

The Model State Health Statistics Act

A Model State Law for the Collection, Sharing, and Confidentiality of Health Statistics

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PREFACE

The Model State Health Statistics Act is designed to be used by State legislators in developing laws for collecting, sharing, and protecting the confidentiality of health statistics. State legislators and State health officers are increasingly finding that:

- (1) An effective health care system is dependent on the availability of accurate and timely health data.
- (2) The confidentiality of data identifying individuals must be assured in order to encourage the voluntary provision of such data.
- (3) The sharing of health data by appropriate agencies within and among States and the Federal Government is of mutual advantage and necessary to determine the status of the health care system and evaluate its operation.

The purpose of the Model State Health Statistics Act, therefore, is to authorize through legislation an agency in the State to collect and maintain accurate health data, protect health data from unwarranted disclosure, share health data for purposes consistent with those for which they were collected, and coordinate health data activities in the State to eliminate unnecessary duplication of data collection and to maximize the usefulness of data collected.

The Act also recognizes the importance of and provides for State participation in the Cooperative Health Statistics System, a cooperative system for producing comparable health statistics at the national, State, and local levels.

This Act does not apply to vital statistics. Each State has already established a vital statistics agency. The National Center for Health Statistics developed in 1977 a revision of the Model State Vital Statistics Act for use by State legislators in revision of existing vital statistics acts. Although the Model State Health Statistics Act and the Model State Vital Statistics Act are designed as separate pieces of legislation, consideration should be given to designating one agency to carry out the purposes of both acts.

The Model State Health Statistics Act is the end product of a process which began in 1975. Based on principles formulated by the Cooperative Health Statistics Advisory Committee, a panel of State and Federal experts on statistics, confidentiality, and legislation drafted the Model State Health Statistics Act. The U.S. National Committee on Vital and Health Statistics endorsed the Model Act and urged its promulgation and wide distribution by the Secretary of Health, Education, and Welfare. The Council of State Governments included the Model Act in

its publication *1979 Suggested State Legislation*. The 1978 Governing Council of the American Public Health Association also recommended its enactment by State governments.

The responsibility for the development of the Model State Health Statistics Act was that of Mr. Garrie J. Losee, Deputy Director, Division of the Cooperative Health Statistics System. Valuable assistance and advice were provided by a number of persons, but particularly by Isabel P. Dunst, Associate General Counsel, Office of the General Counsel, Department of Health, Education, and Welfare.

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THE MODEL STATE HEALTH STATISTICS ACT

Section 1. [*Short Title.*] This Act may be cited as the (State) Health Statistics Act.

Section 2. [*Definitions.*] As used in this Act:

(1) "Agency" means the agency designated to carry out the purposes of this Act.

(2) "Disclosure" means the communication of health data to any individual or organization outside the Agency.

(3) "Health data" means any information, except vital statistics as defined in (appropriate State statute), relating to the health status of people, the availability of health resources and services, and the use and cost of such resources and services.

(4) "Identifiable health data" means any item, collection, or grouping of health data which makes the individual supplying it or described in it identifiable.

(5) "Individual" means a natural person.

(6) "Organization" means any corporation, association, partnership, agency, department, unit, or other legally constituted institution or entity, or part thereof.

(7) "Research and statistical purposes" means the performance of certain activities relating to health data, including, but not limited to: (i) describing the group characteristics of individuals or organizations; (ii) analyzing the interrelationships among the various characteristics of individuals or organizations; (iii) the conduct of statistical procedures or studies to improve the quality of health data; (iv) the design of sample surveys and the selection of samples of individuals or organizations; (v) the preparation and publication of reports describing these matters; and (vi) other related functions. Specifically excluded is the use of the data for an individual or organization to make any determination directly affecting the rights, benefits, or entitlements of that individual or organization.

NOTE: Where the need for variation was apparent, parentheses, "()," have been used.

In uses where recommendations were considered optional, wording was placed in brackets, "[]."

Section 3. [*Organization.*] The (appropriate State Agency) is hereby designated as the Agency to carry out the purposes of this Act.

Section 4. [*Agency Authority.*]

(a) In carrying out the purposes of the Act, the Agency may:

- (1) Collect and maintain health data on:
 - (i) The extent, nature, and impact of illness and disability on the population of the State.
 - (ii) The determinants of health and health hazards.
 - (iii) Health resources, including the extent of available manpower and resources.
 - (iv) Utilization of health care.
 - (v) Health care costs and financing.
 - (vi) Other health or health-related matters.

(2) Undertake and support research, demonstrations, and evaluations respecting new or improved methods for obtaining current data on the matters referred to in Section 4(a)(1).

(b) The Agency may collect health data under other authorities and on behalf of other governmental or not-for-profit organizations.

(c) The Agency shall collect data only on a voluntary basis from individuals and organizations, except when there is specific legal authority to compel the mandatory reporting of the health data so requested. In making any collection of health data from an individual or organization, the Agency must give to that individual or organization a written statement which states:

(1) Whether the individual or organization is required to respond, and any sanctions for noncompliance.

(2) The purposes for which the health data are being collected.

(3) In the case of any disclosure of identifiable health data for other than research and statistical purposes, the items to be disclosed, to whom the data are to be disclosed, and for what purposes.

(d) Except as provided in Section 5, no health data obtained in the course of activities undertaken or supported under this Act may be used for any purpose other

than the purpose for which they were supplied or for which the individual or organization described in the data has otherwise consented.

(e) The Agency shall (1) take such actions as may be necessary to assure that statistics developed under this Act are of high quality, timely, and comprehensive, as well as specific, standardized, and adequately analyzed and indexed; and (2) publish, make available, and disseminate such statistics on as wide a basis as practicable.

(f) The Agency shall take such action as is appropriate to effect the coordination of health data activities within the State to eliminate unnecessary duplication of data collection and maximize the usefulness of data collected.

(g) The Agency shall (1) participate with State, local, and Federal agencies in the design and implementation of the Cooperative Health Statistics System, a system for producing comparable and uniform health information and statistics at the Federal, State, and local levels; (2) undertake and support research, development, demonstrations, and evaluations respecting such cooperative system; and (3) provide the (State) share of the data collection costs under such system.

Section 5. [*Disclosure of Identifiable Health Data.*]

(a) The Agency may make no disclosure of any item, collection, or grouping of health data which makes the individual supplying it or described in it identifiable unless:

(1) The individual described in the data has consented to the disclosure.

(2) The disclosure is to a governmental entity in this State, in another State, or the Federal Government, provided that: (i) the data will be used for a purpose for which the data were collected by the Agency, and (ii) the recipient of the data has entered into a written agreement satisfactory to the Agency that it will protect such data in accordance with the requirements of this Act and will not permit further disclosure without prior approval of the Agency.

(3) The disclosure is to an individual or organization, for a specified time period determined by the Agency, solely for bona fide research and statistical purposes, as determined in accordance with guidelines adopted by the Agency, and the Agency determines that: (i) the disclosure of the data to the requesting individual or organization is required for the research and statistical purposes proposed, and (ii) the requesting individual or organization has entered into a written agreement satisfactory to the Agency that it will protect such data in accordance with the requirements of this Act and will not permit further disclosure without prior approval of the Agency. In no event, however, may the name, address, or other unique personal identifier of an individual supplying the data or described in them be disclosed under this paragraph to the requesting individual or organization.

(4) The disclosure is to a governmental entity for the purpose of conducting an audit, evaluation, or investigation of the Agency and such governmental entity

agrees not to use those data for making any determination affecting the rights, benefits, or entitlements of any individual to whom the health data relate.

(b) Any disclosure provided for in Section 5(a) shall be made at the discretion of the Agency, except that the disclosure provided for in Section 5(a)(4) must be made when the requirements of that paragraph have been met.

(c) No identifiable health data obtained in the course of activities undertaken or supported under this Act shall be subject to subpoena or similar compulsory process in any civil or criminal, judicial, administrative, or legislative proceeding, nor shall any individual or organization with lawful access to identifiable health data under the provisions of this Act be compelled to testify with regard to such health data, except that data pertaining to a party in litigation may be subject to subpoena or similar compulsory process in an action brought by or on behalf of such individual to enforce any liability arising under this Act.

Section 6. [*Security of Health Data.*] The Agency shall take appropriate measures to protect the security of health data, including:

(1) Limiting the access to health data to authorized individuals who have received training in the handling of such data.

(2) Designating a person to be responsible for physical security.

(3) Developing and implementing a system for monitoring security.

(4) Reviewing periodically all health data to evaluate whether it is appropriate to remove identifying characteristics from the data.

(5) Developing a program for the destruction, on a routine scheduled basis, of all forms, records, or magnetic tape files maintained by the Agency which contain information identifying individuals or individual organizations.

Section 7. [*General Powers.*] In addition to any other powers authorized by law, in accordance with State law, the Agency shall have the authority to (1) make and enter into contracts to purchase services and supplies and hire consultants; (2) develop and submit a proposed budget; (3) accept gifts and charitable contributions; (4) apply for, receive, and expend grants; (5) promulgate regulations appropriate to the effective implementation of this Act; (6) establish charges for and collect payment from individuals and organizations for the provision of services, including data dissemination; (7) receive and expend appropriations; (8) enter into a reimbursable work program with other agencies of the State or private agencies under which funds are transferred from such other agencies to this Agency for the performance of activities authorized under this Act; [and] (9) establish and compensate members of advisory boards subject to any State law limiting compensation of advisory board members; [(10) hire employees; (11) appoint an executive director; and (12) provide such other services and perform such other functions as are necessary to fulfill its responsibilities under this Act.]

Section 8. [*Criminal Penalties and Civil Remedies.*]

[(a) In addition to any other criminal penalties under the laws of this State, any individual or organization that willfully violates any provision in Section 5 or any regulations implementing that section shall, upon conviction, be fined not more than \$(0,000.00), or imprisoned for not more than (00) months, or both. Such organizations shall be fined not more than \$(0,000.00).]

[(b) The Agency or an organization acting upon its behalf shall be liable to an individual or organization injured by the intentional or negligent violation of any provisions of Section 5 in an amount equal to the damages sustained by the individual or organization, together with

the cost of the action and reasonable attorney's fee as determined by the court.]

Section 9. [*Appropriations.*] There is hereby authorized to be appropriated sufficient funds to meet the purposes of this Act.

Section 10. [*Severability.*] [Insert severability clause.]

Section 11. [*Repeal.*] [Insert repealer clause.]

Section 12. [*Effective Date.*] [Insert effective date.]

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THE MODEL STATE HEALTH STATISTICS ACT

A MODEL STATE LAW FOR THE COLLECTION, SHARING, AND CONFIDENTIALITY OF HEALTH STATISTICS

PURPOSE, DEVELOPMENT, AND OPERATION OF THE MODEL STATE HEALTH STATISTICS ACT

PURPOSE AND DEVELOPMENT

Health statistics are necessary for a variety of activities related to the provision of health care, including planning, evaluation, and research. These statistics, important for States, localities, and the Nation, are developed from various kinds of health information and data collected by States and localities. (See appendix I for excerpts from laws pertinent to health statistics and appendix II for an example of pertinent rules and regulations.)

The Model State Health Statistics Act (MSHSA) is designed to remedy existing deficiencies in legal authority for health data collection and to specifically authorize State participation in the Cooperative Health Statistics System.

A concern with issues of confidentiality and comparability of State and local health data stimulated the activities which led to the creation of the MSHSA. As States and the Federal Government began cooperative efforts for the development of health statistics, a need for expanding State capacity became evident. The U.S. Congress

in section 306(d) of the Public Health Service Act mandated the following:

“To insure comparability and reliability of health statistics, the Secretary shall, through the [National] Center [for Health Statistics], provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data.”

A review of the legal authority relating to health statistics operations in a sample of 12 States, conducted under the auspices of the National Center for Health Statistics (NCHS), led to an overall compelling conclusion. The necessary legal authority for the conduct of activities basic to the development and sharing of high-quality health statistics was lacking in many States. States differed substantially in legal and organizational structure. Often there was a lack of specific authority to collect, maintain, or transmit health data and therefore corresponding lack of authority to protect the confidentiality of sensitive personal health data.

The absence of confidentiality protection was seen as a barrier to the voluntary provision of health data, particularly during a time when States were enacting public record disclosure laws and similar laws in reaction to fears about government secrecy. Moreover, this lack also appeared to be a barrier to a State's ability to engage in cooperative health statistics efforts.

Thus new legal authority was necessary for two purposes: First, to assure adequate confidentiality protection; second, to enable a State to participate appropriately in cooperative efforts among States and the Federal Government.

To meet these needs, a broadly participatory process that relied strongly on State and local expertise was undertaken to develop a model law. First, the principles for a model law were developed; these were presented to a national meeting of involved State and local officials. Then an expert panel was convened to draft the model law. The panel included State officials representing both the executive and legislative viewpoints and experts in the fields of privacy, confidentiality, and health statistics. During its refinement process, drafts of the MSHSA were widely distributed for comment, and the MSHSA was modified accordingly. The entire process covered a 3-year period.

The development process focused on achieving a simple rather than complex model law. The model law can be easily modified to meet the particular needs of an individual State. The model contains those basic functions necessary to adequately conduct health statistics in a State and protect the confidentiality of individuals identifiable in the data. Optional provisions give a State additional flexibility. The statutory authority to protect the confidentiality of individuals identifiable in the data may well be accomplished by a combination of existing State law and MSHSA provisions.

The MSHSA establishes a system for the collection, transmission, use, and protection of health data. A State may adopt all of the provisions in the MSHSA or only some, depending on existing State law and the need for additional legal authority. A State with complete authority to carry out these activities would not need to consider adopting the MSHSA. However, officials in a State with no authority or only some of

these authorities should seriously consider enacting all or part of the model law to remedy existing deficiencies. Clearly, a thorough analysis of existing laws in each State is necessary for officials to make an informed decision regarding necessary legislative action.

It cannot be overemphasized that the design of the MSHSA enables a State to select those sections necessary to meet State needs and fit them within the existing legal and organizational structure. Officials in a State considering adoption of the MSHSA should remember that it is flexible in two regards: (1) the basic and optional sections to be adopted and (2) the exact language of each section. Variations in State law, organization, and requirements dictate appropriate modification of the MSHSA in each State.

The MSHSA specifically excludes consideration of vital records and vital statistics since each State has adopted specific legislation for these matters. Also, a recently drafted model act, the Model State Vital Statistics Act, is currently available to the States. While the MSHSA and the Model State Vital Statistics Act are designed as separate pieces of legislation, consideration should be given to designating one agency to carry out the purposes of both acts, particularly since vital statistics and health statistics are both components of the Cooperative Health Statistics System.

BASIC CONCEPT

The fundamental principle underlying the MSHSA is that each State has a need to develop and have available accurate health-related data and to share certain health-related data among appropriate agencies in the State, other States, and the Federal Government. The sharing of data for health planning and research and statistical purposes is mutually advantageous and necessary for determining the health status of the people, the status and use of the health care system, and the effect of the system on health resources and services.

The MSHSA provides legal authority for a State organization to collect, use, and share data and at the same time to protect the confidentiality of individuals identifiable in the data. These functions are best achieved if they are all the

responsibility of a single focal organization. The MSHSA offers the necessary organizational structure to meet these requirements. The character and designation of the focal organization, its location within the State government, and its relationship with corresponding Federal, State, and nonpublic organizations must be tailored to meet the unique requirements of a State. Moreover, many States may not need a new organization if they currently have one or more appropriate organizational structures which can be or may have been designated to perform the basic functions in the MSHSA.

The MSHSA recognizes and builds on the premise that a focal statistical agency at the State level will usually have the responsibility for collecting both general-purpose baseline statistical information and programmatic data for State-operated health programs. The MSHSA authorizes the Agency to collect baseline data, but only on a voluntary basis and in the absence of other authorizing legislation. The MSHSA also provides for the collection of programmatic data by the Agency both for itself under separate legal authority and on behalf of other organizational entities. Collections requiring mandatory reporting of health data may be required by separate legislation.

Provision of health information is voluntary. Confidentiality protection must be afforded individual providers and recipients of health care who could be identified in the data; otherwise, they might be reluctant to provide personal information. The MSHSA is designed to give such protection. It severely restricts the transfer of health data in which individuals are identifiable to those situations in which confidentiality will be maintained by the recipient.

While the Agency's primary function is to collect health data for itself, it is anticipated that an entity within the State which is competent to collect health data will serve in this capacity for other entities. Thus the Agency will have the authority to collect data or conduct statistical analyses for other organizational entities.

SUMMARY OF PRINCIPAL FEATURES

The MSHSA balances "society's need to know" and "the individual's right to privacy."

It protects the privacy of the data subject and makes identifiable health data confidential, thus reassuring the individual and the public at large. At the same time, the MSHSA provides a State with the legal authority to accomplish necessary activities related to health statistics within the State and to participate in the Cooperative Health Statistics System both within and outside the State.

Collection, Utilization, and Transmission Authority

The Agency referred to in the MSHSA has specifically described authority to collect, maintain, and utilize health data on a broad range of activities that relate to health. Moreover, the Agency is given authority to participate in cooperative efforts among States and with the Federal Government and has corresponding authority to support and undertake research to improve methods of health data collection and development of statistics.

The Act requires that the respondent be told during the collection process whether his response is voluntary or required; the purposes for which the health data are being collected; and what items will be disclosed, to whom, and for what purposes. This information gives the supplier of health data the basis for an informed decision on whether or not to respond.

The Agency is given broad authority for utilizing health data to generate health statistics. The Agency may transmit confidential health data to another organization in the State, in another State, or in the Federal Government but only when that other organization has the authority to maintain the confidentiality of the health data.

Protection of Health Data

Health data obtained in the course of activities undertaken or supported by the MSHSA are protected in two ways. First, the data may be used only for the purposes for which they were supplied or for purposes to which the individual or organization described in the data later consented. For example, data collected from a hospital for statistical purposes only could not be used for ratesetting, a nonstatistical purpose,

without obtaining consent from the hospital. This important limitation on data use applies to the Agency itself as well as any other recipient of the data.

The second way that the data are protected is in limitations placed on the disclosure, or release, of the health data. (This second protection is not extended to facility data.) The Agency is specifically directed to publish or otherwise release statistics, or aggregated health data, on as wide a basis as practicable. However, it may not release health data in which the individuals supplying the data or described in them are identifiable unless the release is one of only four permissible exceptions to the rule.

The Agency may publish, transmit, or otherwise disclose health data in which individuals are identifiable if such disclosure was consented to by the individuals. Consent may be provided in one of two ways. First, the respondent must be given at the time of collection a written statement of any intended disclosures, to whom they would be made, and the purposes of such disclosures. With this knowledge, the respondent effectively grants informed consent by supplying the requested data. An example would be a physician who knowingly gives personal data to be included in a directory of medical specialists. Health data in which individuals are identifiable may also be disclosed if the individuals give written consent to such disclosure after the data have been collected.

The Agency may transmit health data in which an individual is identifiable to a government entity if the data are to be used only for the intended purpose and if the government entity agrees to protect the health data from further disclosure and has authority for protecting the confidentiality of the health data similar to that of the Agency. Additional exceptions are provided for research purposes under conditions like those mentioned above and for certain audit, evaluation, or investigative purposes that would not allow disclosure of the health data.

The Agency has an obligation to protect the confidentiality of health data by adopting appropriate security measures. Moreover, violations of the confidentiality protection could result in criminal penalties for improper disclosure.

This protection of health data through restrictions on disclosure relates only to health data in which individuals are identifiable. Health data in which individuals are not identifiable, either data on organizations or aggregated data on individuals, must be released on public inquiry when under public record disclosure ("sunshine") laws.

Designation and Coordination

The MSHSA requires the designation of an agency to carry out the functions described in the Act and coordinate, as appropriate, all related data activities within the State. This important coordination authority helps assure that all data and statistics within a State are of high quality, that the costs of statistical activities are minimized by elimination of unnecessary duplication, and that the usefulness of collected data is maximized. While the Act was drafted based on the assumption that a single agency would perform all these functions, a State could conceivably share some of these functions among several agencies, both governmental and private nonprofit.

An important function of the Agency will be to represent the State within the Cooperative Health Statistics System (CHSS). CHSS is the Nation's shared health data system presently being developed by local, State, and Federal users and producers of health data. CHSS permits health data to be collected once and shared among all users. The Federal role in this system is provided by the National Center for Health Statistics, which is authorized to provide the Federal leadership for development of the system. CHSS is designed to enable States and localities to develop the resources and technical expertise for data collection and the production of statistics. CHSS incorporates several principles.

First, good health data can best be assembled by properly trained and experienced personnel at the State and local levels. Second, the data, if standardized, can serve multiple users, thereby conserving resources and avoiding unnecessary duplication. Third, the Federal Government's role should be to encourage and support State and local organizations to perform the functions related to the collection and processing of health

data rather than performing these functions itself. Federal law requires that States participating in CHSS designate a State agency to administer or be responsible for the administration of CHSS statistical activity in the State.

A number of other organizations are now involved in the collection and use of health data and statistics, among which are Health Systems Agencies (HSA's), State Health Planning and Development Agencies (SHPDA's), and Professional Standards Review Organizations (PSRO's). Federal legislation and regulations for these three programs anticipate data sharing among them. However, sharing of data raises concerns about the protection of confidential health data. For the most part, PSRO's adhere to restrictions on disclosure of identifiable health data similar to those contained in the MSHSA, while HSA's and SHPDA's are required to open their records to the public.

Optional Provisions

The MSHSA specifies an identified focal point, the Agency. It can be an existing State agency or a newly created one. As an optional

arrangement, a State may choose to have a non-governmental organization designated. For example, a data consortium could serve as the State Agency or it could provide certain functions for the designated State Agency through a contract or other mechanism. These particular arrangements would need to be specifically detailed in the appropriate MSHSA section and would need to be permitted under State law.

The MSHSA does not afford confidentiality protection to facilities, but a State may have reasons to do so. In this event, appropriate modification of the definition of confidentiality would be necessary. Similarly, a State may seek to have a much more narrow definition of confidentiality and restrict disclosure only of specific types of health data on individuals. Again, an appropriate modification to the definition and other operative sections of the MSHSA would be necessary. Also, a State may seek to have broader authority for providing data to a bona fide research or statistical organization and may, in fact, prefer to allow transmission of unique personal identifiers to such an organization for the purposes of followup or follow-back studies.

SECTION-BY-SECTION ANALYSIS

In this discussion the exact language of each part of the MSHSA is given in smaller type and is followed by analysis and commentary.

Section 1. [*Short Title.*] This Act may be cited as the (State) Health Statistics Act.

The title "State Health Statistics Act" was specifically chosen to both indicate the focus of the Act and to distinguish this Act from the existing vital statistics act of the State.

Section 2. [*Definitions.*] As used in this Act:

Most definitions are self-explanatory and correspond to the usual meaning of the word or

phrase. However, some aspects of the definitions deserve special mention.

(1) "Agency" means the agency designated to carry out the purposes of this Act.

"Agency" is defined to mean the *specific* organization designated to be responsible for health data and health statistics within the State. It is intended that a State government or an appropriate nonprofit organization be so designated. The designers of the Act anticipate that in some States the designated Agency may satisfy certain functions of the Act through the efforts of another State or nonprofit organization.

(2) "Disclosure" means the communication of health data to any individual or organization outside the Agency.

“Communication” means transmission or conveyance in any form—written, oral, or otherwise. Communication within the Agency is not considered a disclosure. The Act prohibits disclosure of identifiable health data collected or supported under this Act except under the conditions described in the Act. (See definition of “identifiable health data.”) Thus the Act protects the confidentiality of identifiable health data, but permits access under certain controllable conditions. Such control would be lost if the Agency were a SHPDA, which cannot protect identifiable health data from disclosure.

(3) “Health data” means any information, except vital statistics as defined in (appropriate State statute), relating to the health status of people, the availability of health resources and services, and the use and cost of such resources and services.

“Health data” is broadly defined to include all forms of health-related information except vital records and vital statistics. Vital records and vital statistics have been excluded since State legislation and policies regarding these already exist in every State. In preparing for legislative action on the Act, each State should review its vital statistics act. Amendments to existing statutes may be needed to insure proper compatibility and accommodation with this Act. The definition of vital statistics is to be incorporated in the Act by citing the vital statistics act of the State.

The definition of health data is intended to include information on the extent and nature of illness, disability, and other aspects of well-being; environmental, social, and other health hazards; determinants of health; health resources, including physicians, dentists, nurses, and other health professionals by specialty and type of practice; institutions, such as hospitals, extended care facilities, and mental health institutions; utilization of health care, including utilization of ambulatory health services according to the specialties and types of practice of the health professionals providing such services, and the services of hospitals, extended care facilities, home health agencies, and other institutions; and health care costs and financing, including trends in health care prices and costs.

(4) “Identifiable health data” means any item, collection, or grouping of health data which makes the individual supplying it or described in it identifiable.

Under this definition only information identifying an individual receives confidentiality protection; information identifying only an institution is not afforded similar protection. A State could, however, elect to include data identifying health care facilities in the protection. Facilities have not been afforded confidentiality treatment in this Act because there appeared to be a greater public interest in the availability of such information and less concern for the confidentiality of facility data than data identifying individuals. Also, facility data have not been granted confidentiality protection under some State licensing laws and under comparable Federal health data laws.

Under certain situations facility data could reveal the identity of an individual. For example, it might be possible to identify a particular surgeon from a table showing distributions of surgical procedures in hospitals in the State. Accordingly, such facility data would need to be characterized as identifiable health data.

The definition of identifiable health data does not provide a standard as to when information is in fact identifiable. It is suggested that the Agency established by this Act consider use of the standard “potentially recognizable” to provide a broad scope of confidentiality protection. The “potentially recognizable” standard protects against disclosure of aggregated data on small numbers of individuals from which identification of an individual could be made. If this standard were used, the Agency would closely scrutinize any intended release of health data to determine if any individuals could be identified through a combination of attributes. If so, the data would be further aggregated to insure confidentiality protection. While the standard for determining when a particular data item is identifiable must be general in character, it is anticipated that each State will provide greater content to the definition through explanatory regulations and guidelines. (See appendix III for comparable guidelines used by NCHS.)

(5) “Individual” means a natural person.

This definition includes only natural persons, alive or deceased. It is *not* intended to include corporations.

(6) "Organization" means any corporation, association, partnership, agency, department, unit, or other legally constituted institution or entity, or part thereof.

The definition of "organization" includes hospitals, nursing homes, other health care facilities, groups of physicians, and corporate persons.

(7) "Research and statistical purposes" means the performance of certain activities relating to health data, including, but not limited to: (i) describing the group characteristics of individuals or organizations; (ii) analyzing the interrelationships among the various characteristics of individuals or organizations; (iii) the conduct of statistical procedures or studies to improve the quality of health data; (iv) the design of sample surveys and the selection of samples of individuals or organizations; (v) the preparation and publication of reports describing these matters; and (vi) other related functions. Specifically excluded is the use of the data for an individual or organization to make any determination directly affecting the rights, benefits, or entitlements of that individual or organization.

The definition of "research and statistical purposes" includes all descriptive and analytical statistical activities relating to health. The listed functions, subsections (i) through (vi), are a basic characterization of likely Agency activities but are not the only permissible activities. Subsection (vi), "other related functions," is intended to include various functions of a less usual nature performed by a statistical agency, such as the publication of lists and directories.

The definition specifically excludes any activity conducted for the purpose of making any determination directly relating to a specified identifiable individual or *organization* and affecting the rights, benefits, or entitlements of that individual or organization. It is designed to distinguish research and statistical purposes from regulatory or administrative use. Information on a particular individual or organization obtained solely for research and statistical purposes cannot be used to determine particular characteristics of any one individual or organization in order to monitor compliance with statutes and regulations. Of course, identifiable health data obtained

for research and statistical purposes cannot be used in making an administrative determination affecting only an identifiable individual or organization. Thus the Agency is not permitted to use health data relating to a particular identifiable individual or organization and collected solely under the authority of this Act in making a determination directly affecting the rights, benefits, or entitlements of that individual or organization in such actions as licensing, certification, registration, or other regulatory proceedings.

The prohibition against regulatory or administrative use does not extend to the use of aggregated data in the form of statistics prepared by the Agency for formation of regulatory standards adopted through legislation or rulemaking, even though such standards might be applied subsequently against one of the individuals or organizations which originally submitted the data.

Indeed, research and statistical activities often have regulatory consequences. A major goal of such activities may be to effect changes in regulatory standards or criteria through legislative modifications or administrative policymaking of one type or another. Such activities, however, must deal only with an entire class of activities, individuals, or organizations.

Finally, the prohibition does not extend to the granting of a specific benefit to a respondent in a health survey. For example, compensation to encourage participation in the survey would be allowed.

Section 3. [*Organization.*] The (appropriate State Agency) is hereby designated as the Agency to carry out the purposes of this Act.

This section permits the designation of a *particular agency*. Because of the substantial variation in organizational structure among the States, as well as the close relationships between research and statistical purposes and other activities involving health data, it is intended that the greatest possible latitude be granted to States in the designation of the Agency.

The Agency is to be the designated entity identified in the Act. The Agency may be either newly established or already in existence. It may be limited to performing only the functions authorized in the substantive provisions of the

Act, or it may have other functions pursuant to other statutory authority, such as functions related to vital records and vital statistics. However, there are advantages to the designation of an Agency whose sole or primary function is the collection of health-related data. The Agency may also have specific mandatory data-collection authority under other legislation. Accordingly, the Agency or an organizational part thereof could combine the functions described in the Act with functions authorized under other legislation. The extent to which functions authorized by other statutory authority are undertaken by the Agency is appropriately left to the discretion of the State.

In order to assure compliance with this Act, provisions on the disclosure of identifiable health data, and other restrictions, it is suggested that the Agency have within the larger organization a separable unit or office for the sole purpose of administering the activities authorized by this Act. Without a distinct separable unit, serious questions could arise regarding which units were authorized to collect, protect, and release data under this Act and the relation of these authorities to other separately authorized functions of the larger organization.

Nothing in the designation of the Agency is intended to preclude the Agency from being a nonprofit private organization or from contracting with a private organization to perform the functions authorized. In fact, in several States data consortia are effectively performing the types of functions envisioned for the Agency. It is anticipated that in some States the Agency will be a consortium or will seek to contract with a consortium to continue providing data services. The Agency may also rely on the participation of other State agencies or nonprofit organizations to facilitate coordination of health data activities within the State and to participate in the design and implementation of the Cooperative Health Statistics System.

Section 4. [Agency Authority.]

(a) In carrying out the purposes of the Act, the Agency may:

- (1) Collect and maintain health data on:
 - (i) The extent, nature, and impact of illness and disability on the population of the State.

(ii) The determinants of health and health hazards.

(iii) Health resources, including the extent of available manpower and resources.

(iv) Utilization of health care.

(v) Health care costs and financing.

(vi) Other health or health-related matters.

(2) Undertake and support research, demonstrations, and evaluations respecting new or improved methods for obtaining current data on the matters referred to in Section 4(a)(1).

Overall the Agency has been provided with that authority thought best to facilitate the collection and utilization of high-quality health data while promoting efficient use of public resources. The authority given the Agency reflects the principles that:

1. Health data should be collected on a voluntary basis when it is to be used only for research and statistical purposes; higher quality data can be expected from voluntary data collection.
2. Identifiable health data cannot be disclosed except under restricted conditions (as set forth in section 5 of this Act) that are designed to safeguard the confidentiality of identifiable information.
3. Health data which are not identifiable should be fully shared.
4. The Agency should be able to provide health data and related services to individuals and organizations outside of the Agency.

Subsection (a) provides broad authority for the Agency to collect and maintain data on the entire range of health and health-related matters. Additionally, it is authorized to participate in research activities. Clearly the Agency would be remiss in not performing analyses designed to improve and evaluate its operations, as well as conducting research and demonstrations designed to improve them.

(b) The Agency may collect health data under other authorities and on behalf of other governmental or not-for-profit organizations.

The Agency is permitted to collect health data under legal authority other than that provided by this Act. For example, it could collect data on the characteristics of health care facili-

ties under an authority to license such facilities. It may also collect health data on behalf of other government agencies or nonprofit organizations. It is anticipated that the Agency's ability to utilize its data-gathering sophistication on behalf of other organizations that want health data will result in improved accuracy and timeliness of health data in the State and more efficient uses of resources. This authority, in effect, permits the Agency to serve as the principal health statistics agency in the State by serving programmatic as well as general-purpose data needs.

(c) The Agency shall collect data only on a voluntary basis from individuals and organizations, except when there is specific legal authority to compel the mandatory reporting of the health data so requested. In making any collection of health data from an individual or organization, the Agency must give to that individual or organization a written statement which states:

(1) Whether the individual or organization is required to respond, and any sanctions for noncompliance.

(2) The purposes for which the health data are being collected.

(3) In the case of any disclosure of identifiable health data for other than research and statistical purposes, the items to be disclosed, to whom the data are to be disclosed, and for what purposes.

The Act provides the authority to collect data only on a voluntary basis. Any other collections must be based on authorities in other statutes. Collecting data on a "voluntary basis" means collecting data without the direct or implied threat or imposition of any penalty or the withholding of any benefits from those who do not cooperate. Whether the Agency should be provided broad, general-purpose authority under the Act to collect data on a mandatory basis has been a matter of considerable discussion, given the data needs of the States as well as existing practices in a number of jurisdictions. The experience of States and the National Center for Health Statistics supports collection of health data on a voluntary basis. Adequate data have been collected on a voluntary basis with assurances that identifiable health data would be protected against inappropriate disclosure. Moreover, it was thought that some would perceive mandating health data collection for research and statistical purposes as an unnecessary intrusion into personal privacy. The drafters recognize,

however, that a State could conceivably wish to enact mandatory data-collection authority for specific well-defined purposes. While the experience of the States and Federal Government recommends against broad mandatory authority, special narrowly defined authority may serve a useful function for a situation of special need.

The Agency's use of such data, like its use of data submitted voluntarily, is limited to the purposes for which the data were collected. This subsection attempts to balance the needs of the Agency to (1) assure confidentiality when acting as a gatherer of health data on a voluntary basis and (2) perform other functions it may have under other authorities, such as collecting data on a mandatory basis for administrative or regulatory purposes, either its own or those of other agencies.

To clarify and emphasize these needs and distinctions, the Agency is required to give suppliers of health data a written statement designed to insure that they are informed as to whether or not they have to respond and are aware of the purposes for which the health data are being collected and how the data may ultimately be used. An individual or organization whose cooperation is requested in a voluntary data collection will have enough information to make an intelligent decision as to whether or not to contribute certain information. Thus the act of voluntarily responding, with the appropriate knowledge of any intended disclosure of identifiable data, explicitly provides evidence of informed consent to such disclosure.

(d) Except as provided in Section 5, no health data obtained in the course of activities undertaken or supported under this Act may be used for any purpose other than the purpose for which they were supplied or for which the individual or organization described in the data has otherwise consented.

The restriction in subsection (d) applies only to data collected under the voluntary authority provided in this Act. It applies whether the data provided under the authority of the Act are on behalf of the Agency itself or on behalf of another entity (subsection 4(b)). It does not apply to data, such as vital statistics, collected under other legal authority.

(e) The Agency shall (1) take such actions as may be necessary to assure that statistics developed under this Act are of high quality, timely, and comprehensive, as well as specific, standardized, and adequately analyzed and indexed; and (2) publish, make available, and disseminate such statistics on as wide a basis as practicable.

Subsection (e) makes an affirmative requirement that the Agency take necessary actions to assure that the statistics developed under this Act are adequate, of high quality, and timely. The drafters of the Act intended that the Agency be so charged to maintain the high standards necessary for health data. Subsection (e) also requires that the Agency make the statistics public on as wide a basis as practical. The mandate reflects the fact that statistics are valuable only when they are readily available.

(f) The Agency shall take such action as is appropriate to effect the coordination of health data activities within the State to eliminate unnecessary duplication of data collection and maximize the usefulness of data collected.

The intent of subsection (f) is to minimize duplication of activities while facilitating data sharing by multiple users. The Agency should not duplicate resources but build on the capacity of existing collection and processing systems and expand resources through interrelationships with other organizations. These interrelationships may include reviewing proposed statistical forms, involving data providers and users representing both the private and public sectors in decisions regarding health data activities within the State, and sharing information and resources through formal or informal arrangements.

(g) The Agency shall (1) participate with State, local, and Federal agencies in the design and implementation of the Cooperative Health Statistics System, a system for producing comparable and uniform health information and statistics at the Federal, State, and local levels; (2) undertake and support research, development, demonstrations, and evaluations respecting such cooperative system; and (3) provide the (State) share of the data collection costs under such system.

Subsection (g) is similar to the authority which enables NCHS to participate at the Federal level in the Cooperative Health Statistics System. It identifies the Agency as a participant in CHSS.

Clause (1) authorizes the Agency to participate with agencies in other States, NCHS, other Federal agencies, and local agencies in the design of CHSS, as well as in collection and other aspects of implementation of the system. A major aspect of the Agencies' participation in the design is definition of minimum data sets, sets of uniform data items providing basic information in each of several specific categories of health data.

Clause (2) authorizes the Agency to assist in the development of CHSS and thereby to make whatever additions or modifications are needed to adequately address specific data needs of the State.

Clause (3) relates to the cost-sharing aspect of CHSS. NCHS provides funding assistance to States for the collection of CHSS data. States participating in CHSS are expected to assume their share of the data-collection costs.

Section 5. [*Disclosure of Identifiable Health Data.*]

(a) The Agency may make no disclosure of any item, collection, or grouping of health data which makes the individual supplying it or described in it identifiable unless:

(1) The individual described in the data has consented to the disclosure.

(2) The disclosure is to a governmental entity in this State, in another State, or the Federal Government, provided that: (i) the data will be used for a purpose for which the data were collected by the Agency, and (ii) the recipient of the data has entered into a written agreement satisfactory to the Agency that it will protect such data in accordance with the requirements of this Act and will not permit further disclosure without prior approval of the Agency.

(3) The disclosure is to an individual or organization, for a specified time period determined by the Agency, solely for bona fide research and statistical purposes, as determined in accordance with guidelines adopted by the Agency, and the Agency determines that: (i) the disclosure of the data to the requesting individual or organization is required for the research and statistical purposes proposed, and (ii) the requesting individual or organization has entered into a written agreement satisfactory to the Agency that it will protect such data in accordance with the requirements of this Act and will not permit further disclosure without prior approval of the Agency. In no event, however, may the name, address, or other unique personal identifier of an individual supplying the data or described in them be disclosed under this paragraph to the requesting individual or organization.

(4) The disclosure is to a governmental entity for the purpose of conducting an audit, evaluation, or investigation of the Agency and such governmental entity

agrees not to use those data for making any determination affecting the rights, benefits, or entitlements of any individual to whom the health data relate.

Section 5 protects the confidentiality of identifiable health data collected under the authority in the Act; data collected by the Agency under another authority would be subject to restrictions on disclosure imposed by that legal authority; other health data collected under the authority in this Act may be disclosed at the discretion of the Agency or upon a request that meets the criteria of the State's public record disclosure law.

Disclosure of identifiable health data collected under the authority in this Act is permitted only under four situations.

1. The purpose of this exception is to permit access to information in which an individual is identifiable through consent of the individual so identified. This consent can be provided either prior to or subsequent to the collection of the health data. The Agency may obtain either consent for only one purpose or a broad consent allowing disclosure for multiple purposes.
2. The purpose of this exception is to permit the transfer of uniform health data to NCHS and other participants in CHSS in the State and other States without compromising the confidentiality of the health data by disclosure outside CHSS. This exception permits States and the Federal Government to meet their data needs without duplication of data collection and processing. NCHS, for example, has legal authority to protect data from disclosure. For the purposes of this subparagraph, the term "governmental entity" includes nonprofit private organizations that perform a government function—for example, a PSRO, which is a private nonprofit organization and operates under Federal law that protects the confidentiality of identifiable health data. In contrast, an HSA, also a nonprofit organization operating under Federal law, could not receive data under this subparagraph since HSA's lack authority to protect the confidentiality of identifiable health data.

3. The purpose of this provision is to provide organizations like the Institute of Medicine, university researchers, and other users of health statistics access to data in the form in which it is most useful. Disclosure is permitted only for the period of time specified by the Agency and according to guidelines adopted by the Agency. It is anticipated that the Agency will promulgate detailed regulations and guidelines in this regard. Moreover, before allowing disclosure the Agency must determine that the data are required for the proposed research and statistical purposes. The drafters intended that the Agency determine that no other source of the data is available.

Moreover, the requester must enter a written agreement with the Agency assuring that it will protect such data in accordance with the requirements of the Act and will not permit further disclosure without prior approval of the Agency. This written agreement must satisfy the Agency that the requester can comply with the requirements of the Act for data protection.

The final sentence under this permitted disclosure requires further explanation. The exception permits the disclosure on a record-by-record basis of all information contained in a file of statistical records of individuals except for names, addresses, or other unique personal identifiers such as social security numbers. A file of statistical records of individuals with such unique personal identifiers removed can still be regarded as identifiable health data if the identity of one or more individuals can be reasonably deduced from other characteristics contained in the file. Examples include a surgeon who performed a certain type of surgery in a certain hospital or a black female who is a manager with a high income in a certain industry in a particular city.

It is believed that identifiable health data without unique personal identifiers serve most of the purposes of statistical research and provide health data to researchers with detail not usually available

to them. This exception does not permit the recipient researcher or research organization to link the disclosed file with other files on a record-by-record basis nor to use the file as a frame for conducting surveys of the individuals in it. Thus it provides an additional safeguard to the eventual use and disposition of the identifiable health data disclosed. If such an additional safeguard is not deemed necessary or consistent with goals for sharing health data, this limitation to full disclosure of identifiable health data can be either omitted or modified to give the Agency the discretion for providing identifiable health data either with or without unique personal identifiers.

4. The requirements of this disclosure seek to insure that the authority requesting disclosure for an audit, evaluation, or investigation agrees to maintain the prohibition on the use of identifiable health data for regulatory or compliance purposes against any identified individual.

(b) Any disclosure provided for in Section 5(a) shall be made at the discretion of the Agency, except that the disclosure provided for in Section 5(a)(4) must be made when the requirements of that paragraph have been met.

All disclosures made under subsections (a)(1), (a)(2), and (a)(3) are discretionary with the Agency but disclosure under subsection (a)(4) is required.

(c) No identifiable health data obtained in the course of activities undertaken or supported under this Act shall be subject to subpoena or similar compulsory process in any civil or criminal, judicial, administrative, or legislative proceeding, nor shall any individual or organization with lawful access to identifiable health data under the provisions of this Act be compelled to testify with regard to such health data, except that data pertaining to a party in litigation may be subject to subpoena or similar compulsory process in an action brought by or on behalf of such individual to enforce any liability arising under this Act.

Subsection (c) prohibits release of identifiable health data for any administrative, judicial, or legislative proceeding unless the action is actually brought by or on behalf of the identifiable individual or organization to enforce liability arising under the Act. Furthermore, where identifiable

health data are available from a primary data source, such as the patient's health record maintained by a provider of care, this source, rather than the abstract of requested data given to the Agency by the provider of care, should be the subject of a subpoena. This complete protection is deemed appropriate to maximize voluntary submission of identifiable health data.

Section 6. [*Security of Health Data.*] The Agency shall take appropriate measures to protect the security of health data, including:

- (1) Limiting the access to health data to authorized individuals who have received training in the handling of such data.

- (2) Designating a person to be responsible for physical security.

- (3) Developing and implementing a system for monitoring security.

- (4) Reviewing periodically all health data to evaluate whether it is appropriate to remove identifying characteristics from the data.

- (5) Developing a program for the destruction, on a routine scheduled basis, of all forms, records, or magnetic tape files maintained by the Agency which contain information identifying individuals or individual organizations.

Section 6 provides a series of requirements designed to implement basic principles for achieving security and integrity of health data. The provisions create administrative requirements to prevent unnecessary, unwarranted, or accidental disclosure of identifiable health data. After much discussion, the drafters felt that each State should determine the content of these safeguards based on the existence of other legislation and administrative practice, but the safeguards should be consistent with these provisions. Technology related to security of health data is evolving rapidly, and the Agency will need to become familiar with such technological advancements as they occur.

Implicit in subsection (1) is the necessity for training personnel in the appropriate handling of identifiable health data. Subsection (2), in keeping with principles of good management and data security, recognizes that a particular person should be responsible and held accountable for the physical security of the health data. Subsections (4) and (5) recognize that in the future there may be less need for information that identifies persons or organizations. Subsection (5) emphasizes that it is appropriate to routinely

destroy information identifying individual persons or organizations as soon as such data are no longer needed.

It is anticipated that the Agency will implement the provisions of section 6 in a manner consistent with good research and statistical standards.

Section 7. [*General Powers.*] In addition to any other powers authorized by law, in accordance with State law, the Agency shall have the authority to (1) make and enter into contracts to purchase services and supplies and hire consultants; (2) develop and submit a proposed budget; (3) accept gifts and charitable contributions; (4) apply for, receive, and expend grants; (5) promulgate regulations appropriate to the effective implementation of this Act; (6) establish charges for and collect payment from individuals and organizations for the provision of services, including data dissemination; (7) receive and expend appropriations; (8) enter into a reimbursable work program with other agencies of the State or private agencies under which funds are transferred from such other agencies to this Agency for the performance of activities authorized under this Act; [and] (9) establish and compensate members of advisory boards subject to any State law limiting compensation of advisory board members; [(10) hire employees; (11) appoint an executive director; and (12) provide such other services and perform such other functions as are necessary to fulfill its responsibilities under this Act.]

Section 7 contains the general powers and authorities that need to be included in the Act unless otherwise provided by other statutory authority within the State. These powers are necessary if the Agency is to perform its authorized functions. For example, the power to enter into contracts to purchase services is necessary in order to engage services for the collection of data; the power to apply for, receive, and expend grants is necessary in order to provide services to data users; the power to establish charges and collect payments for services provided under the MSHSA is necessary in order for the Agency to collect data on behalf of other government entities and private not-for-profit organizations; the power to enter into reimbursable work programs is desirable in order to enable the Agency to add staff capability; and the power to establish advisory boards and compensate members is linked to a CHSS contract requirement to establish advisory committees.

A State will need to tailor these general powers to fit its particular legal and organiza-

tional structure. A State may also wish more specific provisions. For example, the composition and functions of an advisory board could be included.

Section 8. [*Criminal Penalties and Civil Remedies.*]

Section 8, while a bracketed optional provision, was thought by the drafters to be important for inclusion in a State code. The provisions of the Act that prohibit improper disclosure of data must be enforceable. Section 8 provides specific criminal penalties and civil remedies for violations of the Act. These provisions are in addition to and not in place of any penalties or remedies provided under existing State law. Questions of jurisdiction, venue, and applicable statutes of limitations are to conform to existing State law.

[(a) In addition to any other criminal penalties under the laws of this State, any individual or organization that willfully violates any provision in Section 5 or any regulations implementing that section shall, upon conviction, be fined not more than \$(0,000.00), or imprisoned for not more than (00) months, or both. Such organizations shall be fined not more than \$(0,000.00).]

Subsection (a) provides criminal penalties for *willful* violations of any provision in section 5 or regulations promulgated thereunder relating to disclosure of identifiable health data. The criminal penalties have been left blank in order to permit the State to establish appropriate penalties commensurate with existing sanctions or penalties for similar offenses within the State.

[(b) The Agency or an organization acting upon its behalf shall be liable to an individual or organization injured by the intentional or negligent violation of any provisions of Section 5 in an amount equal to the damages sustained by the individual or organization, together with the cost of the action and reasonable attorney's fee as determined by the court.]

Subsection (b) permits an action to be brought against the Agency or an organization acting on its behalf for damages that result from either *intentional* or *negligent* violations of the restrictions on disclosure. The determination of damages and the question of punitive damages are left to controlling State law. This subsection permits the courts to assess court costs and

reasonable attorney's fees if the plaintiff prevails. This provision is included so that the substantial costs involved in litigation will not discourage individuals from bringing meritorious actions even though actual damages may be small.

Section 9. [*Appropriations.*] There is hereby authorized to be appropriated sufficient funds to meet the purposes of this Act.

Whether section 9 is necessary depends on the law in a particular State considering adoption of the Act. The financial needs of each Agency will be dependent on a variety of factors, including the extent to which an existing organization performs some of the functions authorized in the Act.

Section 10. [*Severability.*] [Insert severability clause.]

Section 10 will contain the standard severability provision used in the State for the unlikely event that any of the Act's provisions are subsequently held invalid.

Section 11. [*Repeal.*] [Insert repealer clause.]

Section 11 will contain a standard repealer clause listing any statute or statutes which are to be repealed because of the enactment of the Act. Each State must review existing legislation which may affect the Act in order to assure appropriate repeal of any State law which potentially conflicts with the Act's provisions. Each State is urged to review existing legislation such as freedom of information acts, public record disclosure laws, and fair information practices acts which may, in part, conflict with the restrictions on disclosure of identifiable health data contained in this Act. It is recommended that disclosure provisions of this Act should apply since they are specifically tailored to meet the unique needs of the Agency.

Section 12. [*Effective Date.*] [Insert effective date.]

Section 12 will specify the Act's effective date.

LEGAL ASPECTS OF THE MODEL STATE HEALTH STATISTICS ACT

FEDERAL LAW

During development of the MSHSA, consideration was given to the experience of the Federal Government and the States with laws for collecting and protecting health data. This description deals with pertinent Federal legislation, focusing primarily on matters of privacy, confidentiality, release of data, and organizational arrangements.

Authority

The Public Health Service Act¹ authorizes the National Center for Health Statistics to collect, utilize, and assure the confidentiality of data on a variety of health matters. The language

¹As amended by Public Law 93-353, enacted July 28, 1974, and Public Law 95-623, enacted November 9, 1978 (42 USC 242a-242m).

in the MSHSA has been made to correspond to the Federal law. Subsection 306(b)(1) (42 USC 242k(b)) requires that the Secretary, acting through the Center, collect statistics on the following:

“(A) the extent and nature of illness and disability of the population of the United States....

“(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....

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

“(D) determinants of health,

“(E) health resources, including physicians, dentists, nurses, and other health professionals...and the supply of services by hospitals... and other health institutions,

- “(F) utilization of health care....
- “(G) health care costs and financing....
- “(H) family formation, growth, and dissolution.”

The Public Health Service Act also specifically authorizes establishment of the Cooperative Health Statistics System for the purpose of producing comparable and uniform health information and statistics. Subsection 306(e) requires the following:

“(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 participating in the System produce uniform and timely data and assure appropriate access to such data.”

The 1978 amendment (Public Law 95-623) adds a new requirement—designation of the State Agency. It is expected that the Agency’s initial designation in most States will be made by the Governor, and in fact the Governors of several States have already made such a designation. However, States should additionally con-

sider designating the Agency through the MSHSA. This procedure would allow the Agency to gain the benefits of the Law’s various provisions and a broader acceptance of its role.

Decisions regarding the definition of CHSS, its administration, and the data it produces are shared among the participants at the Federal, State, and local levels and the community of users CHSS serves. The design principles of CHSS include: (1) Utilization of a single data collection for various purposes; (2) involvement of both public and private agencies in data collection and management of the system; (3) sharing of data by local, State, and national agencies; and (4) decentralization of data collection and processing so they are closer to the source of the data and the location of the primary user of the data.

NCHS also has the authority to provide technical aid to States and localities. The Public Health Service Act (subsection 306(d)) provides the following:

“To insure comparability and reliability of health statistics, the Secretary shall, through the Center, provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data.”

Confidentiality and Data Disclosure

The confidentiality of health data transmitted to NCHS is guaranteed. Subsection 308(d) of the Public Health Service Act (42 USC 242m(d)) prohibits the publication or release of health data in which individuals are identifiable without the consent of the person or establishment supplying the information or described in it. Moreover, health information can be used only for those purposes for which it was supplied. Confidentiality protections afforded to the health data acquired by NCHS supersede any rights granted to the public or to individuals by either the Federal Freedom of Information Act or the Privacy Act of 1974.

The Freedom of Information Act (5 USC 552) provides the public a right to gain access to information held by the Federal Government and prevents the Government from refusing its re-

lease. However, certain information, such as NCHS health data, is statutorily exempted from the right to access by subsection 308(d) of the Public Health Service Act.

The Privacy Act of 1974 (5 USC 552a) was designed to provide safeguards for individuals against an invasion of personal privacy by the Federal Government. Federal agencies must limit the uses to which information is put and must give the individual a right to gain access to his individual records maintained by the Federal Government, with an opportunity to correct errors. The Privacy Act provides safeguards against the misuse of information and prevents records obtained for one purpose from being used for another purpose without an individual's consent. Only individual information, and not that on organizations, is protected. When a statute requires a "system of records" to be maintained and used solely for "a statistical purpose," the Privacy Act permits the head of the Federal agency to exempt such records from many of the requirements of the Act. The Secretary of Health, Education, and Welfare (HEW), for example, has exempted certain records maintained and used by NCHS solely as statistical records.

Organization

The Public Health Service Act establishes NCHS as an organization that conducts health statistics activities. To the maximum extent feasible, NCHS must review statistical activities undertaken and supported throughout the various organizational units of HEW to assure that they are consistent with CHSS. Coordinated utilization of CHSS information is mandated for certain Federal health data systems. Such mandates can be found in Federal legislation authorizing national health planning and professional standards review organizations (PSRO's). Also, under the most recent amendment to the Public Health Service Act (1978), NCHS is required to produce guidelines to assure that statistical activities within the States participating in CHSS produce uniform and timely data and assure appropriate access to such data.

The National Health Planning and Resources Development Act of 1974, Public Law 93-641, subsection 1513(b) (42 USC 300l-2(b)(1)), spe-

cifically states that a health systems agency (HSA), in analyzing and assembling health data, "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 306(e)." (42 USC k(e)) HSA's must also coordinate their data activities with PSRO's (Public Law 93-641, subsection 1513(d) (42 USC 300l-2(d))). PSRO's are required to coordinate and cooperate with other data systems under section 1165 of Public Law 92-603 (42 USC 1320c-14). The confidentiality of PSRO data and sharing of these data with HSA's are the subject of HEW regulation 42 CFR 476.

In summary, under the HEW regulations, information from public sources can be shared, as can data from CHSS-defined minimum data sets in which individuals are not identified. Of course, data that are aggregated and thus conceal the identity of individuals can be freely shared.

The Cooperative Health Statistics System is mentioned in another Federal law, the Medicare-Medicaid Anti-Fraud and Abuse Amendments, Public Law 95-142. Subsection 1121(a) of that act requires that uniform reporting systems be established for health services facilities and organizations to the extent practicable and consistent with CHSS.

STATE LAW

Whereas the Federal Government has comprehensive authorization for the collection and utilization of health data, many States lack similar authority. All States have legislation authorizing them to collect and maintain vital records and vital statistics, but a study, conducted under the auspices of HEW in 1976, on the legislation in a sample of 12 States showed that few States have comparable specific authority for health data and statistics. Further support for this conclusion appeared in written comments from various State officials on early drafts of the MSHSA. Some States appear to collect health data under general, and often vague, authority. Without sufficient authority, a State may lack the legal basis for protecting the confidentiality of identifiable health data and thus lack the ability to

participate in and benefit from shared data systems, such as those being established by CHSS.

The legislatures in a growing number of States have adopted the principles found in the Federal Freedom of Information Act and the Privacy Act of 1974. Sunshine laws, public record disclosure laws, and other similarly named statutes correspond to the Federal Freedom of Information Act. Usually a government-maintained record must be released upon public inquiry unless specific statutory authority establishes confidentiality protection. A data subject in States with such legislation could have his most personal health information available to the public upon a routine request unless identifiable health data had been specifically exempted from release.

On the other hand, State privacy laws also create inherent difficulties when they place unreasonable and costly burdens on a health statistics agency. A privacy act gives the data subject the right to gain access to and correct data relating to him. The purpose is to afford the individual the right to know what information is maintained about him and to insure the accuracy of individual data items utilized for administrative

or regulatory purposes. For statistical purposes, however, there is no such need for a personal right to insure accuracy because aggregated data do not expose such inaccuracy. To provide the opportunity for access to and correction of data is to encourage senseless costs. The Federal Privacy Act of 1974 exempts statistical records from such requirements. Unless a State has a similar privacy act with a comparable exemption, the health data agency is subject to an expensive burden lacking a corresponding public benefit.

Because there are a variety of very different laws in the States, any attempt to classify or further evaluate them would lead to confusion. The laws relating to health statistics, health data, and public health and safety are as diverse as the States in which they are found. Moreover, the interpretation of these laws and their implementation vary even more. A State considering adoption of the MSHSA needs to make a thorough study of its related, and possibly conflicting, laws with a view to resolving any conflicts by appropriate modification of the MSHSA.

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APPENDIX I

EXCERPTS FROM LAWS PERTINENT TO
HEALTH STATISTICS
THE PUBLIC HEALTH SERVICE ACT

Section 306, 42 USC Section 242k:

NATIONAL CENTER FOR HEALTH STATISTICS

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

(b) In carrying out section 304(a), the Secretary, acting through the Center—

(1) shall collect statistics on—

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

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

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

(D) determinants of health,

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

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

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

(H) family formation, growth, and dissolution;

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

(3) may undertake and support (by grant or contract) 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.

Amounts appropriated to the Secretary from payments made under arrangements made under paragraph (4) shall be available to the Secretary for obligation until expended.

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

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

(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 activi-

ties within States participating in the system produce uniform and timely data and assure appropriate access to such data.

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

(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. Each State or registration area shall be paid by the Secretary the Federal share of its reasonable costs (as determined by the Secretary) for collecting and transcribing (at the request of the Secretary and by whatever method authorized by him) its records for such data.

(i) The Center may provide to public and nonprofit private entities engaged in health planning activities technical assistance in the effective use in such activities of statistics collected or compiled by the Center.

(j) In carrying out the requirements of section 304 (c) 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) (1);

(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 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 nineteenth day after the date of the completion of the review of the collection.

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

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

(B) Of the members first appointed—

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

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

and

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

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

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

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

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

(B) to stimulate studies of such problems by other organizations and agencies whenever possible or to

make investigations of such problems through subcommittees;

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

(D) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health, Education, and Welfare, with respect to the Cooperative Health Statistics System established under subsection (e), and with respect to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j)(1);

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

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

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

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

Section 308(d), 42 USC Section 242m(d):

(d) No information obtained in the course of activities undertaken or supported under section 304, 305, 306, 307, or 309 may be used for any purpose other than the purpose for which it was supplied unless authorized by guidelines in effect under section 306(1) (2) or under regulations of the Secretary; and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section 304 or 306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form, and (2) in the case of information obtained in the course of health services research, evaluations, or demonstrations under section 304 or 305, such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

THE NATIONAL HEALTH PLANNING AND RESOURCES DEVELOPMENT ACT

Public Law 93-641

Section 1513(b), 42 USC Section 300l-2(b)(1):

“(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 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 long-term health conditions.

Coordination
with cooper-
ative system.
42 USC 242d.

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 306(e).”

Section 1513(d), 42 USC Section 300i-2(d):

“(d) Each health systems agency shall coordinate its activities with— Coordination.

 “(1) each Professional Standards Review Organization (designated under section 1152 of the Social Security Act), 42 USC 1320c-1.

 “(2) entities referred to in paragraphs (1) and (2) of section 204(a) of the Demonstration Cities and Metropolitan Development Act of 1966 and regional and local entities the views of which are required to be considered under regulations prescribed under section 403 of the Intergovernmental Cooperation Act of 1968 to carry out section 401(b) of such Act, 42 USC 3334.

 “(3) other appropriate general or special purpose regional planning or administrative agencies, and 42 USC 4233, 4231.

 “(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, enter into agreements with them which will assure that actions taken by such entities which alter the area’s health system will be taken in a manner which is consistent with the HSP and the AIP in effect for the area, and, to the extent practicable, provide technical assistance to such entities.”

Section 1522(a) and (b)(1)-(7):

"STATE ADMINISTRATIVE PROGRAM

- 42 USC 300m-1. "SEC. 1522. (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 1523. The Secretary may not approve a State Program for a State unless it—
- Conditions.
- "(1) meets the requirements of subsection (b) ;
 - "(2) has been submitted to the Secretary by the Governor of the State at such time and in such detail, and contains or is accompanied by such information, as the Secretary deems necessary; and
 - "(3) has been submitted to the Secretary only after the Governor of the State has afforded to the general public of the State a reasonable opportunity for a presentation of views on the State Program.
- Functions.
- "(b) The State Program of a State must—
- "(1) provide for the performance within the State (after the designation of a State Agency and in accordance with the designation agreement) of the functions prescribed by section 1523 and specify the State Agency of the State as the sole agency for the performance of such functions (except as provided in subsection (b) of such section) and for the administration of the State Program;
 - "(2) contain or be supported by satisfactory evidence that the State Agency has under State law the authority to carry out such functions and the State Program in accordance with this part and contain a current budget for the operation of the State Agency;
 - "(3) provide for adequate consultation with, and authority for, the Statewide Health Coordinating Council (prescribed by section 1524), in carrying out such functions and the State Program;
 - "(4) (A) set forth in such detail as the Secretary may prescribe the qualifications for personnel having responsibilities in the performance of such functions and the State Program, and require the State Agency to have a professional staff for planning and a professional staff for development, which staffs shall be of such size and meet such qualifications as the Secretary may prescribe;
 - "(B) provide for such methods of administration as are found by the Secretary to be necessary for the proper and efficient administration of such functions and the State Program, including methods relating to the establishment and maintenance of personnel standards on a merit basis consistent with such standards as are or may be established by the Civil Service Commission under section 208(a) of the Intergovernmental Personnel Act of 1970 (Public Law 91-648), but the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with the methods relating to personnel standards on a merit basis established and maintained in conformity with this paragraph;
- 42 USC 4728.
- "(5) require the State Agency to perform its functions in accordance with procedures and criteria established and published by it, which procedures and criteria shall conform to the requirements of section 1532;
 - "(6) require the State Agency to (A) conduct its business meetings in public, (B) give adequate notice to the public of such meetings, and (C) make its records and data available, upon request, to the public;
 - "(7) (A) provide for the coordination (in accordance with regulations of the Secretary) with the cooperative system provided for under section 306(e) of the activities of the State Agency for the collection, retrieval, analysis, reporting, and publication
- Coordination of information.
42 USC 242d.

Reports.

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.”

THE SOCIAL SECURITY ACT

Section 1121(a), Part A, Title XI, 42 USC Section 1320a:

Uniform Reporting Systems for Health Services Facilities and Organizations¹

Sec. 1121. (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:

(1) The aggregate cost of operation and the aggregate volume of services.

(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) (1) 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 specified uniform reports to be provided to the Secretary.

¹ Section 1121 was added by sec. 19(a) of P.L. 95-142. See also sec. 19(c) which is printed in this document on p. 800.

Correlation of Functions Between Professional Standards Review Organizations and Administrative Instrumentalities

Sec. 1165. The Secretary shall by regulations provide for such correlation of activities, such interchange of data and information, and such other cooperation consistent with economical, efficient, coordinated, and comprehensive implementation of this part (including, but not limited to, usage of existing mechanical and other data-gathering capacity) between and among—

(a) (1) agencies and organizations which are parties to agreements entered into pursuant to section 1816, (2) carriers which are parties to contracts entered into pursuant to section 1842, and (3) any other public or private agency (other than a Professional Standards Review Organization) having review or control functions, or proved relevant data-gathering procedures and experience, and

(b) Professional Standards Review Organizations, as may be necessary or appropriate for the effective administration of title XVIII, or State plans approved under this Act.

Prohibition Against Disclosure of Information¹

Sec. 1166. (a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, shall be held in confidence and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part, (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care, or (3) in accordance with subsection (b).

(b) A Professional Standards Review Organization shall provide, in accordance with procedures established by the Secretary, data and information—

(1) to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse, which data and information shall be provided by such organization to such agencies at the request of such agencies at the discretion of such Organization on the basis of its findings with respect to evidence of fraud or abuse; and

(2) to assist the Secretary, and such Federal and State agencies recognized by the Secretary as having health planning or related responsibilities under Federal or State law (including health systems agencies and State health planning and development agencies), in carrying out appropriate health care planning and related activities, which data and information shall be provided in such format and manner as may be prescribed by the Secretary or agreed upon by the responsible Federal and State agencies and such Organization, and shall be in the form of aggregate statistical data (without identifying any individual) on a geographic, institutional, or other basis reflecting the volume and frequency of services furnished, as well as the demographic characteristics of the population subject to review by such Organization.

The penalty provided in subsection (c) shall not apply to the disclosure of any data and information received under this subsection, except that such penalty shall apply to the disclosure (by the agency receiving such data and information) of any such data and information described in paragraph (1) unless such disclosure is made in a judicial, administrative, or other formal legal proceeding resulting from an investigation conducted by the agency receiving the data and information.

¹ Section 1166 was amended by sec. 5(h) of P.L. 95-142.

(c) It shall be unlawful for any person to disclose any such information other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than \$1,000, and imprisoned for not more than six months, or both, together with the costs of prosecution.

(d) No patient record in the possession of a Professional Standards Review Organization, a Statewide Professional Standards Review Council, or the National Professional Standards Review Council shall be subject to subpoena or discovery proceedings in a civil action.

THE FREEDOM OF INFORMATION ACT

5 USC Section 552:

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying—

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register; and

(C) administrative staff manuals and instructions to staff that affect a member of the public;

unless the materials are promptly published and copies offered for sale. To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agency may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, or staff manual or instruction. However, in each case the justification for the deletion shall be explained fully in writing. Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967, and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of such index on request at a cost not to exceed the direct cost of duplication. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if—

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

(3) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(4)(A) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying a uniform schedule of fees applicable to all constituent units of such agency. Such fees shall be limited to reasonable standard charges for document search and duplication and provide for recovery of only the direct costs of such search and duplication. Documents shall be furnished without charge or at a reduced charge where the agency determines that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action.

(C) Notwithstanding any other provision of law, the defendant shall serve an answer or otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court otherwise directs for good cause shown.

(D) Except as to cases the court considers of greater importance, proceedings before the district court, as authorized by this subsection, and appeals therefrom, take precedence on the docket over all cases and shall be assigned for hearing and trial or for argument at the earliest practicable date and expedited in every way.

(E) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

(F) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the withholding, the Civil Service Commission shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Commission, after investigation and consideration of the evidence submitted, shall submit its findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Commission recommends.

(G) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall—

(i) determine within ten days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination; and

(ii) make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

(B) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the reasons for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days. As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular request—

(i) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(ii) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

(C) Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request. Any notification of denial of any request for records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request.

(b) This section does not apply to matters that are—

(1) (A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.

(c) This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

(d) On or before March 1 of each calendar year, each agency shall submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report shall include—

(1) the number of determinations made by such agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;

(2) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information;

(3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each;

(4) the results of each proceeding conducted pursuant to subsection (a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

(5) a copy of every rule made by such agency regarding this section;

(6) a copy of the fee schedule and the total amount of fees collected by the agency for making records available under this section; and

(7) such other information as indicates efforts to administer fully this section.

The Attorney General shall submit an annual report on or before March 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subsections (a)(4)(E), (F), and (G). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

(e) For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

THE PRIVACY ACT

Public Law 93-579

5 USC Section 552a:

5 USC 552a.

“§ 552a. Records maintained on individuals

“(a) DEFINITIONS.—For purposes of this section—

5 USC 552.

“(1) the term ‘agency’ means agency as defined in section 552 (e) of this title;

“(2) the term ‘individual’ means a citizen of the United States or an alien lawfully admitted for permanent residence;

“(3) the term ‘maintain’ includes maintain, collect, use, or disseminate;

“(4) the term ‘record’ means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph;

“(5) the term ‘system of records’ means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual;

“(6) the term ‘statistical record’ means a record in a system of records maintained for statistical research or reporting purposes only and not used in whole or in part in making any determination about an identifiable individual, except as provided by section 8 of title 13; and

13 USC 8.

“(7) the term ‘routine use’ means, with respect to the disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was collected.

“(b) CONDITIONS OF DISCLOSURE.—No agency shall disclose any record which is contained in a system of records by any means of communication to any person, or to another agency, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains, unless disclosure of the record would be—

“(1) to those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties;

“(2) required under section 552 of this title;

“(3) for a routine use as defined in subsection (a) (7) of this section and described under subsection (c) (4) (D) of this section;

“(4) to the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of title 13;

“(5) to a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

“(6) to the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has such value;

“(7) to another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which

maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

"(8) to a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon such disclosure notification is transmitted to the last known address of such individual;

"(9) to either House of Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

"(10) to the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office; or

"(11) pursuant to the order of a court of competent jurisdiction.

"(c) ACCOUNTING OF CERTAIN DISCLOSURES.—Each agency, with respect to each system of records under its control, shall—

"(1) except for disclosures made under subsections (b)(1) or (b)(2) of this section, keep an accurate accounting of—

"(A) the date, nature, and purpose of each disclosure of a record to any person or to another agency made under subsection (b) of this section; and

"(B) the name and address of the person or agency to whom the disclosure is made;

"(2) retain the accounting made under paragraph (1) of this subsection for at least five years or the life of the record, whichever is longer, after the disclosure for which the accounting is made;

"(3) except for disclosures made under subsection (b)(7) of this section, make the accounting made under paragraph (1) of this subsection available to the individual named in the record at his request; and

"(4) inform any person or other agency about any correction or notation of dispute made by the agency in accordance with subsection (d) of this section of any record that has been disclosed to the person or agency if an accounting of the disclosure was made.

"(d) ACCESS TO RECORDS.—Each agency that maintains a system of records shall—

"(1) upon request by any individual to gain access to his record or to any information pertaining to him which is contained in the system, permit him and upon his request, a person of his own choosing to accompany him, to review the record and have a copy made of all or any portion thereof in a form comprehensible to him, except that the agency may require the individual to furnish a written statement authorizing discussion of that individual's record in the accompanying person's presence; Personal review.

"(2) permit the individual to request amendment of a record pertaining to him and— Amendment request.

"(A) not later than 10 days (excluding Saturdays, Sundays, and legal public holidays) after the date of receipt of such request, acknowledge in writing such receipt; and

"(B) promptly, either—

"(i) make any correction of any portion thereof which the individual believes is not accurate, relevant, timely, or complete; or

"(ii) inform the individual of its refusal to amend the record in accordance with his request, the reason for the refusal, the procedures established by the agency for the individual to request a review of that refusal by the head of the agency or an officer designated by the head of the agency, and the name and business address of that official;

"(3) permit the individual who disagrees with the refusal of the agency to amend his record to request a review of such refusal, Review.

and not later than 30 days (excluding Saturdays, Sundays, and legal public holidays) from the date on which the individual requests such review, complete such review and make a final determination unless, for good cause shown, the head of the agency extends such 30-day period; and if, after his review, the reviewing official also refuses to amend the record in accordance with the request, permit the individual to file with the agency a concise statement setting forth the reasons for his disagreement with the refusal of the agency, and notify the individual of the provisions for judicial review of the reviewing official's determination under subsection (g) (1) (A) of this section;

Notation of
dispute.

"(4) in any disclosure, containing information about which the individual has filed a statement of disagreement, occurring after the filing of the statement under paragraph (3) of this subsection, clearly note any portion of the record which is disputed and provide copies of the statement and, if the agency deems it appropriate, copies of a concise statement of the reasons of the agency for not making the amendments requested, to persons or other agencies to whom the disputed record has been disclosed; and

"(5) nothing in this section shall allow an individual access to any information compiled in reasonable anticipation of a civil action or proceeding.

"(e) AGENCY REQUIREMENTS.—Each agency that maintains a system of records shall—

"(1) maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required to be accomplished by statute or by executive order of the President;

"(2) collect information to the greatest extent practicable directly from the subject individual when the information may result in adverse determinations about an individual's rights, benefits, and privileges under Federal programs;

"(3) inform each individual whom it asks to supply information, on the form which it uses to collect the information or on a separate form that can be retained by the individual—

"(A) the authority (whether granted by statute, or by executive order of the President) which authorizes the solicitation of the information and whether disclosure of such information is mandatory or voluntary;

"(B) the principal purpose or purposes for which the information is intended to be used;

"(C) the routine uses which may be made of the information, as published pursuant to paragraph (4) (D) of this subsection; and

"(D) the effects on him, if any, of not providing all or any part of the requested information;

"(4) subject to the provisions of paragraph (11) of this subsection, publish in the Federal Register at least annually a notice of the existence and character of the system of records, which notice shall include—

"(A) the name and location of the system;

"(B) the categories of individuals on whom records are maintained in the system;

"(C) the categories of records maintained in the system;

"(D) each routine use of the records contained in the system, including the categories of users and the purpose of such use;

"(E) the policies and practices of the agency regarding storage, retrievability, access controls, retention, and disposal of the records;

"(F) the title and business address of the agency official who is responsible for the system of records;

"(G) the agency procedures whereby an individual can be notified at his request if the system of records contains a record pertaining to him;

Publication
in Federal
Register.

"(H) the agency procedures whereby an individual can be notified at his request how he can gain access to any record pertaining to him contained in the system of records, and how he can contest its content; and

"(I) the categories of sources of records in the system:

"(5) maintain all records which are used by the agency in making any determination about any individual with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual in the determination;

"(6) prior to disseminating any record about an individual to any person other than an agency, unless the dissemination is made pursuant to subsection (b) (2) of this section, make reasonable efforts to assure that such records are accurate, complete, timely, and relevant for agency purposes;

"(7) maintain no record describing how any individual exercises rights guaranteed by the First Amendment unless expressly authorized by statute or by the individual about whom the record is maintained or unless pertinent to and within the scope of an authorized law enforcement activity;

"(8) make reasonable efforts to serve notice on an individual when any record on such individual is made available to any person under compulsory legal process when such process becomes a matter of public record;

"(9) establish rules of conduct for persons involved in the design, development, operation, or maintenance of any system of records, or in maintaining any record, and instruct each such person with respect to such rules and the requirements of this section, including any other rules and procedures adopted pursuant to this section and the penalties for noncompliance;

"(10) establish appropriate administrative, technical, and physical safeguards to insure the security and confidentiality of records and to protect against any anticipated threats or hazards to their security or integrity which could result in substantial harm, embarrassment, inconvenience, or unfairness to any individual on whom information is maintained; and

"(11) at least 30 days prior to publication of information under paragraph (4) (I) of this subsection, publish in the Federal Register notice of any new use or intended use of the information in the system, and provide an opportunity for interested persons to submit written data, views, or arguments to the agency.

"(f) AGENCY RULES.—In order to carry out the provisions of this section, each agency that maintains a system of records shall promulgate rules, in accordance with the requirements (including general notice) of section 553 of this title, which shall—

"(1) establish procedures whereby an individual can be notified in response to his request if any system of records named by the individual contains a record pertaining to him;

"(2) define reasonable times, places, and requirements for identifying an individual who requests his record or information pertaining to him before the agency shall make the record or information available to the individual;

"(3) establish procedures for the disclosure to an individual upon his request of his record or information pertaining to him, including special procedure, if deemed necessary, for the disclosure to an individual of medical records, including psychological records, pertaining to him;

"(4) establish procedures for reviewing a request from an individual concerning the amendment of any record or information pertaining to the individual, for making a determination on the request, for an appeal within the agency of an initial adverse agency determination, and for whatever additional means may be necessary for each individual to be able to exercise fully his rights under this section; and

"(5) establish fees to be charged, if any, to any individual for making copies of his record, excluding the cost of any search for and review of the record.

Rules of
conduct.

Confidentiality
of records.

Publication
in Federal
Register.

5 USC 553.

Fees.

Publication
in Federal
Register.

The Office of the Federal Register shall annually compile and publish the rules promulgated under this subsection and agency notices published under subsection (e) (4) of this section in a form available to the public at low cost.

“(g) (1) CIVIL REMEDIES.—Whenever any agency

“(A) makes a determination under subsection (d) (3) of this section not to amend an individual’s record in accordance with his request, or fails to make such review in conformity with that subsection;

“(B) refuses to comply with an individual request under subsection (d) (1) of this section;

“(C) fails to maintain any record concerning any individual with such accuracy, relevance, timeliness, and completeness as is necessary to assure fairness in any determination relating to the qualifications, character, rights, or opportunities of, or benefits to the individual that may be made on the basis of such record, and consequently a determination is made which is adverse to the individual; or

“(D) fails to comply with any other provision of this section, or any rule promulgated thereunder, in such a way as to have an adverse effect on an individual,

Jurisdiction.

the individual may bring a civil action against the agency, and the district courts of the United States shall have jurisdiction in the matters under the provisions of this subsection.

Amendment
of record.

“(2) (A) In any suit brought under the provisions of subsection (g) (1) (A) of this section, the court may order the agency to amend the individual’s record in accordance with his request or in such other way as the court may direct. In such a case the court shall determine the matter de novo.

“(B) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this paragraph in which the complainant has substantially prevailed.

Injunction.

“(3) (A) In any suit brought under the provisions of subsection (g) (1) (B) of this section, the court may enjoin the agency from withholding the records and order the production to the complainant of any agency records improperly withheld from him. In such a case the court shall determine the matter de novo, and may examine the contents of any agency records in camera to determine whether the records or any portion thereof may be withheld under any of the exemptions set forth in subsection (k) of this section, and the burden is on the agency to sustain its action.

“(B) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this paragraph in which the complainant has substantially prevailed.

Damages.

“(4) In any suit brought under the provisions of subsection (g) (1) (C) or (D) of this section in which the court determines that the agency acted in a manner which was intentional or willful, the United States shall be liable to the individual in an amount equal to the sum of—

“(A) actual damages sustained by the individual as a result of the refusal or failure, but in no case shall a person entitled to recovery receive less than the sum of \$1,000; and

“(B) the costs of the action together with reasonable attorney fees as determined by the court.

“(5) An action to enforce any liability created under this section may be brought in the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, without regard to the amount in controversy, within two years from the date on which the cause of action arises, except that where an agency has materially and willfully misrepresented any information required under this section to be disclosed to an individual and the information so misrepresented is material to establishment of the liability of the agency to the individual under this section, the

action may be brought at any time within two years after discovery by the individual of the misrepresentation. Nothing in this section shall be construed to authorize any civil action by reason of any injury sustained as the result of a disclosure of a record prior to the effective date of this section.

“(h) RIGHTS OF LEGAL GUARDIANS.—For the purposes of this section, the parent of any minor, or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction, may act on behalf of the individual.

“(i) (1) CRIMINAL PENALTIES.—Any officer or employee of an agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section or by rules or regulations established thereunder, and who knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

“(2) Any officer or employee of any agency who willfully maintains a system of records without meeting the notice requirements of subsection (e) (4) of this section shall be guilty of a misdemeanor and fined not more than \$5,000.

“(3) Any person who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than \$5,000.

“(j) GENERAL EXEMPTIONS.—The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553 (b) (1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from any part of this section except subsections (b), (c) (1) and (2), (e) (4) (A) through (F), (e) (6), (7), (9), (10), and (11), and (i) if the system of records is—

“(1) maintained by the Central Intelligence Agency; or

“(2) maintained by an agency or component thereof which performs as its principal function any activity pertaining to the enforcement of criminal laws, including police efforts to prevent, control, or reduce crime or to apprehend criminals, and the activities of prosecutors, courts, correctional, probation, pardon, or parole authorities, and which consists of (A) information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; (B) information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or (C) reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision.

At the time rules are adopted under this subsection, the agency shall include in the statement required under section 553(c) of this title, the reasons why the system of records is to be exempted from a provision of this section.

“(k) SPECIFIC EXEMPTIONS.—The head of any agency may promulgate rules, in accordance with the requirements (including general notice) of sections 553 (b) (1), (2), and (3), (c), and (e) of this title, to exempt any system of records within the agency from subsections (c) (3), (d), (e) (1), (e) (4) (G), (H), and (I) and (f) of this section if the system of records is—

“(1) subject to the provisions of section 552(b) (1) of this title; 5 USC 552.

“(2) investigatory material compiled for law enforcement purposes, other than material within the scope of subsection (j) (2) of this section: *Provided, however*, That if any individual is denied any right, privilege, or benefit that he would otherwise be entitled by Federal law, or for which he would otherwise be

eligible, as a result of the maintenance of such material, such material shall be provided to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence;

18 USC 3056.

"(3) maintained in connection with providing protective services to the President of the United States or other individuals pursuant to section 3056 of title 18;

"(4) required by statute to be maintained and used solely as statistical records;

"(5) investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence;

"(6) testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service the disclosure of which would compromise the objectivity or fairness of the testing or examination process; or

"(7) evaluation material used to determine potential for promotion in the armed services, but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to the effective date of this section, under an implied promise that the identity of the source would be held in confidence.

5 USC 553.

At the time rules are adopted under this subsection, the agency shall include in the statement required under section 553 (c) of this title, the reasons why the system of records is to be exempted from a provision of this section.

44 USC 3103.

"(1) (1) ARCHIVAL RECORDS.—Each agency record which is accepted by the Administrator of General Services for storage, processing, and servicing in accordance with section 3103 of title 44 shall, for the purposes of this section, be considered to be maintained by the agency which deposited the record and shall be subject to the provisions of this section. The Administrator of General Services shall not disclose the record except to the agency which maintains the record, or under rules established by that agency which are not inconsistent with the provisions of this section.

Publication
in Federal
Register.

"(2) Each agency record pertaining to an identifiable individual which was transferred to the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, prior to the effective date of this section, shall, for the purposes of this section, be considered to be maintained by the National Archives and shall not be subject to the provisions of this section, except that a statement generally describing such records (modeled after the requirements relating to records subject to subsections (e) (4) (A) through (G) of this section) shall be published in the Federal Register.

"(3) Each agency record pertaining to an identifiable individual which is transferred to the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, on or after the effective date of this section, shall, for the purposes of this section, be considered to be maintained by the National Archives and shall be exempt from the requirements of this section except subsections (e) (4) (A) through (G) and (e) (9) of this section.

“(m) GOVERNMENT CONTRACTORS.—When an agency provides by a contract for the operation by or on behalf of the agency of a system of records to accomplish an agency function, the agency shall, consistent with its authority, cause the requirements of this section to be applied to such system. For purposes of subsection (i) of this section any such contractor and any employee of such contractor, if such contract is agreed to on or after the effective date of this section, shall be considered to be an employee of an agency.

“(n) MAILING LISTS.—An individual’s name and address may not be sold or rented by an agency unless such action is specifically authorized by law. This provision shall not be construed to require the withholding of names and addresses otherwise permitted to be made public.

“(o) REPORT ON NEW SYSTEMS.—Each agency shall provide adequate advance notice to Congress and the Office of Management and Budget of any proposal to establish or alter any system of records in order to permit an evaluation of the probable or potential effect of such proposal on the privacy and other personal or property rights of individuals or the disclosure of information relating to such individuals, and its effect on the preservation of the constitutional principles of federalism and separation of powers.

“(p) ANNUAL REPORT.—The President shall submit to the Speaker of the House and the President of the Senate, by June 30 of each calendar year, a consolidated report, separately listing for each Federal agency the number of records contained in any system of records which were exempted from the application of this section under the provisions of subsections (j) and (k) of this section during the preceding calendar year, and the reasons for the exemptions, and such other information as indicates efforts to administer fully this section.

“(q) EFFECT OF OTHER LAWS.—No agency shall rely on any exemption contained in section 552 of this title to withhold from an individual any record which is otherwise accessible to such individual under the provisions of this section.”

Notice to
Congress and
OMB.

Report to
Speaker of
the House
and Presi-
dent of the
Senate.

5 USC 552.

APPENDIX II

RULES AND REGULATIONS CONCERNING CONFIDENTIALITY: HEALTH CARE FINANCING ADMINISTRATION

[4110-35]

Title 42—Public Health

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER D—PROFESSIONAL STANDARDS REVIEW

PART 476—CONFIDENTIALITY AND DISCLOSURE OF INFORMATION BY PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Final rule.

SUMMARY: This rule sets forth policies for disclosure of information acquired by Professional Standards Review Organizations (PSROs). Section 1166(a) of the Social Security Act requires regulations for the release of PSRO information for other than the purposes of the PSRO statute. The intent is that PSRO information which was previously published or is in aggregate statistical form be provided to parties who need it, without violating the privacy rights of patients and health care practitioners, and without undue burden. Observance of the rule is intended also to protect PSROs against the risk of penalties under section 1166(b) of the Act.

EFFECTIVE DATE: These regulations are effective on January 16, 1978.

FOR FURTHER INFORMATION CONTACT:

Lois Eberhard, 301-443-2808.

SUPPLEMENTARY INFORMATION:

BACKGROUND

PSROs review Medicare, Medicaid and Maternal and Child Health and Crippled Childrens' services. Some of the information acquired by PSROs in carrying out the review functions are of a sensitive or personal nature, requiring stringent safeguards. Other information is public in nature prior to receipt by the PSRO or in the form of statistical summaries that do not identify individuals. PSRO information can be useful to other parties. These regulations are necessary to provide for the release of information without subjecting PSRO personnel to the risk of penalties under section 1166(b) of the Act.

The notice of proposed rulemaking published on December 3, 1976 (41 FR 53215), codified these policies under Subpart Q of Part 101 of Title 42, of the Code of Federal Regulations.

Regulations effective October 1, 1977 established a new Chapter IV in Title 42 of the CFR and transferred all Health Care Financing Administration regulations to that new chapter. Accordingly, these final regulations are codified under 42 CFR Part 476.

DISCUSSION OF COMMENTS

Comments, suggestions and objections received in response to the December proposal were considered and are summarized below along with our responses thereto and the changes in the proposed rule.

1. *Proposal is too narrow.* Several comments objected to the publication of an interim regulation providing only for limited disclosure and advocated the immediate development and issuance of a comprehensive regulation. The majority of these comments recommended much broader disclosure to meet the needs of the public for more information on health providers and services, but still protect the privacy rights of patients. However, regulations that permit the disclosure of comparatively nonsensitive and public information can be published sooner. It takes time to resolve the broader, more complex issues that underlie a comprehensive regulation. Suggestions that are pertinent to these issues are currently being considered in developing the comprehensive regulation.

2. *Additional disclosure under the interim regulation.* It was recommended that the proposed rule be expanded to include the disclosure of the norms, criteria and standards used by the PSRO and data collected solely for PSRO purposes, such as the number of days certified and Medical Care Evaluation Studies. The Secretary has determined that disclosure of PSRO norms, criteria and standards is permissible under section 1166(a)(1) of the act without regulations. Data collected solely for PSRO purposes is beyond the scope of the interim rule. However, the comprehensive regulation under development will reflect this recommendation.

3. *Disclosure on PSRO's own initiative.* The proposed rule required PSROs to disclose specified types of data or information only upon receipt of a request. Several comments suggested that PSROs also be permitted to disclose the same data or information on their own initiative, when appropriate. This suggestion has been accepted and included in the final rule.

4. *Burden on PSROs.* Several comments expressed concern that the implementation of this interim regulation would place an excessive burden on PSROs to provide data services. It is recognized that the provision of data by PSROs will place a burden on some PSROs. Nevertheless it is considered important that such data, heretofore inaccessible in many geographic areas, be readily available to health agencies and the public. This approach will make it unnecessary for those agencies to duplicate the collection and processing efforts of the PSRO. Moreover, by requiring that requests clearly define the data or infor-

mation desired and by permitting the PSRO to charge a fee for data or information not routinely compiled for PSRO use, it is expected that the burden will be eased somewhat.

The interim regulation does not require a PSRO to automatically meet all requests for data or information; rather it requires the PSRO to exercise judgment regarding the conditions of disclosure. These conditions involve matters such as the assurance that individuals are not indirectly identified in the data or information to be disclosed. However, in recognition of the need to establish a procedure for review of a PSRO decision to deny a request for data or information, the interim regulation has been amended to provide for Secretarial review of such denials.

5. *Confidentiality determined by source of information.* A number of respondents understood that § 476.2 would permit the source of public information to determine that such information was confidential, even after it had been published, and thus prevent its disclosure by the PSROs. Since it was not the intent of the provision to permit sources to so control the data, the rule has been clarified. The purpose of the rule is to require disclosure of data or information which was published prior to receipt by the PSRO. Examples of this type of data or information are newspaper articles and annual reports of health care institutions which are publicly distributed by the institutions.

6. *Statistics identify health care institutions.* The proposed rule provided for the disclosure of summary statistics as long as neither patients nor health care practitioners could be identified through these summaries. A number of comments objected to this rule, because it permits the disclosure of data or information which identify health care institutions. It is the intention of the Department to make such institutional data available to meet a variety of needs for health data, including identification of problem areas, health planning and the funding of health services. The disclosure of data about identifiable institutions is also consistent with court decisions that have held that institutions have no right of privacy under the Constitution, *U.S. v. Morton Salt*, 338 U.S. 632, 70 S.Ct. 357 (1950) and with section 1106(d) of the Act, which requires that various Medicare contractor performance reports, provider evaluation reports and provider survey reports be available for public inspection.

On the other hand, the Secretary is mindful that such institutional information may be misinterpreted in the absence of an appropriate context. Accordingly, the proposed regulation provides institutions with an opportu-

nity to comment and requires PSROs to forward those comments to the recipient of the data or information in order to correct errors or inaccurate impressions.

7. *Use of computer tape.* Several comments suggested that PSROs be permitted to provide UHDDS data or information on computer tape as well as in the form of aggregate statistics. The Department recognizes that the disclosure of UHDDS computer tapes with personal identifiers deleted may make the data more useful to some users and reduce the burden on PSROs. However, techniques do not exist for determining if an individual could be identified from the data on the tape. Therefore, the Department has rejected the suggestion until such techniques for assuring the privacy of individuals are available.

8. *Disclosure on basis of need to know.* It was suggested that the rule be revised to permit a PSRO to disclose information if the PSRO determines that the requesting party has an appropriate need to know the data. This approach would be broader than the criteria for disclosure set out under section 1166 of the Act, which permits disclosure of PSRO data only if it is necessary to carry out the purposes of title XI, part B of the act or if such disclosure has been determined by the Secretary to be appropriate and is specified in regulations.

9. *Availability to State Governments.* A number of States urged that all PSRO data or information be available to State Governments. It is the position of the Department that a great deal of PSRO data is available to State Medicaid agencies presently, even in the absence of regulations. The States are now authorized by the Secretary to monitor PSRO activities and may obtain certain data to do so. PSRO data necessary to make Medicaid payments must be disclosed to State Medicaid agencies under section 1158 of the act. Also, data or information for other activities necessary for a State Medicaid agency to carry out the purposes of title XI, part B of the act can be disclosed to States under section 1166(a) without regulations. Finally, the comprehensive regulations under development are expected to provide for further disclosure of PSRO data or information to State agencies.

10. *Waiver of NOI.* Several commenters objected to the publication of a Notice of Proposed Rulemaking without publishing a Notice of Intent beforehand, and maintained that the regulatory policies of the Department (40 FR 34811) were not followed. While the regulatory policies of the Department encourage the use of the NOI, they do not require the Publication of an NOI in every case. As stated in the preamble to the proposed rule,

the proposed rule was published without the use of a Notice of Intent (NOI) "because there is an urgent requirement for these regulations and over an extended period of time there has been significant interaction between the Department and medical and consumer organizations and interested individuals in the development of the approach contained in the NPRM which has satisfied the spirit and intent of the NOI."

11. *Publicize existence of PSRO data.* It was urged that the public should be informed of the existence of the PSRO data system. No revision in the present regulation was needed since each PSRO is required, under its contract with the Department, to publish a notice of the existence, scope and purposes of the PSRO data system.

12. *Obtain public information from original source.* Comment was received suggesting that PSROs refer requests for public information to the source of the information, rather than furnish it themselves. This suggestion was rejected because such referrals might often be time consuming and onerous, thereby making it more difficult for persons to obtain a large variety of useful public data.

13. *Applicability of the Privacy Act.* Comments were received suggesting that the "Privacy Act of 1974" (5 U.S.C. 552a) was applicable to PSROs and the provisions of that Act should be reflected in PSRO confidentiality regulations. It is the Department's view that section (m) of 5 U.S.C. 552(a), which makes the Privacy Act applicable to government contractors whose contract provides for the operation of a system of records on behalf of a government agency, does not apply to PSRO contractors. PSROs collect data primarily to carry out purposes specified by statute as PSRO responsibilities, not the responsibility of the Secretary, and each PSRO directly manages its own review operations and the records collected for such purposes.

14. *Time limit on interim regulations.* It was proposed by some commenters that a limit be set on the length of time that the interim regulations are in effect, to assure that comprehensive regulations are published as quickly as possible. It is the intention of the Department to publish comprehensive regulations on PSRO confidentiality as quickly as the outstanding policy issues are resolved and the procedures necessary for publication of regulations are completed. However, since this time period is very difficult to predict, it was decided that the interim regulations should not have a limit on the time for which they are effective.

15. *Determining whether data identifies individuals.* Comments asked what particular method would be used

in determining whether individual patients or practitioners were "identifiable" from the PSRO data to be disclosed. Of particular concern is the indirect identification of individuals through a combination of attributes such as sex, age, dates of admission or discharge, diagnosis or procedures. Such "identifiable" data would not be required to be disclosed under the interim regulations. Since statistical techniques for implicit identification of individuals from statistical information are highly technical in nature and vary with the type of data involved, it was not feasible to specify such methods in the regulations. HEW will issue guidelines which will be provided to PSROs on this subject to suggest methods whereby statistical data can be displayed to avoid the identification of individuals.

16. *No regulation until all PSROs are in full operation.* One comment suggested that the proposed regulation be withdrawn until all PSROs are fully operational. To restrict the use of data or information acquired by PSROs until such time as all PSROs are fully operational would conflict with the intent of the Department to meet the current needs of many users of health data.

17. *Information on existence and classification of data.* Some comments asked that the regulation establish a practical procedure to inform individuals of the types of information available and the manner in which the information is labeled by the PSRO. Since the disclosures, except for previously published information, required under the interim regulation are limited to data available only from the UHDDS, there should be little confusion over the specific data available from this source. In addition, the Secretary believes it would be too great a burden on PSROs to require all PSROs to publish regularly a description of all the previously published data which it has acquired. 42 CFR Chapter IV, Subchapter D, is amended by adding a new Part 476 to read as follows:

- Sec.
476.1 Applicability.
476.2 Disclosure of public information acquired by PSROs.
476.3 Disclosure of Uniform Hospital Discharge Data Set acquired by a PSRO.
476.4 Secretarial Review.

AUTHORITY: Sec. 1166, Social Security Act, 86 Stat. 1443 (42 U.S.C. 1320C-15); section 1102 of the Social Security Act, 49 Stat. 647, as amended (42 U.S.C. 1302).

§ 476.1 Applicability.

The provisions of this part are applicable to the disclosure of information acquired by a PSRO in the exercise of its duties and functions under the Social Security Act in accordance with section 1166 of the Act.

§ 476.2 Disclosure of public information acquired by PSROs.

(a) A PSRO shall, upon receipt of a request for specific information in its possession, provide to the person making the request a copy of that information if:

(1) The information had, prior to the request, been published or otherwise disclosed to the public by any individual or entity other than the PSRO or its employees, members or directors, and

(2) The disclosure of the information is not prohibited by Federal or State law.

(b) A PSRO may, on its own initiative, provide to a person whom it determines to have an appropriate need for such information, a copy of any information described in paragraph (a) of this section.

(c) Information provided under this section shall be in the form in which it is received by the PSRO or in the form in which it is maintained for PSRO use.

(d) The PSRO may require the payment of a fee, for furnishing information under this section, not to exceed the reasonable cost of doing so.

§ 476.3 Disclosure of Uniform Hospital Discharge Data Set (UHDDS) acquired by a PSRO.

(a) A PSRO shall, upon receipt of a request that clearly defines the specific

information desired, provide to the person making the request, summary statistics derived from the Uniform Hospital Discharge Data Set (the multi-purpose, basic data set containing information on a hospital discharge approved by the Secretary for use in Federal health programs, including the PSRO program) which does not directly or indirectly identify a particular patient or health care practitioner.

(b) A PSRO may provide to a person whom it determines to have an appropriate need for it, summary statistics acquired by the PSRO from the UHDDS which does not directly or indirectly identify a particular patient or health care practitioner.

(c) Information described in paragraphs (a) and (b) of this section, if routinely compiled for PSRO use, shall be provided without charge.

(d) The PSRO may require the payment of a fee for furnishing information under this section, not to exceed the reasonable cost of doing so.

(e) If information provided under this section identifies a particular health care institution, the PSRO shall notify the institution, at least 15 days before disclosing the information, of its intention to do so. The identified health care institution may submit to the PSRO comments concerning the information to be disclosed, which shall be attached by the PSRO to such

information if received prior to its disclosure or forwarded separately by the PSRO to the recipient, if the comments are received after the information was disclosed.

(f) The PSRO may attach a statement of comment to any disclosure made under this section.

§ 476.4 Secretarial review.

Any person whose request for information is denied by the PSRO may request that the Secretary review the decision of the PSRO. If the Secretary determines that the PSRO has improperly denied the request, he shall direct the PSRO to provide the requested information and it shall do so.

NOTE.—The Health Care Financing Administration has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11821 as amended by Executive Order 11949, and OMB Circular A-107.

Dated: November 4, 1977.

ROBERT A. DERZON,
*Administrator, Health Care
Financing Administration.*

Approved: January 3, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

(FR Doc. 78-661 Filed 1-13-78; 8:45 am)

NCHS GUIDELINES TO PREVENT DISCLOSURES OF IDENTIFIABLE DATA ²

10. Avoiding Inadvertent Disclosures in Published Data

10.1 *Problem.* In their zeal to make available to the public a full set of information on a given subject, statisticians may—and sometimes do—present so much detail in published tabulations that they accidentally reveal confidential information about particular study subjects. This may happen in several ways. For example,

- A. A single case falls in cell $x_i y_i$ of a statistical table. If one knows the individual in the population with characteristic x_i , the table has disclosed that that individual also has characteristic y_i .
- B. Two cases fall in cell $x_i y_i$ of a statistical table. An individual in the population with characteristics $x_i y_i$ can now know that the other individual in the population with characteristic x_i also has the characteristic y_i .
- C. All cases in line y_i of a statistical table fall in the cell in column x_i . We then know that any individual in the population with characteristic y_i also has characteristic x_i .
- D. Cell $x_i y_i$ gives the total income of all individuals with characteristics x_i and y_i . If there are only two individuals, a and b , in the population with that combination of characteristics, then a , knowing his own income, will be able to determine b 's income by simple subtraction, and b will also be able to determine a 's income.
- E. A table gives the total annual receipts for all five nursing homes in county m . However, nursing home a is much larger than all the rest combined; it accounts, in fact, for three-fourths of all nursing home receipts in the county. Knowing the county total, the manager of nursing home a is able to calculate the incomes of the other four homes, at least within some fairly narrow limits.
- F. A Standard Metropolitan Statistical Area (SMSA) contains two counties, a and b . Four hospitals are located in county a and only one in county b . A statistical report is published, giving confidential hospital data totaled for each SMSA. Another report is published with confidential data on hospitals by county, but only for counties with three or more hospitals. Using the two reports one can subtract the data for county a from the SMSA data, deriving the confidential data for the lone hospital in county b .

²Excerpted from: National Center for Health Statistics: *Staff Manual on Confidentiality, NCHS*. DHEW Pub. No. (PHS) 78-1244. Public Health Service, DHEW, Hyattsville, Md., July 1978.

- G. The maximum Social Security benefit for an individual retired person is, say, \$235 per month. A published table shows that white males aged 70 to 74 in county *a* receive an average benefit of \$235 per month. It is now known that *every* white male aged 70 to 74 in county *a* who receives a Social Security payment receives \$235 a month.

These examples imply the existence of several general types of situations in which statistical disclosure may occur. An additional possibility may be found in a group of three or more tables of subsets of a given population from which disclosures are possible through the solution of simultaneous equations. Center guidelines as set forth in Section 10.3 take into account the several possible disclosure situations.

10.2 *Types of Disclosure.* Center policy recognizes and attempts to deal with several classes of disclosure:

- A. *Exact versus approximate disclosures.* Exact disclosure is the disclosure of a specific characteristic, such as race, sex, or a particular pathological condition. Approximate disclosure is the disclosure that a subject has a characteristic that falls within a certain range of possibilities, such as being between 45 and 55 years of age or having an income between \$15,000 and \$25,000. An approximate disclosure *may* in a given situation be considered harmless because of its indefinite nature.
- B. *Probability-based versus certainty disclosures.* Data in a table may indicate that members of a given population segment have an 80-percent chance of having a certain characteristic; this would be a probability-based disclosure as opposed to a certainty disclosure of information on given individuals. In a sense, every published table containing data or estimates of descriptors of a specific population group provides probability-based disclosures on members of that group, and only in unusual circumstances could any such disclosure be considered unacceptable. It is possible that a situation could arise in which data intended for publication would reveal that a highly specific group had an extremely high probability of having a given sensitive characteristic; in such a case the probability-based disclosure perhaps should not be published.
- C. *Internal versus external disclosures.* Internal disclosures are those that result completely from data published from one particular study. External disclosures occur when outside information is brought to bear upon the study data to create disclosures. This possibility must be recognized in any disclosure analysis.

10.3 *Special Guidelines for Avoiding Disclosure.* Except where otherwise indicated, the following guidelines apply to all Center publications of statistics:

- A. In no table should all cases of any line or column be found in a single cell.
- B. In no case should a single cell of a cross-tabulation contain only one or two cases.

- C. In no case should a quantity figure be based upon fewer than three cases.
- D. In no case should a quantity figure be published if one case contributes more than 60 percent of the amount.
- E. In no case should data on an identifiable case, nor any of the kinds of data listed in preceding items A-D, be derivable through subtraction or other calculation from the combination of tables published on a given study.
- F. Data published by NCHS should never permit disclosure when used in combination with other known data.

Report writers and editors in the Center are to follow these guidelines. If a guideline appears unreasonable in a given situation, approval for a special exception to the guideline should be requested from the Director or the Deputy Director. The following types of cases represent exceptions to the above guidelines which do not require special approval from the Director or Deputy Director:

- A. It has been a longstanding tradition in the field of vital statistics not to suppress small frequency cells in the tabulation and presentation of data. For example, it has been considered important to know that there were two deaths from rabies in Rio Arriba County, N. Mex., in a given year, or that there were only one infant death and two fetal deaths in Aitkin County, Minn. These types of exceptions to general NCHS practices in other programs are followed because they have been accepted traditionally and because they rarely, if ever, reveal any information about individuals that is not known socially.
- B. Tables may show simple *counts* of number of persons, even though the number in a cell is only "1" or "2," provided the classifying data are not judged to be sensitive in the context of the table. For example, publication of counts of health manpower personnel by occupation by area are considered acceptable, if not accompanied by other distinguishing characteristics, or other cross-classifications that have the effect of adding descriptive information about the same persons. However, publication of counts of personnel for a specified occupation by area by income is not acceptable for cells of less than three persons because that would reveal sensitive income data.

10.4 *Evaluating a Disclosure Problem.* There may be mitigating circumstances in a given situation which may make it acceptable to publish data that, strictly speaking, could result in "disclosures." Such circumstances could provide grounds for requesting the "special exception" to the previously noted rules:

- A. When data in a study are based upon a small-fraction sample, for example, less than 10 percent of the universe, it might generally be assumed that disclosure will not occur through published tabulations. However, there could be exceptions. So much detail may be presented that an individual unique in the population is identified through the tables, or a member of the sample may find himself and others in the data. The usual rules precluding

publication of sample estimates that do not have a reasonably small relative sampling error should prevent any disclosures from occurring in tabulations from sample data.

- B. The existence of errors or imputations in the data brings some small reduction in the likelihood of disclosure through table publication.
- C. Incompleteness of reporting, which often occurs even where studies are supposed to include 100 percent of a given group in the population, also reduces the certainty of any disclosure taking place through publication of data.
- D. In some instances the danger of disclosure might be mitigated by the fact that the data in question have no sensitivity. They may already have appeared in a published directory, or they may involve entirely obvious characteristics, or they may relate to an earlier time. Since that time, many changes have occurred, so that the data have become completely innocuous.

10.5 *Measures To Avoid Disclosure.* Two methods customarily used in the Center to prevent disclosures from taking place through tabulations:

- A. The table is reduced in size when rows or columns are combined into larger categories, eliminating the particular cells that would otherwise produce disclosures.
- B. Unacceptable data in cells are suppressed. When this is done, it is necessary also to suppress other cells in the table to prevent determination of the unacceptable cell figure through subtraction. It is usually necessary to suppress four cells in a cross-tabulation in order to avoid disclosure through one cell—the offending cell (x_i, y_i) , another cell in the same row (x_j, y_i) , another cell in the same column as the offending cell (x_i, y_j) , and also the cell (x_j, y_j) at the intersect of the additional row and column involved in the newly suppressed cells.

11. Avoiding Inadvertent Disclosures Through Release of Microdata Tapes

It is Center policy to make its files on individual elementary data units available at cost to the scientific community so that additional analyses can be made of these data for the country's benefit. The scientific community has shown great interest in such tapes, and requests for the Center's tapes have increased rapidly in recent years. Except when the file contains no confidential information, these "public use microdata tapes" are released without any identifiers, such as name or address, or the reporting units.

11.1 *Problem.* Even though all personal identifiers are removed from cases in a microdata file, a few items of information which appear as variables on the tape may identify data subjects to any person who has access to the information from another source. Thus, for example, if tape descriptors indicate that the data subject is an attorney who grad-

uated from the University of Maryland but show nothing else about his personal characteristics, the subject is not identified. If the tape goes on to indicate that the attorney graduated in 1964, has a wife who graduated from Radcliffe in 1966, has three children, and lives in Fairfax County, Va., the subject is now probably identified uniquely, and all information in the file about the subject would be disclosed to anyone with access to the file who could then identify the person from the given set of characteristics. The place of residence, especially when it is not a heavily populated area, is particularly useful in the identification process.

The low-ratio sample that the Center uses in its surveys would usually frustrate a person who is trying to locate a known individual in the Center's survey files. Thus, if a survey involves a 1:1,000 sample, the investigator would have only one chance in a thousand of finding in the file a particular individual whose data he is searching. However, if the investigator goes on a "fishing expedition" to find "anyone" in a file who might be identified, chances are much better.

11.2 *Mitigating Circumstances.* The only absolutely sure way to avoid disclosure through microdata tapes is to refrain completely from releasing any microdata tapes, but this would deprive the Nation of a great deal of very important health research. Therefore the Center must make a determination as to when the public's need is sufficiently great to justify the risk of disclosure. It is the Center's policy to release microdata tapes for purposes of statistical research only when the risk of disclosure is judged to be extremely low. Some factors bearing upon the acceptability of this risk are the following:

- A. As noted, when a survey involves only a proportionately very small sample of establishments or individuals, there is small chance that it will identify a given case of interest. (This assumes, of course, that an investigator would not have a means of determining what cases fell into the sample.) Identification of an individual case would require a great deal of outside information not likely to be found outside the survey itself. However, if the sample is stratified and cases in certain strata are selected with high probability, there is little or no advantage in reducing risk of disclosure through sampling as far as cases in those strata are concerned.
- B. Identifying individuals in the microdata file would usually be an expensive undertaking, hardly justified by the kind of information in the file. Public-use microdata files, in fact, should not contain any information that would likely harm or embarrass the individual or establishment if it should happen to be disclosed.

11.3 *The Rules.* The following rules apply to all microdata tapes released by NCHS which contain any information about individual persons or establishments, except where the supplier of information was told, prior to his giving the information, that the information would be made public:

- A. The tape must not contain any detailed information about the subject that could facilitate identification and that is not essential for research purposes (e.g., exact date of the subject's birth).

- B. Geographic places that have fewer than 250,000 people are not to be identified on the tape.
- C. Characteristics of an area are not to appear on the tape if they would uniquely identify an area of less than 250,000 people.
- D. Information on the drawing of the sample which might assist in identifying a data subject must not be released outside the Center. Thus, the identities of primary sampling units are not to be made available outside the Center.
- E. Before any new or revised microdata tapes are published, they, together with their full documentation, must be approved for publication by the Director or Deputy Director.
- F. A microdata tape containing confidential data on unidentified individuals or facilities may not be released to any person or organization outside NCHS until that person, or a responsible representative of that organization, has first signed the statement on the Order Form, whereby he gives assurance that the data provided will be used only for statistical reporting or research purposes.

If it appears in any particular instance that the strict application of one or more of these rules is inappropriate, a request should be submitted to the Director or Deputy Director to allow an exception.

Some organizations have the policy of introducing random errors into their public-use microdata tapes in order to reduce the probability of disclosure. This practice is undesirable from the standpoint that it inevitably lessens the value of the tape for making sensitive statistical analyses. Center staff are encouraged to study the feasibility and advisability of taking such steps in order to reduce further the risk of disclosures through use of the Center's public-use tapes.

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