, and shall include, among others, standards to assure— (i) maintenance of a quality control program adequate and appropriate for accuracy of the laboratory procedures and services; (ii) maintenance of records, equipment, and facilities necessary to proper and effective operation of the laboratory; (iii) qualifications of the director of the laboratory and other supervisory professional personnel necessary for adequate and effective professional supervision of the operation of the laboratory (which shall include criteria relating to the extent to which training and experience shall be substituted for education); and (iv) participation in a proficiency testing program established by the Secretary. " [Jointly administered with the Center for Disease Control.]
b) Social Security Act ● P.L. 74-241 §1106 as added by Act of Aug. 10, 1939, §802 and amended ● 42 USC §1306	Implied	(d) "Notwithstanding any other provision of this section the Secretary shall make available to each State agency operating a program under subchapter XIX of this chapter and shall, . . . make available for public inspection in readily accessible form and fashion, the following official reports . . . dealing with the operation of the health programs established by subchapters XVIII and XIX of this chapter— . . . (3) program validation survey reports and other formal evaluations of the performance of providers of services, including the reports of follow-up reviews except that such reports shall not identify individual patients, individual health care practitioners, or other individuals. " [Jointly administered with Medicare, and Medicaid (HCFA).]

B. Health Standards and Quality Bureau—continued

Legal citation	Type of authority	Legislative text
c) Social Security Act • P.L. 74-241 §1155, as added by P.L. 92-603 §249F (b), (1972), and amended • 42 USC §1320c-4	General	(f)(l) "An agreement entered into under this part between the Secretary and any organization . . . designated as the Professional Standards Review Organization for any area shall provide that such organization will— (B) collect such data relevant to its functions and such information and keep and maintain such records in such form as the Secretary may require to carry out the purposes of this part and to permit access to and use of any such records as the Secretary may require for such purposes."
d) Social Security Act • P.L. 74-241 §1156, as added by P.L. 92-603 §249F (1972), and amended • 42 USC §1320c-5	Specific	(a) "Each Professional Standards Review Organization shall apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice in its regions (including typical lengths-of-stay for institutional care by age and diagnosis) as principal points of evaluation and review. The National Professional Standards Review Council and the Secretary shall provide such technical assistance to the organization as will be helpful in utilizing and applying such norms of care, diagnosis, and treatment. * * * (c)(l) The National Professional Standards Review Council shall provide for the preparation and distribution, to each Professional Standards Review Organization and to each other agency or person performing review functions . . . of appropriate materials indicating the regional norms to be utilized pursuant to this part. Such data concerning norms shall be reviewed and revised from time to time. The approval of the National Professional Standards Review Council of norms of care, diagnosis, and treatment shall be based on its analysis of appropriate and adequate data. . . . (d)(l) Each Professional Standards Review Organization shall— (B) require that there be included in any such certification [of medical necessity for in-patient treatment] with respect to any patient such information as may be necessary to enable such organization properly to evaluate the medical necessity of the further institutional health care recommended by the physician executing such certification.
	Implied	(2) The points in time at which any such certification will be required . . . shall be consistent with and based on professionally developed norms of care and treatment and data developed with respect to length of stay in health care institutions of patients having various illnesses, injuries. or health

B. Health Standards and Quality Bureau—continued

Legal citation	Type of authority	Legislative text
		conditions, and requiring various types of health care services or procedures. ”
e) Social Security Act • P. L.74-241 §1163, as added by P.L. 92-603 §249F(b) (1972) and amended • 42 USC §1320c-12	General	(a)(l) “There shall be established a National Professional Standards Review Council (hereinafter in this section referred to as the “Council”). (e) It shall be the duty of the Council to– * * * (2) provide for the development and distribution, among Statewide Professional Standards Review Councils and Professional Standards Review Organizations of information and data which will assist such review Councils and organizations in carrying out their duties and functions; . . . (4) make or arrange for the making of studies and investigations with a view to developing and recommending to the Secretary and to the Congress measures designed more effectively to accomplish the purposes and objectives of this part.”
f) Social Security Act • P.L. 74-241 §1171, as added by P.L. 95-142, §5 (1977) • 42 USC §1320 c-20	General	(e)(2) “Each Professional Standards Review Organization shall provide to the State agency for the State in which it is located, upon request, data or information which the Secretary requires such organizations to report to him routinely on a periodic basis, and such other data or information as the Secretary authorizes to be disclosed. ”
g) Social Security Act • P.L. 74-241$1172, as added by P.L. 95-142, §5 (1977) • 42 USC §1320c-21	Specific	“The Secretary shall submit to the Congress not later than April 1, 1978, and not later than April 1 of each year thereafter, a full and complete report on the administration, impact, and cost of the program under this part during the preceding fiscal year, including data and information on— * * * (2) the number of health care institutions and practitioners whose services are subject to review by Professional Standards Review Organizations, and the number of beneficiaries and recipients who received services subject to such review during such year; (5) changes in utilization rates and patterns, and changes in medical procedures and practices, attributable to the activities of Professional Standards Review Organizations;

B. Health Standards and Quality Bureau—continued

Legal citation	Type of authority	Legislative text
		(6) the results of program evaluation activities, including the operation of data collection systems and the status of Professional Standards Review Organization data policy and implementation; . . . "

C. Medicaid

a) Social Security Act • P.L. 74-241 §1106, as added by Act of Aug. 10, 1939, §802 and amended • 42 USC §1306	Implied	(d) "Notwithstanding any other provision of this section the Secretary shall make available to each State Agency operating a program under subchapter XIX of this chapter and shall, . . . make available for public inspection in readily accessible form and fashion, the following official reports . . . dealing with the operation of the health programs established by subchapters XVIII and XIX of this chapter— . . . (3) program validation survey reports and other formal evaluations of the performance of providers of services, including the reports of follow-up reviews, except that such reports shall not identify individual patients, individual health care practitioners, or other individuals. " [Jointly administered with Medicare and the Health Standards and Quality Bureau (HCFA).]
b) Social Security Act • P.L. 74-241 §1902, as added by P.L. 89-97 $121(a), (1965), and amended by P.L. 95-142 §19, (1977) • 42 USC §1396a	General	(a) "A State plan for medical assistance must— . . . (6) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time require, and comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports . . . (27) provide for agreements with every person or institution providing services under the State plan under which such person or institution agrees (A) to keep such records as are necessary fully to disclose the extent of the services provided to individuals receiving assistance under the State plan, and (B) to furnish the State agency or the Secretary with such information, regarding any payments claimed by such persons or institution for providing services under the State plan, as the State agency or the Secretary may from time to time request; . . .

C. Medicaid—continued

Legal citation	Type of authority	Legislative text
	Specific	(4o) require each health services facility or organization which receives payments under the plan and of a type for which a uniform reporting system has been established under section 1121(a) [42 USC §1320a] to make reports to the Secretary of information described in such section in accordance with the uniform reporting system (established under such section) for that type of facility or organization. "
c) Social Security Act • P.L. 74-241 §1903 (a)(3) as added by P.L. 92-603 §§235(a), 249B, 299 E(a), (1972) and amended • 42 USC §1396b	Implied	(a) "The Secretary . . . shall pay to each State which has a plan approved under this subchapter, for each quarter, beginning with the quarter commencing January 1, 1966— (3) an amount equal to— (A)(i) 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such mechanized claims processing and information retrieval systems as the Secretary determines are likely to provide more efficient, economical, and effective administration of the plan and to be compatible with the claims processing and information retrieval systems utilized in the administration of subchapter XVIII of this chapter, . . . and (B) 75 per centum of so much of the sums expended during such quarter as are attributable to the operation of systems . . . of the type described in subparagraph (A)(i) ., . "
d) Social Security Act • P.L. 74-241, §1908, as added by P.L. 90-248 §236(b) (1968), and amended • 42 USC §1396g	Implied	(c) "It shall be the function and duty of such agency or board [responsible for the licensing of administrators of nursing homes] to— . . . (2) develop and apply appropriate techniques, including examinations and investigations, for determining whether an individual meets such standards [e.g. standards to ensure that nursing home administrators are of good character]; . . . (6) conduct a continuing study and investigation of nursing homes and administrators of nursing homes within the State with a view to the improvement of the standards imposed for the licensing of such administrators and of procedures and methods for the enforcement of such standards with respect to administrators of nursing homes who have been licensed as such."

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D. Medicare

a) Social Security Act • P.L. 74-241$1106, as added by Act of Aug. 10, 1939, §802 and amended • 42 USC §1306	Implied	(d) "Notwithstanding any other provision of this section the Secretary shall make available to each State agency operating a program under subchapter XIX of this chapter and shall . . . make available for public inspection in readily accessible form and fashion, the following official reports . . . dealing with the operation of the health programs established by subchapters XVIII and XIX of this chapter— * * * (3) program validation survey reports and other formal evaluations of the performance of providers of services, including the reports of follow-up reviews, except that such reports shall not identify individual patients, individual health care practitioners, or other individuals. " [Jointly administered with Medicaid and the Health Standards and Quality Bureau (HCFA).]
b) Social Security Act • P.L. 74-241 §1816, as added by P.L. 89-97 $102(a) (1965), and amended • 42 USC §1395h	General	(b) "The Secretary shall not enter into or renew an agreement with any agency or organization under this section unless— * * * (2) such agency or organization agrees— (A) to furnish to the Secretary such of the information acquired by it in carrying out its agreement under this section, and (B) to provide the Secretary with access to all such data, information, and claims processing operations, as the Secretary may find necessary in performing his functions under this part; . . . "
c) Social Security Act • P.L. 74-241 §1842, as added by P.L. 89-97 $102(a), (1965), and amended • 42 USC §1395u	General	(b)(3) "Each such contract [with carriers to provide for administration of benefits under subchapter XVIII—Health Insurance for the Aged and Disabled] shall provide that the carrier— . . . (D) will furnish to the Secretary such timely information and reports as he may find necessary in performing his functions under this part; and (E) will maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under

D. *Medicare—continued*

Legal citation	Type of authority	Legislative text
		subparagraph (D) and otherwise to carry out the purposes of this part; . . . "
d) Social Security Act • P.L. 74-241, §1874, as added by P.L. 89-97 §§102(a), ill(a), (1965) and amended • 42 USC §1395kk	General	(b) "The Secretary may contract with any person, agency, or institution to secure on a reimbursable basis such special data, actuarial information, and other information as may be necessary in the carrying out of his functions under this subchapter. "
e) Social Security Act • P.L. 74-241$1875, as added by P.L. 89-97 §102(a) (1965) and amended • 42 USC §1395*ll*	General	(a) "The Secretary shall carry on studies and develop recommendations to be submitted from time to time to the Congress relating to health care of the aged and disabled, including studies and recommendations concerning (1) the adequacy of existing personnel and facilities for health care for purposes of the programs under parts A and B of this subchapter; (2) methods for encouraging the further development of efficient and economical forms of health care which are a constructive alternative to inpatient hospital care; and (3) the effects of the deductibles and coinsurance provisions upon beneficiaries, persons who provide health services, and the financing of the program. (b) The Secretary shall make a continuing study of the operation and administration of the insurance programs under parts A and B of this subchapter (including a validation of the accreditation process of the Joint Commission on the Accreditation of Hospitals, the operation and administration of health maintenance organizations authorized by section 1395mm of this title, the experiments and demonstration projects authorized by section 1395b-1 of this title, and the experiments and demonstration projects authorized by Section **222(a)** of the Social Security Amendments of 1972), and shall transmit to the Congress annually a report concerning the operation of such programs. "

D. Medicare—continued

Legal citation	Type of authority	Legislative text
f) Social Security Act • P.L. 74-24151881, as added by P.L. 95-292 §2 (1978) • 42 USC §1395rr	General	(b)(4) "pursuant to agreements with approved providers of services and renal dialysis facilities, the Secretary may make payments to such providers and facilities for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients whose self-care home dialysis is under the direct supervision of such provider or facility . . . (s) An agreement under paragraph (4) shall require . . . that the provider or facility will— * * * (B) perform all such administrative functions and maintain such information and records as the Secretary may require to verify the transactions and arrangements described in subparagraph (A); (C) submit such cost reports, data, and information as the Secretary may require with respect to the costs incurred for equipment supplies and services furnished to the facility's home dialysis patient population; and (D) provide for full access for the Secretary to all such records, data, and information as he may require to perform his functions under this section . . .
	Specific	(c)(l)(A) For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secretary shall establish, in accordance with such criteria as he finds appropriate, renal disease network areas, such network organizations . . . as he finds necessary to accomplish such purpose, and a national end stage renal disease medical information system. The Secretary may by regulations provide for such coordination of network planning and quality assurance activities and such exchange of data and information among agencies with responsibilities for health planning and quality assurance activities under Federal law as is consistent with the economical and efficient administration of this section and with the responsibilities established for network organization under this section . . . (2) The network organizations of each network shall be responsible, in addition to such other duties and function as may be prescribed by the Secretary for— . . . (E) submitting an annual report to the Secretary on July 1 of each year which shall include a full statement of the network's goals, data on the network's performance in meeting its goals (including data on the comparative performance of facilities and providers with respect to the identification and placement of suitable candidates in self-care settings and

D. **Medicare—continued**

Legal citation	Type of authority	Legislative text
		transplantation), identification of those facilities that have consistently failed to cooperate with network goals, and recommendations with respect to the need for additional or alternative services or facilities in the network in order to meet the network goals, including self-dialysis training, transplantation, and organ procurement facilities * * *
	General	(e)(1) Notwithstanding any other provision of this title, the Secretary may, pursuant to agreements with approved providers of services and renal dialysis facilities, reimburse such providers and facilities . . . for the reasonable cost of the purchase, installation, maintenance and reconditioning for subsequent use of artificial kidney and automated dialysis peritoneal machines . . . which are to be used exclusively by entitled individuals dialyzing at home. (2) An agreement under this subsection shall require that the provider or facility will— * * * (C) provide for full access for the Secretary to all records and information relating to the purchase, maintenance, and use of the equipment; and (D) submit such reports, data, and information as the Secretary may require with respect to the cost, management, and use of the equipment. * * *
	Specific	(g) The Secretary shall submit to the Congress on April 1, 1979, and April 1 of each year thereafter a report on the end stage renal disease program, including but not limited to— (1) the number of patients, nationally and by renal disease network, on dialysis (self-dialysis or otherwise) at home and in facilities; (2) the number of new patients entering dialysis at home and in facilities during the year; (3) the number of facilities providing dialysis and the utilization rates of those facilities; (4) the number of kidney transplants by source of donor organ; (5) the number of patients awaiting organs for transplant; (6) the number of transplant failures; (7) the range of costs of kidney acquisitions, by type of facility and by region; (8) the number of facilities providing transplants and the number of transplants performed per facility; (9) patient mortality and morbidity rates; (10) the average annual cost of hospitalization for an-

D. Medicare—continued

Legal citation	Type of authority	Legislative text
		cillary problems in dialysis and transplant patients, and drug costs for transplant patients; (11) medicare payment rates for dialysis, transplant procedures, and physician services, along with any changes in such rates during the year and the reasons for those changes; (12) the results of cost-saving experiments; (13) the results of basic kidney disease research conducted by the Federal Government, private institutions, and foreign governments; (14) information on the activities of medical review boards and other networks organizations; and (15) estimated program costs over the next five years."

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