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.

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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.

REFERENCES

1. Rice, D., Director, National Center for Health Statistics. Speech given before the National Leadership Conference, sponsored by the ***National Journal.*** Washington, D.C. May 23, 1978.
2. U.S. Department of Commerce, Office of Federal Statistical Policy and Standards. ***A Framework for U.S. Federal Statistics for the*** *1980's.* U.S. Government Printing Office. 1978.
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.
4. Wunderlich, G.. Director, Office of Policy Development and Planning, Office of Assistant Secretary of Health. Memorandum to George Hall, Statistical Policy Division, Office of Management and Budget. June 20, 1977.

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.