REPORT AND
RECOMMENDATIONS

ETHICAL GUIDELINES FOR THE DELIVERY OF HEALTH SERVICES BY DHEW

THE NATIONAL
COMMISSION FOR
THE PROTECTION OF
HUMAN SUBJECTS
OF BIOMEDICAL AND
BEHAVIORAL RESEARCH

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National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our report and recommendations on "Ethical Guidelines for the Delivery of Health Services by DHEW." This is one of several topics of study identified in our mandate under Public Law 93-348, which directs the Commission to submit its reports to the President, the Congress, and the Secretary of Health, Education, and Welfare.

In previous reports, the Commission has made recommendations for the protection of various categories of human subjects in biomedical and behavioral research. In this report, by contrast, the Commission makes recommendations regarding the rights of patients who receive health services under programs conducted or supported by the Department of Health, Education, and Welfare. Although the scope of this report is limited to the provision of health care under such departmental programs, the principles and guidelines set forth are suitable for more general application.

The Commission found a similarity of objectives in the protection of research subjects and the protection of patients receiving health care in federally funded programs. Specifically, not only should the basic ethical principles of respect for persons, beneficence and justice underlie the conduct of both activities, but there should be corresponding mechanisms for their application in each domain. Of paramount concern is respect for persons, reflected in procedures to assure that consent is informed and unconstrained and that individual privacy and dignity are maintained. Of equal importance is the active involvement of individuals other than health care providers in determining eligibility for benefits and the extent of services to be provided.

The Commission believes that the federal government should make clear its intent that persons eligible to receive health services under federally mandated programs be understood as having a legal right to such care and a correlative right to effective remedies if appropriate care is not received. The objective should be to provide health services equivalent to those available in the private sector, to the extent it is economically feasible.

We appreciate the opportunity to develop a report which we hope will provide guidance for individuals at federal, state and local levels who are involved in the design and administration of health care programs conducted or supported by the Department of Health, Education, and Welfare.

Respectfully,

Kenneth J. Ryan, M.D.
Chairman

National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The Honorable Walter F. Mondale
President of the United States Senate
Washington, D.C. 20510

Dear Mr. President:

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Chairman

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Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The Honorable Thomas P. O'Neill, Jr.
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

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Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The Honorable Joseph A. Califano, Jr.
Secretary of Health, Education, and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

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NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

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INTRODUCTION

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established in 1974 under the National Research Act (Public Law 93-348) to develop ethical guidelines for the conduct of research involving human subjects, and to make recommendations for the application of such guidelines to research conducted or supported by the Department of Health, Education, and Welfare (DHEW). The Act also directs the Commission to consider the applicability of these guidelines to DHEW health care delivery programs. The specific duties of the Commission with regard to this mandate are set forth in Section 202(a)(1) of the National Research Act as follows:

> (A) The Commission shall (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects, (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles, and (iii) make recommendations to the Secretary (I) for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the Secretary, and (II) concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research. . . .
>
> (C) The Commission shall consider the appropriateness of applying the principles and guidelines identified and developed under subparagraph (A) to the delivery of health services to patients under programs conducted or supported by the Secretary.

The Commission's findings and recommendations pursuant to its mandate under paragraph (A) are available in separate reports;* they are described in summary form in Chapter 5 of this report. To fulfill its duties under paragraph (C), the Commission surveyed the types of health service delivery programs conducted or supported by DHEW, giving particular attention to existing mechanisms for protecting the rights of patients in those programs and to the unsolved problems remaining. The National Minority Conference on Human Experimentation, convoked by the Commission to assure that viewpoints of minority groups would be brought to the Commissioners' attention, made recommendations with respect to these health care programs. Health care administrators, consumer advocates, federal health officials, and health professionals from academic institutions presented their views on this topic at a colloquium convened by the Commission. Views of a similarly diverse group were presented to the Commission at a public hearing. In addition, members of the Commission made a site visit to facilities of the Indian Health Service in the Phoenix, Arizona area. The Commission also reviewed reports and papers prepared under contract on the issues involved in this charge from the perspectives of philosophy, sociology, medicine, and health policy. Finally, the Commission conducted deliberations in public meetings, and developed its recommendations on the applicability of the ethical principles and guidelines for research to health care programs conducted or supported by DHEW.

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* The Belmont Report: Ethical Guidelines for the Protection of Human Subjects of Research, DHEW Publication No. (OS)78-0012; Report and Recommendations: Institutional Review Boards, DHEW Publication No. (OS)78-0008.

The Commission's recommendations are set forth at the end of this report, following chapters presenting background information on health care programs supported by DHEW, summaries of reports and views presented to the Commission, review of relevant law, and the Commission's deliberations and conclusions. An appendix to this report contains the papers prepared for the Commission under contract, materials reviewed by the Commission in the course of its study and deliberations, and comments of the Commission on proposed DHEW regulations governing sterilization.

Chapter 1. Health Care Delivery Programs Conducted or Supported by the Department of Health, Education, and Welfare

The health care delivery programs of the Department of Health, Education, and Welfare long predate the establishment of the Department. In 1798 Congress passed a law providing for federal health care for merchant seamen. The program established to implement the law became the system of Public Health Service hospitals and clinics that was transferred in 1953 from the Department of Commerce to the new Department of Health, Education, and Welfare. The federal government also assumed responsibility for health care of American Indians beginning with treaties in 1832. A system of comprehensive health care for Indians gradually evolved under the Department of War and, after 1849, the Department of the Interior. This program has matured and expanded since being transferred to DHEW as the Indian Health Service in 1955. The Maternal and Child Health Service program, established under Title V of the Social Security Act in 1935, also came preexisting into the Department.

The 1960s and early 1970s were periods of marked expansion of health programs under DHEW jurisdiction. Some of these have been service delivery programs enacted by Congress to fill gaps in the private health care delivery system (*e.g.*, Children and Youth Clinics, Maternity and Infant Care Clinics, Community Mental Health Centers). Others began as part of poverty programs in the Office of Economic Opportunity (OEO) and were later transferred to DHEW (*e.g.*, Neighborhood Health Centers, Family Planning Clinics). Other efforts have focused not on direct provision of services, but rather on facility construction (under the Hill-Burton Act), health planning

(*e.g.*, Health Systems Agencies and State Health Planning and Development Agencies), manpower provision (*e.g.*, Health Professions Scholarships, National Health Service Corps), quality assurance and cost control (*e.g.*, Professional Standards Review Organizations), and medical-social problems (*e.g.*, Drug Addict Rehabilitation, Alcoholism Rehabilitation). Finally, enactment of Title XVIII (Medicare) and Title XIX (Medicaid) of the Social Security Act added a new dimension to DHEW health programs: reimbursement for services provided in public programs or the private sector. Medicare and Medicaid have grown rapidly, and represent by far the largest share of the Department's health care expenditures. A list of most of these programs, grouped according to the type and extent of DHEW control over their operation, and indicating the number of persons served and budget of each in fiscal year 1976, is provided in Table 1 (page 20). Total federal outlays for medical and health-related activities in FY 1976 approximated $42.5 billion. Of this total, $31.7 billion was spent by DHEW, with over 80% of the funds going for health services to patients.

Problems arising in these health service delivery programs provided the impetus for inclusion by Congress of a mandate to the Commission to consider the appropriateness of applying the basic ethical principles and mechanisms devised for protecting human subjects in research programs to the protection of patients in DHEW health care programs. Probably the most noteworthy of these problems involved the sterilization of two mentally retarded black teenage girls in a Montgomery, Alabama family planning clinic funded by OEO. Congressional hearings on this matter received widespread publicity and led to several sets of DHEW regulations for sterilization that, among other things,

prohibit the use of DHEW funds for sterilization of persons under age 21. Another specific problem associated with these programs that received Congressional attention was the use of the drug Depo-Provera in Tennessee family planning programs as an injectable long-term contraceptive, and in a state institution for the retarded to prevent menstruation. This was done as medical practice at a time when the drug was approved by the FDA for these purposes for investigational (research) use only.

But ethical problems in health service delivery can arise at points other than where the services are delivered. Decisions on funding or eligibility for services in the programs, made in Congress or at the administering agency, also have ethical dimensions, and may have more far-reaching effects on program beneficiaries than does day-to-day treatment in the program. The debate over funding of abortions through Medicaid is a prime example.

The Department of Health, Education, and Welfare exerts varying amounts of control over these health care programs, depending on whether it has direct responsibility for delivering the services, supports the delivery of services by grant or contract, funds the support structure for service delivery, or merely reimburses services delivered post facto. Consequently different types of subject protection mechanisms have evolved in these programs. Despite their differences, all these programs have some mechanisms available for protecting patients. In considering applicability to these programs of ethical principles and guidelines developed for research, the Commission reviewed the activities of some of these programs, considered their existing

mechanisms for protecting patients' rights, noted their parallels to the research mechanisms, and examined their successes and shortcomings. An analysis of each of the myriad of programs and protection mechanisms was beyond the scope of the Commission's duties; therefore, selected programs were reviewed as examples.

1. Services Provided in Programs Conducted Directly by DHEW. The purest example of this type of program, in which care is provided by DHEW employees in DHEW facilities with all costs borne by DHEW, is the system of Public Health Service (PHS) Hospitals and Clinics, initially established to provide health care for merchant seamen. Other primary beneficiaries receiving free comprehensive health care from this system are coastguardsmen and their dependents, PHS Commissioned Officers, and any persons with leprosy. Care is provided at eight general hospitals and the National Leprosarium, at 26 outpatient clinics, and by contract with several hundred private physicians. In addition, PHS personnel provide care in Coast Guard facilities and ships.

The Division of Hospitals and Clinics allocates resources from the fixed annual Congressional appropriation to the various hospitals and clinics based primarily on the number of patients served and the variety of services provided. A base level of support is established for each facility as necessary to provide high quality health care for all beneficiaries. Allotments over this amount permit support of progressive programs and provision of care to additional secondary beneficiaries. Reduced levels of funding are dealt with by limiting the range of services provided outside the primary

care core, or by reducing the number of secondary beneficiaries served, but basic services are not diminished in quality or quantity.

The PHS hospitals and clinics have adopted the Patient's Bill of Rights developed by the American Hospital Association, and require all new employees engaged in patient care and all patients admitted for the first time to be given a copy of it. The Bill of Rights includes the right of patients to receive considerate and respectful care; to obtain complete current information concerning their diagnosis, treatment, and prognosis in terms they can understand; to receive from the physician the information necessary to give informed consent before the start of any procedure or treatment; to refuse treatment to the extent permitted by law; and the right to privacy and confidentiality of records. In addition to the AHA Bill of Rights, the PHS hospitals and clinics are bound by Departmental regulations governing research and informed consent, and by the provisions of the Freedom of Information Act and the Privacy Act as they apply to patient records.

Until recently the only formal patient input has been through filing traditional grievances or complaints, with retrospective investigations. However, in August 1977 a system of Patient Advisory Councils was initiated at each unit to provide prospective advice from consumers as well as to present grievances and problems to the professional and administrative staff. Some PHS hospitals are also establishing a patient advocate program.

Because of the nature of certain medical procedures, special guidelines have been issued for them by the Division of Hospitals and Clinics to guide physicians and protect patients. For example, guidelines for sterilization

have indicated that the decision is a matter between the patient and physician, suggested but not required spousal consent, required the physician to provide the necessary information for an informed decision, and required that "written informed consent shall be obtained from the patient and placed in the medical record." A provision added in 1977 required also that patients be told orally that no federal benefits would be withheld if they chose not to be sterilized. Guidelines for abortion have changed over the years as court decisions and Congressional legislation have evolved, from initial requirements that each facility establish its own policy and procedures based on state law, to requiring compliance with the Supreme Court's decision in Roe v. Wade irrespective of state law, to requiring compliance with Congressional directives restricting availability of abortion. Guidelines for decisions on use of cardiopulmonary resuscitation for patients with terminal illnesses, issued in August 1977, directed facilities "to establish medical or institutional practice committees (similar to institutional ethical review boards which review human research protocols)," for the purpose of "reviewing and approving proposed resuscitation therapy for dying patients and, in effect, setting standards for recommending optimum care for hopelessly ill patients." The guidelines suggest the composition of such committees and forbid participation of the attending physician in their deliberations.

A second program providing direct comprehensive health care in PHS facilities by PHS personnel is the Indian Health Service (IHS) program. Health services are provided to approximately 518,000 American Indians and Alaska Natives through a system of 51 hospitals, 99 health centers, and over three

hundred field installations. Contracts with private physicians and hospitals are utilized to provide services in areas remote from these facilities, and for some specialized care.

Some of the appropriation the Indian Health Service receives from Congress is earmarked for special projects in specific tribes or regions. Decisions by IHS on allocation of the remaining funds are based on maintaining the previous year's commitments, with increased funds divided on the basis of unmet needs. Each IHS Area reports its unmet needs, based on a national standard of health care; funds are then distributed to each Area based on its percentage of the total IHS unmet needs. Resource distribution at the local level is on an as-needed basis, with emergencies having top priority. Local Health Boards appointed or elected by the tribes advise IHS on needs and desires of the people in allocating elective services. Some have developed special alcoholism programs, others have focused on diabetes, and others on tuberculosis or providing transportation. When limited resources will not permit delivery of a higher quality of services, lower or less acceptable quality care is provided in lieu of none at all. Variations in funding over the years have resulted in widely varying quality of care being available in different regions. The Resource Allocation Criteria process, based on unmet needs, is an attempt to bring about a more equitable distribution of resources.

Since 1975 the IHS has required each Area to develop and promulgate, with the assistance and concurrence of the Area Indian Health Board, a written statement of patients' rights. The statements must include at a minimum an affirmation of the right to services, considerate and respectful treatment, privacy and confidentiality of medical information, information on what

services are available and how to obtain them, information on their medical condition and the right to give or withhold consent for treatment or request referral or transfer, interpreter services, and access to an established grievance procedure. Each Service Unit must disseminate information on patients' rights and the grievance process to the community, and include this information in the orientation of all new IHS staff.

The IHS also requires each area to establish a formal grievance procedure, with a grievance committee at each service unit. The committee must include Indian representatives and be approved for the purpose by the local tribal government and the IHS. The Service Unit Director is required to investigate and respond in writing to all grievances forwarded to that office. Several extensive systems are utilized to fulfill this requirement for receiving advice and grievances from the Indian people. Elected Indian Health Advisory Boards at the local level provide advice on policy and needs, and in some instances also serve as the grievance committee. Each local Health Advisory Board sends a representaive to an Area board, which is then represented on the National Indian Health Advisory Board. This group serves a policy advisory role to the IHS and to the government in general, and performs a lobbying and education role as well. The IHS employs Tribal Affairs Officers in each Area office to serve as a focal point for the tribes in communicating grievances and requests to the IHS; their status as IHS employees has raised questions about their ability to act as effective advocates for the Indians in grievance proceedings. A separate system has been set up by IHS and the tribes, wherein the tribes receive contracts from IHS to train and employ Community Health

Representatives (CHRs). The CHRs work among the community as health outreach workers, helping people get to a source of care or comply with prescribed care at home. They also serve as patient advocates in seeking remedies for grievances. In a special program in the Phoenix Area, the Health Advisory Board employs Patient Representatives who serve specifically as patient advocates in the hospital setting, explaining care and procedures in the patient's own tongue, describing the Patient's Bill of Rights, participating with physicians in obtaining informed consent, and presenting grievances on behalf of patients. In addition to these formal representatives and grievance procedures, the Indian people frequently appeal to their Congressional representatives with grievances, with a resulting Congressional inquiry to the IHS.

Guidelines for special procedures such as sterilization or abortion within the IHS have generally been developed in response to Department-wide policy decisions, and thus have been similar to those described for the PHS Hospitals and Clinics. The recent restrictions imposed by Congress on use of DHEW funds for abortions have not affected the IHS, however, because its funds come from the budget of the Department of the Interior, and the restrictions applied only to the DHEW budget. By contrast, sterilization procedures are a matter of Department policy irrespective of funding source. Thus, in the IHS as in other DHEW programs, sterilization has been governed by stringent Departmental regulations since April 1974, including a requirement that informed consent be obtained, with the elements of informed consent borrowed from the research context and specified as:

(1) A fair explanation of the procedures to be followed;

(2) A description of the attendant discomforts and risks;

(3) A description of the benefits to be expected;

(4) An explanation concerning appropriate alternative methods of family planning and the effect and impact of the proposed sterilization including the fact that it must be considered to be an irreversible procedure;

(5) An offer to answer any inquiries concerning the procedures; and

(6) An instruction that the individual is free to withhold or withdraw his or her consent to the procedure at any time prior to the sterilization without prejudicing his or her future care and without loss of other project or program benefits to which the patient might otherwise be entitled.

Booklets in simple language have subsequently been required as well. Sterilization of persons who are under age 21 or mentally incompetent to give informed consent is prohibited.

2. Services Provided in Programs Supported Directly by DHEW. The next step removed from health care services provided directly by DHEW is health care provided in programs that are established and supported by DHEW funds. Although the federal government exercises less control over these programs, there are nonetheless a significant number of DHEW regulations governing the operation of the programs and the provision of care. The extent of this federal control varies according to the funding mechanism and, to a lesser extent, the nature of the program.

Maximum DHEW control over federally supported programs is provided in programs funded through contracts. The federal government describes a

particular "workscope" of services to be provided and the conditions under which they are to be given, and has broad monitoring and enforcement authority. Only a few programs use this mechanism. A different mechanism, more generally employed, is the project grant, in which an organization applies for federal funds to support a specific kind of health care delivery program. The program may be targeted to a particular population (based on age, geographic location, or income level) or to a particular health problem (such as lead poisoning, hemophilia, family planning, or alcoholism). There is wide variation in the type and degree of federal control and oversight of these programs, but in general the grantee must comply with general guidelines and meet minimal standards as to organization, consumer participation, and services provided. A different type of grant program is the formula grant, in which states receive funds to assist them in delivering various health services rather than to support specific projects. In general the states determine how these funds are used, and there is little federal control over programs they support and less accountability for funds used or services provided than in the project grant programs.

A fourth mechanism for supporting the provision of services is funding of personnel for either training or to provide health services. Professionals are given salary support to train others or to receive specialized training in specific fields; in the course of training or being trained they provide services to patients. The costs of these services are in effect borne by the training grant, without which patients would not receive the care. The federal government has minimal control over how these services are provided. Personnel are also supported by DHEW solely to provide health care in the National

Health Service Corps (NHSC) program; federal and community involvement vary widely from one setting to another.

These programs are described and categorized in Table 1, but it must be recognized that several mechanisms of support may coexist in one program. In addition, several programs may operate together; for example, in Seattle NHSC personnel may work in a Community Health Center operating from a PHS Hospital caring for urban Indians.

The Community Health Centers program is a major example of the DHEW project grant mechanism for supporting health care delivery. This program provides funds to establish primary health care facilities in medically underserved areas (primarily inner cities and rural poverty areas), to support staff salaries and to pay for care for persons who have no insurance and who cannot afford to pay for care on their own. Decisions at the federal level regarding allocation of appropriated funds are based on need, as established by the criteria for designating an area as medically underserved (physician to population ratio, health indices such as infant mortality rate, percentage of population with income below the poverty level, and demographic factors such as proportion of the population over age 65) and on a project's likely success in reaching the target population.

The primary and supplementary health care services that must be provided in the Centers are set forth in the authorizing legislation and in regulations; decisions on allocation of resources in providing these services at the local level are made by the governing board of the Center. Regulations require governing boards to consist of nine to twenty-five members, with a majority

being individuals served by the Center and representing the racial, sexual and ethnic mix of the population served. The governing board hires and may remove the Center director, determines the scope and availability of services, sets the budget and priorities, and is required to establish a mechanism for hearing and resolving patient grievances.

In addition, the Centers are required to have an ongoing quality assurance program to review utilization and quality of services provided and to make indicated changes. They are also required to have a system for maintaining confidentiality of patients' records, to comply with federal nondiscrimination requirements in employment and in providing services, and to provide services even if patients are unable to pay. When Centers serve populations that include substantial numbers of persons with limited English-speaking ability, they must provide services in the language and cultural context appropriate for such persons, and have staff who are fluent in that language.

Adherence to these regulations is assured by project monitoring and technical assistance from DHEW to promote the most productive and effective provision of services, use of resources, and fulfillment of regulatory requirements. The Centers, as are all projects, are required to comply with the same federal guidelines for sterilization and abortion that govern PHS hospitals and clinics.

3. Services Provided in the Private Sector and Reimbursed by DHEW. The Medicare and Medicaid programs constitute by far the largest federal financial commitment to the provision of health care. Both are operated under

"open-ended" appropriations, so that restraints on the use of the funds are imposed not by Congressional authorization or by reducing the level of appropriations, but primarily by decisions on beneficiary eligibility, reimbursement rates, and the services that are covered. In Medicare, decisions on these matters other than those established by legislation are made at the federal level by DHEW; by contrast, under Medicaid most of the decisions are made by the participating states. Thus, differences in the structure of the two programs result in differences in the nature and extent of DHEW control over their operations and the protections afforded patients.

Medicare is a federal program of hospitalization insurance (Part A) and physician care insurance (Part B-optional) for nearly all persons over age 65, and for persons with endstage renal disease, in which the federal government pays a percentage of the provider's fee for hospital care. Criteria for eligibility are set by the federal government, which also makes decisions regarding the services that are covered and the rates of reimbursement. Funds for Medicare are derived from a federal Trust Fund established for that purpose. In attempting to contain costs under this program, legislation has been considered to set ceilings on annual hospital rate increases.

Medicaid, by contrast, consists of 49 separate state programs (plus programs in the District of Columbia and three territories), in which the federal government reimburses the states for 50 to 83% of the funds they spend for medical care for welfare recipients and other medically needy persons. States may elect to have no Medicaid program at all; if they do participate, they may set their own criteria for beneficiary eligibility within federal guidelines. The states also have broad latitude in determining what services will be

reimbursed under Medicaid so long as basic benefits are provided, although Congress has recently acted to limit the use of federal Medicaid funds for certain procedures (*i.e.*, abortions). Medicaid legislation requires that all participating states provide reimbursement for in- and out-patient hospital services, laboratory and X-ray services, skilled nursing home services, home health services, family planning services, and physician's care, for eligible recipients, as well as early and periodic screening and treatment for eligible children under age twenty-one. Medicaid is financed by annual appropriations authorized by federal legislation to be a sum sufficient to carry out the purposes of the program; the states, however, determine the reimbursement rates.

Despite the distance that DHEW is removed from the point of delivery of services in the Medicare and Medicaid programs, a number of regulatory provisions and administrative mechanisms are used to protect patients. Patients are allowed to choose their own providers, but to help assure that competent care is given, hospitals or nursing homes must be accredited by the Joint Commission on Accreditation of Hospitals or meet rigid Medicare standards, and physicians (who may choose not to be providers) must be licensed by the state. Both programs attempt to prevent differential economics from resulting in second-class treatment for their patients by reimbursing providers for their services based on a reasonable charge for the services in the locality. Patients also have the right to a hearing and review of eligibility determinations or of the amounts of reimbursement allowed. There are special provisions to protect a patient against having a claim denied after treatment has been rendered; further, to protect the patient

against illegal demands from the provider, DHEW may suspend or terminate payments to providers for engaging in false billing or demanding kickbacks or rebates.

In addition to these protections, skilled nursing facilities participating in the Medicare and Medicaid programs are required to give each entering patient a copy of a patient's bill of rights, to which the facility must adhere. The bill of rights must include the right to be informed of available services and their charges, to be informed by a physician of their medical condition and to participate in the planning of their treatment, to refuse to participate in research, to be transferred or discharged only for medical reasons and with reasonable advance notice, to voice grievances or recommend changes without restraint, to manage personal financial affairs or be given an accounting of transactions made on their behalf, to be free from mental and physical abuse and from physical or chemical restraint (except in emergencies), to have medical and personal records treated confidentially, to be treated with dignity and respect, to communicate freely with others inside and outside the facility, to retain and use personal clothing and possessions, and to be assured privacy for visits of the spouse.

In addition to these regulatory protections, administrative actions have also been taken to protect and assist patients. Every beneficiary receives a Medicare Handbook containing information about program benefits, payment limitations, and patients' rights. The more than 1300 Social Security district offices have personnel to help beneficiaries file claims for medical expenses and follow through to assure payments are received.

These offices also have been designated as grievance centers to receive reports of patient mistreatment or other complaints.

Assuring that care received by beneficiaries of these programs has been of good quality and medically necessary has received special attention, in the interest of protecting patients as well as containing costs. Amendments to the Social Security Act established a nationwide system of Professional Standards Review Organizations (PSROs) in 1974. The PSROs review inpatient care provided by physicians and institutions to Medicare and Medicaid patients to determine whether the services were medically necessary, whether the quality met professionally recognized standards of health care, and whether the services could have been provided as well and more economically on an outpatient basis or in a different type of inpatient facility. The law also gives PSROs authority to make determinations regarding the necessity and location of proposed care prior to either elective admissions or extended or costly treatments. In conducting their operations PSROs have attempted to make their determinations according to professionally developed standards of care, diagnosis, and treatment based on typical patterns of practice in the region in which they are located.

The regulations governing procedures such as sterilizations or abortions that apply to the PHS hospitals and clinics and DHEW grant-supported programs have also been applied to payments under the Medicaid and Medicare programs. The difference is that instead of imposing the requirements as a condition for receiving treatment, the requirements are imposed as a condition for receiving reimbursement for the service provided.

4. Other DHEW Programs with Impact on Delivery of Health Services.

A number of DHEW programs that do not directly support the delivery of health services nonetheless have significant impact on health care. They range from the epidemiologic, public health technical assistance, and urban rat control programs of the Center for Disease Control, to educational efforts of the Office of Education to prevent drug and alcohol abuse, to the hospital construction funds provided under the Hill-Burton Program. A relatively new program which will have an increasing effect on the delivery of health care regardless of source of funds is the broad range of planning activities conducted under Public Law 93-641, establishing a national network of Health Systems Agencies (HSAs) to conduct comprehensive health planning. Each HSA is responsible for planning within its own jurisdiction, and acts within guidelines established by a National Council on Health Planning and Development, in order to achieve goals and priorities established by Congress. Foremost among these planning priorities is provision of primary care services for medically underserved populations, especially in rural or economically depressed areas. Other priorities include consolidation of institutional services, development of group practices, increased use of physician assistants, disease prevention, and improving the quality of care.

The governing board of each HSA is required by law to have a majority (but no more than 60%) of its members be residents of the area served who are consumers and not providers of health care. Taking into account data on use and availability of health services and unmet needs, each HSA, working with its professional staff, is required to develop a health systems plan, and work with a state agency in implementing that plan for improving

health services delivery. This system has authority to determine the size, location, and type of new health care facilities, and is responsible for setting and implementing national standards for hospital beds and health services. In carrying out this role, under DHEW guidance, it will probably have an increasing impact on health care delivery.

TABLE 1
HEALTH SERVICE PROGRAMS CONDUCTED OR SUPPORTED BY THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, FY 1977

Program	Agency	Objective	Function	Budget FY 76	Persons Served FY 76
			Programs Conducted by DHEW		
Public Health Service Hospitals and Clinics	HSA	To provide comprehensive health care for legally authorized beneficiaries including American seamen, coast guardsmen and dependents, PHS Commissioned Corps personnel, FECA patients, and persons with leprosy	Provide inpatient and outpatient medical care through a system of 8 PHS hospitals, the National Leprosarium, 26 clinics, and contracts with private physicians and dentists	$114,564,000	400,000
Indian Health Service	HSA	To extend, support and improve health care services for American Indians and Alaska Natives	Provide full range of curative, preventive and rehabilitative services including public health nursing, maternal and child health care, dental and nutrition services, psychiatric care and health education	$283,795,562	518,000
			Programs Supported by DHEW: Contracts		
Narcotic Addict Rehabilitation Act Contracts	ADAMHA	To provide for civil commitment of narcotic addicts for examination and treatment, and rehabilitation and aftercare services for addicts	Provide 6 months of inpatient treatment followed by 3 years in a community rehabilitation program	$ 753,000	250
Drug Abuse Service Programs, Migrant Health, Drug Abuse Demonstrations		See Project Grants			
			Programs Supported by DHEW: Project Grants		
Community Health Centers	HSA	To improve the accessibility and organization of health care in medically underserved communities	Support the development and operation of community health centers which provide primary, supplemental, and environmental health services to medically underserved populations	$196,648,000	1,999,160

Program	Agency	Objective	Function	Budget FY 76	Persons Served FY 76
Programs Supported by DHEW: Project Grants (continued)					
Migrant Health Grants	HSA	To improve the health status of migratory and seasonal farmworkers and their families to that of the general population	Provide comprehensive health services which are accessible to people as they move and work; improve their environment to assure healthful, safe living and working conditions	$ 25,000,000	250,000
Family Planning Projects	HSA	To provide educational and comprehensive medical and social services in the area of family planning and promote maternal and infant health	Provide contraceptive advice and services, physical examinations including cancer detection tests, and treatment services for infertility	$ 94,500,000	2,600,000
Emergency Medical Services	HSA	To improve the quality of emergency care and reduce morbidity and mortality	Assist and encourage development of comprehensive regional emergency medical service systems throughout the country	$ 29,115,300	44,100,000 covered
Home Health Services Grant Program	HSA	To expand home health agencies and services as defined under the Medicare program and to provide funds for the training of professional and paraprofessional personnel	Provide funds to agencies to hire professional personnel to provide home health services and support agency operations	$ 3,000,000	—
Health Maintenance Organization Development	HSA	To stimulate development of a variety of prepaid, comprehensive health maintenance organizations throughout the U.S.	Facilitate the development of HMOs by supporting costs of planning, development, and operations	$ 18,170,340	900,000
Community Mental Health Centers - Staffing and Construction	ADAMHA	To provide funds to finance building of public nonprofit community mental health centers; to provide convenient treatment and care; to pay part of initial personnel costs	Reimburse partial costs of staffing center	Construction $ 2,579,000 Staffing $130,251,000	2,000,000
Community Mental Health Centers - Comprehensive Service Support	ADAMHA	To provide comprehensive mental health services through a system of community mental health centers	Provide facilities assistance, planning grants, grants for initial operations, consultation and education services, conversion grants and financial distress grants	$ 52,002,400	
Mental Health - Children's Services	ADAMHA	To stimulate innovative approaches to children's mental health problems	Provide staffing grants to broaden resources for children's mental health services, emphasizing prevention, and coordination of community services	$ 25,868,000	—

Program	Agency	Objective	Function	Budget FY 76	Persons Served FY 76
		Programs Supported by DHEW: Project Grants (continued)			
Mental Health - Hospital Improvement Grants	ADAMHA	To encourage transition to open institutions, and develop cooperative relationships with community programs for mental health	Provide state mental hospitals with funds for projects to improve quality of care, treatment, and rehabilitation of patients	$ 5,116,000	–
Alcohol Community Service Programs	ADAMHA	To prevent and control alcoholism	Provide comprehensive services under proper medical auspices through a community based program involving other public and non-governmental agencies	$ 7,964,000	312,000
Alcohol Demonstration Programs	ADAMHA	To prevent and control alcoholism	Assist development of projects relating to the provision of prevention and treatment approaches for population groups; evaluate programs; demonstrate effective methods of delivery of services	$ 44,607,000	
Drug Abuse Community Service Programs	ADAMHA	To locate, treat and rehabilitate narcotic addicts, drug abusers and drug dependent persons, through community based services	Provide inpatient, outpatient, intermediate, 24-hour emergency services, and community-wide consultation and education services	$119,158,000	102,000
Drug Abuse Demonstration Programs	ADAMHA	To prevent and control drug abuse	Support projects that establish, conduct and evaluate drug abuse treatment, rehabilitation, and prevention programs	$ 9,854,000	–
Cancer Centers Support	NIH	To establish cancer centers which utilize a multidisciplinary approach in basic and clinical research toward the cause, prevention, diagnosis, and treatment of cancer	Provide grants to establish multidisciplinary cancer research centers emphasizing community outreach to lay and professional population. Funds support personnel salaries, equipment, supplies, inpatient and outpatient hospital care, and construction	$ 41,107,000	–
Cancer Control	NIH	To bridge the gap between research and application in the practice of medicine and public health so as to minimize illness and death from cancer	Provide research grants and contracts to develop and support community outreach programs, develop clinical oncology programs in community hospitals, train staff in continuing care and rehabilitation of cancer patients	$ 56,228,000	–

Program	Agency	Objective	Function	Budget FY 76	Persons Served FY 76
Programs Supported by DHEW: Project Grants (continued)					
Sudden Infant Death Syndrome - Information and Counseling Program	HSA	To collect, analyze and furnish information relating to the causes of sudden infant death syndrome, and provide information and counseling to families affected by the syndrome	Provide funds to support staff to provide counseling for families and education for health professionals and others, to collect data and to perform autopsies	$ 2,500,000	1,500 families counseled
Comprehensive Hemophilia Diagnostic and Treatment Centers	HSA	To expand availability of comprehensive outpatient diagnostic and treatment centers for persons with hemophilia	Supply funds to initiate or expand diagnostic and treatment centers, provide training of professional and paraprofessional personnel, provide social, vocational and genetic counseling	$ 3,000,000	2,300
National Sickle Cell Disease Program	NIH and HSA	To devise methods for reducing the morbidity and mortality from sickle cell disease through research, education, screening, counseling, and improved patient care	Support comprehensive sickle cell centers for research to develop clinical treatments and community programs; support screening, education and counseling clinics; conduct a national education program; support research through grants and contracts	$15,000,000	200,000 screened and counseled 1,000 treated
Child Abuse and Neglect Prevention and Treatment	OHD	To assist state, local and voluntary agencies in developing programs to prevent, identify and treat child abuse and neglect	Provide technical assistance, support multidisciplinary training programs, and establish and maintain centers to provide a broad range of activities including parent self-help to prevent and treat child abuse	$17,894,000	8,000 children 5,000 families
Childhood Lead-Based Paint Poisoning Control	CDC	To develop comprehensive lead-based paint poisoning control programs	Assist states in establishing centralized laboratory facilities for analyzing biological and environmental lead specimens obtained from detection programs, communicate the health hazard to the community, operate screening programs to detect children with elevated blood lead levels	$ 3,500,000	512,532
Disease Control - Project Grants	CDC	To contribute to national protection against diseases or conditions of national significance which are amenable to reduction	Provide funds to states for projects of venereal disease prevention and control, and the control of vaccine preventable diseases	$24,800,000	10,000,000

Program	Agency	Objective	Function	Budget FY 76	Persons Served FY 76
			Programs Supported by DHEW: Project Grants (continued)		
School Health and Nutrition Services for Children from Low-Income Families	OE	To demonstrate means of organizing a system of comprehensive health and education services through effective coordination of existing resources	Provide project grants to local education agencies to extend, coordinate and utilize existing health and education resources to serve children at the local level, but not to purchase health care directly	$ 950,000	–
Child Development - Head Start	OHD	To improve the quality of life of economically disadvantaged children, and help them attain overall social competence	Provide comprehensive health, educational, nutritional, social and other services primarily to economically disadvantaged children and their families	$432,598,000 (approximately 10% for health care)	350,000
Developmental Disabilities - Special Projects	OHD	To improve the quality of services available to the developmentally disabled	Provide partial support for public awareness and informational programs; demonstration of new or improved service delivery; training; coordination of available community resources; and provide technical assistance	$ 13,065,000	54,000
Developmental Disabilities - Demonstration Facilities and Training (UAFs)	OHD	To assist with the cost of administration and operation of demonstration facilities and interdisciplinary training programs for personnel needed to render specialized services to persons with developmental disabilities	Provide salary support for personnel and operating costs for University-Affiliated Facilities that provide services to persons with developmental disabilities	$ 4,144,000	16,600 trainees
			Programs Supported by DHEW: Formula Grants		
Comprehensive Public Health Services	HSA	To assist state health and mental health departments in providing comprehensive health services	Generally: support health service delivery for both the general population and high-risk groups. Specifically: support communicable disease control, environmental health programs, laboratory services, vital statistics programs, cervical cancer screening. Some use funds to support new approaches to delivery of health care	$ 73,445,000	–
Crippled Children's Services	HSA	To provide financial assistance to states to extend medical and related services to crippled children and children suffering from conditions that lead to crippling (especially in rural and economically depressed areas)	Locating crippled children and providing medical, surgical, corrective and diagnostic services and training of professional personnel	$ 76,500,000	560,000

Program	Agency	Objective	Function	Budget FY 76	Persons Served FY 76
			Programs Supported by DHEW: Formula Grants (continued)		
Maternal and Child Health Services	HSA	To extend and improve services for reducing infant mortality and improving health of mothers and children	Provide financial support to states for prenatal care, labor and delivery, hospitalization, medical care for premature and other high risk newborns; both medical and dental screening, diagnosis and treatment for children; family planning, immunizations	$219,200,000	3,500,000
Alcohol Formula Grants	ADAMHA	To assist state alcohol abuse treatment and rehabilitation programs	Help states plan, establish, maintain and coordinate alcohol abuse programs as well as evaluate treatment and rehabilitation programs	$ 55,500,000	–
Drug Abuse Prevention Formula Grants	ADAMHA	To develop and implement more effective drug abuse prevention functions	Assist states in planning, establishing, conducting and coordinating and evaluating drug abuse prevention programs	$ 35,000,000	–
Developmental Disabilities - Basic Support	OHD	To meet needs of persons who have a disability resulting from mental retardation, cerebral palsy, epilepsy, or autism which originates before age 18	Assist states in developing a comprehensive plan for meeting the needs of such persons, implementing a system for protection and advocacy of individual rights, and constructing facilities to serve this population	$ 13,065,000	54,000
			Programs Supported by DHEW: Personnel		
Maternal and Child Health Training	HSA	To train personnel for health care and related services for mothers and children, especially the handicapped	Train a wide variety of professionals and provide a full range of clinical services to thousands of mentally retarded and multiple handicapped children	$ 18,408,000	–
Mental Health Clinical or Service Related Training Grants	ADAMHA	To develop mental health specialist manpower	Support clinical, or services related training in the area of mental health to primary care providers, and consultants to primary care providers. Trainees deliver services in course of training	$ 75,076,000	–
National Health Service Corps	HSA	To improve delivery of health care in areas critically short of health personnel	Provide understaffed communities with primary care medical, dental, general, family, and nurse practitioners, internists and pediatricians	$ 20,000,000	331 communities staffed by 600 health care personnel

Program	Agency	Objective	Function	Budget FY 76	Persons Served FY 76
		Programs Providing DHEW Reimbursement for Health Services			
Medicare-Hospital Insurance (Part A)	SSA	To provide hospital insurance protection to any person 65 or over and to certain disabled persons for covered services	Reimburse providers for hospital or nursing home care given to eligible population	$12,266,803,000	25,000,000 covered 5,900,000 had benefits paid
Medicare-Supplementary Medical Insurance (Part B)	SSA	To provide insurance protection against most of the costs of health care to persons 65 or over and to certain disabled persons	Eligible persons who elect this additional coverage and pay the monthly premium have the costs of services furnished to them by physicians reimbursed	$ 4,671,006,000	24,790,000 covered 14,836,000 had benefits paid
Medical Assistance Program	SRS	To provide financial assistance to states for payments of Medical Assistance on behalf of cash assistance recipients and, in some states, the medically needy	Provide matching grants to states, on a formula based on state per capita income, to reimburse states for payments they make to providers under the state plan for providing health care to eligible population	$ 8,324,053,000	24,500,000
		Other DHEW Programs Impacting on Delivery of Health Services			
Urban Rat Control	CDC	To control rat infestations and conditions conducive to such infestations	Support comprehensive community programs in rat control	$ 13,100,000	35,626 city blocks
Center for Disease Control - Investigations, Surveillance and Technical Assistance	CDC	To assist states and localities in the control of communicable diseases and other preventable health conditions	Assist case detection and prevention activities for gonorrhea, syphilis, rubella, diphtheria, mumps, measles, rat infestations and leadbased paint poisoning. Also help develop criteria for occupational safety & health standards	$ 138,653,000	—
Alcohol and Drug Abuse Prevention	OE	To alleviate the alcohol and drug abuse crisis among youth by attacking the causes rather than merely treating the symptoms	Provide grants to schools and education agencies to develop and conduct alcohol and drug abuse education demonstration projects in schools and communities	$ 1,747,000	—
Medical Facilities Construction - Project Grants (Hill-Burton)	HRA	To eliminate safety hazards in publically owned or operated medical facilities and to avoid noncompliance by such facilities with licensure or accreditation standards	Assist modernization projects by providing funds for replacement or remodeling of existing facilities, buildings and equipment	FY 77 est. $ 11,387,200	—

Program	Agency	Objective	Function	Budget FY 76	Persons Served FY 76
Other DHEW Programs Impacting on Delivery of Health Services (continued)					
State Health Planning and Development Agencies	HRA	To support state health planning agencies that conduct physical and mental health planning and development functions	Provide operational funds for state health planning agencies and State Health Coordinating Councils	$19,000,000	–
Health Planning - Health Systems Agencies	HRA	To provide for effective health resources planning	Develop area-wide plans to deal with problems in health care delivery, maldistribution of health care facilities and manpower, and increasing cost of health care. Funds used to compensate agency personnel, collect data, and develop plans	$63,000,000	–

Chapter 2. Activities of the Commission

National Minority Conference on Human Experimentation

In order to assure that minority viewpoints would be heard, the Commission contracted with the National Urban Coalition to organize a conference on the issues in the Commission's mandate. The conference was held on January 6-8, 1976, in Reston, Virginia. Attended by over 200 representatives of racial and ethnic minority groups, it provided a format for presentations of papers and workshop discussions from which a set of recommendations emerged. The papers and the recommendations relevant to the application of research principles and guidelines to DHEW health care delivery programs are summarized below.

William A. Darity, Ph.D. Dr. Darity stated that human experimentation will continue to be carried out in the health care delivery setting and that it is essential to conduct research if we are to improve the health of all people. He stressed the need to preserve human dignity in both research and health care through the application of ethical standards. This is particularly important for ethnic minorities who find themselves at a disadvantage because of their economic situation and their minority status. Their overrepresentation among users of public clinics and health care programs argues for special guidelines to assure that they are not exploited in these programs.

Lionel H. deMontigny, M.D. Dr. deMontigny began with an historical overview of health care delivery to American Indian populations. He indicated that there are three systems for the provision of medical care to American

Indians: 1) traditional tribal healing methods, 2) private practitioners, and 3) the federal government, through the Public Health Service. He traced improvement in Indian health to the delivery of health care by the Indian Health Service, the increasing involvement of tribal councils in overseeing provision of health care, and the increasing number of Indian health professionals. Although there is a tremendous federal presence in Indian health care, Dr. deMontigny feels that there is a great need for consumer groups to assist in protecting the rights of Native Americans. Expanding the activities of these groups and increasing the number of tribal health institutions owned, operated, and controlled by Indians themselves were suggested as the best mechanisms to provide this protection.

Arturo E. Raya, Ph.D. Dr. Raya stated that persons of Spanish origin depend largely on public hospitals (including teaching hospitals) and outpatient clinics for their health care. He feels, therefore, that the federal government should be aware of the unique problems related to culture, language, and social and economic lifestyle that arise when persons of Spanish origin enter the federal health care system. He urged that to maintain the rights of the Spanish ethnic population (with particular reference to the Spanish speaking), the predominantly non-Spanish practitioners should be both sensitive to and tolerant of the role of religion, the family, and folk medicines in health care delivery for many Spanish speaking persons. Fear of being involved in experimentation must be removed as a barrier to seeking health care in public clinics. He concluded by suggesting that regulations developed for the protection of patients and human subjects should address the special problems of bilingual-bicultural citizens.

Recommendations of Minority Conference Panel and Workshops on Ethical Issues in Health Care Delivery. The participants in the Conference expressed concern about the way in which the Commission's mandate addressed the issue of protecting DHEW health care recipients. It was felt by many of the participants that health care is such a critical issue that it should not be tied to research guidelines that may be wholly inappropriate, but should be the subject of separate recommendations to Congress regarding protection of patients' rights in all areas of health care delivery.

Rather than focusing on whether the research guidelines should apply, the Minority Conference workshops made specific recommendations for improving protection of recipients of health care. These recommendations included requiring all programs funded by DHEW to give assurance that patients will not be involved in experimentation unknowingly or without their authorization; increasing the number and quality of minority health care practitioners as a means of protecting minority group members; increasing access to health services for the rural and urban poor; increasing community control over the design and implementation of health systems; providing federal funds to local groups to educate patients as to their rights with regard to health care practices; requiring all medical personnel to receive training in ethics with special emphasis on the requirements of informed consent and problems of minorities; informing patients as to the student or training status of their health care provider, with the opportunity for care by a fully trained professional if requested; restoring funds needed to provide quality medical care in DHEW programs before additional human experimentation is funded;

placing stricter controls on sharing with other agencies any individually identifiable information from the medical or administrative record of patients in health care programs; and applying DHEW guidelines for "subjects at risk" to all federally funded programs in which there are "patients at risk."

Colloquium

The Commission sponsored a colloquium on June 17-19, 1976, to elicit the views of health care administrators and public interest groups on the applicability of research principles and guidelines to the delivery of health services under programs conducted or supported by DHEW, and other approaches that might be taken to protect the rights of recipients of such services. Participants included health care administrators, consumer advocates, federal health officials, professionals from academic institutions with expertise in the area of health care delivery, and members and staff of the Commission.

There was general agreement among the participants that the ethical principles of respect for persons, justice, and beneficence are applicable to the delivery of health services. Some felt, however, that there may be other principles which are equally relevant. Further, many participants suggested that the best method of protecting recipients of health services supported by DHEW might be through the development of principles and guidelines designed specifically for the protection of such patients rather than through the application of research principles and guidelines.

The participants discussed at length the extent to which research principles should apply to health care provided directly by DHEW as contrasted with that which is only supported or reimbursed by DHEW. Here, as was true in most instances, no consensus was achieved. Some participants argued that the concern should be with services provided by the government rather than with programs such as Medicaid which merely support such services. The basis of this argument was that the private physician is out of reach of effective regulation, so that enforcement would be nearly impossible. An additional argument was that the protection of patients is best achieved at the institutional level, where greater sanctions are available. Other participants suggested that perhaps there should be different guidelines for federally provided health care than for services which are merely funded by the government. Others countered these arguments by stressing the need to protect patients whose health care is funded by DHEW just as strenuously as one would protect those who receive health care directly from DHEW. It was felt that the potential for abuse is just as great, if not greater, in programs such as Medicaid where patients may be forced to seek treatment in less desirable settings, either because of location or because of reluctance of physicians to treat them.

Another issue discussed at the colloquium was the purpose of the health care system; that is, whether its goal is to provide <u>good medical practice</u> or to provide <u>good health</u>, and what the difference between the two might be. The answer to that question could determine in large part the nature of the guidelines that might be recommended. If the more

holistic answer is given, *i.e.*, to ensure good health, then regulations and guidelines that go beyond ensuring good medical practice would have to be devised. For example, it would be consonant with this position to ban cigarette smoking, particularly for patients whose health care is provided or supported by DHEW. No widespread endorsement for this position was expressed.

There was lengthy discussion about six proposed norms for health care practice:

(1) Reasonable expectation of success, *i.e.*, to have mutally agreed upon objectives and a treatment plan that adheres to standards;

(2) Qualified health professionals and adequate facilities, ensured through periodic review and recertification;

(3) Identification of the consequences of therapy plans, through explication of alternatives and accountability structures;

(4) Informed consent of the patient;

(5) No fault compensation either for all practice not conducted for the benefit of the patient, or for all practice in general; and

(6) Application of the principles of justice in the selection of patients, *i.e.*, to each according to his or her essential need.

These norms, which were proposed to insure the good practice of medicine, closely parallel the norms developed for the conduct of research. There was general agreement that the norms were appropriate for the protection of recipients of health services provided by DHEW, although serious questions were raised about their implementation.

The colloquium participants were in agreement that there are distinctions between the public and private health care delivery systems. A consensus regarding the importance and moral relevance of these differences was, however, difficult to achieve. One participant suggested that public health services might offer only limited kinds of treatment which may be inferior to those offered in the private sector. This person's concern was that the government may be willing to pay only for specified procedures, drugs, etc., which are routine and accepted, thus restricting patients' access to innovative treatment.

Another discussion focused on the nature and extent of the government's responsibility to patients in federally supported health programs. One participant noted that in a research program, the obligation of the researcher to his subject ends with the closing of the research project, unless complications arise. Similarly, in federally supported health programs, patients may be left with little or no continuing medical care when the program ends. This participant felt that there should be guidelines to protect classes of persons, who are dependent upon the federal government for their health care, from administrative decisions which may cut off their access to certain services.

The final topic of discussion was a concern regarding the various tensions that are present in the health care delivery system. One participant suggested that the environment of the health care delivery system is coercive because of the professionals' monopoly over information. Another suggested that cultural differences between the patient and the provider compound the problem of communication and make the protection of patients'

rights even more difficult. Some participants felt that the complexity of the health care system almost defies change. In addition, it was suggested that conflicts between the providers and the consumers could be reduced only by reducing the federal role in health care delivery. Other suggestions included providing ombudsmen in health care facilities and increasing citizen participation in decision-making.

Site Visit

Members of the Commission, accompanied by staff, visited Indian Health Service facilities in the Phoenix, Arizona area on January 30-31, 1978. The Phoenix Service Unit is responsible for providing health care for 22,000 Indians living within approximately a 150-mile radius of Phoenix.

The Executive Director and members of the Phoenix Service Unit Indian Health Advisory Board met with the Commission. The Board is composed of elected representatives from each tribal organization in the area. Since 1968 this Board has advised area IHS officials regarding programs and priorities for health services provided. The Board also serves as a channel for all communications between the Indian people and the IHS, and for complaints regarding health care received by Indian patients. In addition, this incorporated Board has initiated and operates several programs on its own, using tribal funds and government grants and contracts from IHS, the Department of Labor, and other sources. The programs include employment of a coordinator to develop a comprehensive program for treating alcoholics, employment of a nurse in Phoenix for follow-up treatment of Indians suffering from tuberculosis, and employment of health representatives who work in the

community to help people with health care problems and assist them in obtaining health care.

The newest program initiated and supported by the Board is the Patient Representative Program which is unique to the Phoenix area. Because of its success, the Board is encouraging other areas to adopt it. Current representatives met with the Commission members and described their function, which is to explain the system of hospital care and medicine to patients, explain procedures and discuss options, and meet with the patient and doctor when the nature of the illness and its treatment are discussed, and participate in the consent process. They also provide a vehicle for bringing patient complaints to the attention of IHS staff or the Board. The Patient Representative Program began after a Patients' Bill of Rights was adopted by the IHS and the Indian Health Advisory Board in 1974. The Patient Representatives were envisioned as the enforcement mechanism for the Bill of Rights, a copy of which is given to each patient upon entering the hospital.

The Representatives and Board members identified several factors that contributed to the success of this program in reducing the number of grievances and improving the quality of care in the Phoenix Unit. First, acceptance of both the Bill of Rights and the Patient Representatives by the IHS providers has been excellent; second, the representatives function outside the PHS bureaucracy -- they are employed by the Board (under contract from IHS) and thus are responsible to the Board.

The Board members indicated they believe they have an important impact on the health services provided. In addition to presenting problems and

evaluating services from the consumer viewpoint during their regular meetings with the unit IHS director, they also participate in the planning and resource allocation process (what health programs to initiate or, more frequently, what to close down to accommodate budget cuts). They said they are having increasing success in placing Indian people in provider roles (*e.g.*, nurses, aides, technicians, etc.), and that the primary problem in that effort is not so much lack of opportunity for training as it is the rate of drop-out of trainees in the programs.

The Phoenix Service Unit Indian Health Advisory Board is near the bottom of the Indian's own health bureaucracy. Below it are the health committees of the tribe's local government. The tribe elects a representative to the Service Unit Board; the Chairman of the Board represents the Unit on the Area Health Board (comprising units from Arizona, Nevada, and Utah); each Area Health Board then sends a representative to the National Indian Health Board, with headquarters in Denver. This Board, along with the tribes, performs a lobbying function with IHS and Congress, and represents Indian interests in matters such as planning for national health insurance.

The Service Unit Director and Clinical Director of the hospital described some of the programs and problems in the area. The hospital serves as a referral center for a four-state area and provides outpatient general medical care for 17,000 Indians. Currently, 59 of the hospital's 200 beds are closed due to lack of funds; the remaining beds have an 85% + occupancy rate. In addition, beds and services in other hospitals in Phoenix are being provided under IHS contract due to lack of positions in the Service Unit hospital. In some ways, contract services are more expensive than those provided

directly; they are also more difficult to monitor for quality and empathy. The directors both felt that Indian patients identify with their own hospital and generally prefer going there rather than to a community hospital. The Clinical Director indicated that he believes the patient representatives perform a valuable service and prevent more problems than they cause for him. He attempts to investigate and resolve complaints about care, and to reply to the patient, patient representative and the Board. In response to a question regarding sterilizations, he indicated that they were done but only infrequently, and that he believes the waiting period required is keeping some people who want sterilization from getting it.

Commission members also toured the hospital, including the research facilities of the National Institute of Arthritis, Metabolism, and Digestive Diseases, on the fifth floor. The unit there and one on the Pima reservation at Sacaton were opened in the 1960s when studies indicated that Pimas have the world's highest incidence of diabetes mellitus (50% over age 35 have an abnormal glucose tolerance test). Research has focused on epidemiology, the relation of weight and weight reduction to the disease, and characterization of the Pimas' biochemical abnormalities as compared to non-Pima diabetics. More recently research has begun on gallstone formation because of the discovery that 70% of Pima women have cholesterol gallstones by age 35. All protocols are reviewed by an intramural Institutional Review Board (IRB) at NIH, and by another for IHS in the Phoenix area (which includes an Indian member). In addition, they must be reviewed and approved by the Pima tribal governing body, which also receives annual reports on the research. The Indians recognize the threat diabetes poses to their health and accept

(even welcome) the research program and the investigators, Indian Board members indicated.

Commission members also visited two IHS facilities on the Gila River Indian Reservation. The first, Gila Crossing Clinic, provides outpatient medical and dental care. The second, Sacaton Indian Hospital, provides outpatient care and hospitalization for minor conditions; serious illnesses, surgery, and obstetrical deliveries are referred to the IHS Hospital in Phoenix, an hour away. The Lieutenant-Governor of the Pima-Maricopa Gila River Reservation also spoke to Commission members regarding tribal governance and health care. He reported that one of the benefits offered as an option by the tribal government to its employees is private health insurance. Despite the availability of free care of good quality from the IHS, many Indians choose private insurance, feeling that they get more personal care with less inconvenience and perhaps better quality from the private system, so that they are willing to pay part of the cost themselves.

Public Hearing

The Commission held a public hearing at Bethesda, Maryland, on October 14, 1977, to receive testimony from the public regarding the application of ethical principles and guidelines governing research to health service programs conducted or supported by DHEW. Nine representatives of government, professional societies, and public interest groups testified before the Commission. Summaries of their testimony follow.

Brewster Smith, Ph.D. (American Psychological Association (APA)) emphasized that the Commission should include consideration of mental health in its

deliberations on health care delivery. The APA recognizes that abuses of patients' rights have occurred and supports the concept of a mechanism for ethical review of the delivery of health services. However, the APA noted that differences exist between research and practice so that the strict application of the recommendations for research involving individuals institutionalized as mentally infirm to the delivery of mental health services is not advisable. Instead, the already existing Professional Standards Review Organization and Professional Standards Review Committee mechanisms might be adapted to include ethical review of delivery of health services on a sampling basis. In addition, grievance procedures for patients might include ombudsmen who would have the authority to refer problem cases to the PSRO/PSRC for review. Dr. Smith noted that the standards of informed consent that apply in the treatment of patients differ from those that apply to research subjects; and in the area of mental health, unique problems arise. In particular, the anxiety and confusion of mental patients affect their decision-making ability. Further, it is rarely possible to specify at the outset of therapy exactly what the treatment plan will be; thus, mental patients can consent initially only to a general process of therapy, not to a specific set of procedures. Dr. Smith argued that patients should realize that good clinical practice requires flexibility on the part of the therapist and that changes in the process of therapy must remain in the hands of the professional. All mental patients should be informed, however, about the grievance procedures that exist and be assured that they are free to withdraw from therapy at any time.

Karen Mulhauser (National Abortion Rights Action League) urged that federal provision of health services be guided by the three ethical principles identified by the Commission: respect for persons, beneficence, and justice. Their applicability to health service delivery is demonstrated in connection with the medical problem of abortion. Ms. Mulhauser argued that the government has a moral obligation to provide ethical medical procedures under its health programs. An ethical medical procedure must satisfy two conditions; it must be a healing process and it must add to the quality of life. Abortion, she argued, satisfies these two conditions and should therefore be provided under a comprehensive health service program. In making decisions regarding the exclusion of certain services, such as abortion, from health service programs, three questions that correspond with the basic ethical principles should be asked. Beneficence: Does the policy place the patient's interests and health above other considerations, including political convenience and pressure? Respect for persons: Does the policy protect individual rights to choose? Justice: Is the allocative and funding policy ethical and equitable? Ms. Mulhauser asserted that government should not deny access to a medical procedure on non-medical grounds whether they be religious, political or whatever. A government that denies access to a generally available medical procedure only to the poor who require assistance violates the basic principles of justice, beneficence, and respect for persons.

George I. Lythcott, M.D. (Health Services Administration (HSA)) accompanied by James D. Felsen, M.D. (Indian Health Service) outlined the broad goals and functions of the Health Services Administration and then discussed in more detail the health care delivery aspects of the Indian Health Service

and Public Health Service Hospitals and Clinics. The objective of each program is to insure that all eligible patients are provided with equal and high quality treatment. Dr. Lythcott asserted that positive steps are being taken to protect the rights of IHS patients by requiring that all Indian Health Service facilities develop and follow a written statement of patients' rights. He also reported that all PHS hospitals now have Patient Advisory Councils which perform educational and advocacy functions and also review the quality, acceptability and convenience of the services provided. The hospitals also have a Central Committee on Human Research to review the risks involved to subjects recommended for clinical research projects. Furthermore, the HSA has developed guidelines governing sterilization, abortion and termination of cardiopulmonary resuscitation in PHS hospitals. In response to questioning, Dr. Lythcott and Dr. Felsen indicated that decisions as to which medical procedures will be provided by available public funds are made at the local level by representatives of the community and the health care providers.

The Reverend Grover Bagby (Religious Coalition for Abortion Rights) presented the Coalition's position on federally funded abortion: that every woman should have the legal right to choose abortion, consistent with good medical practice, and in accordance with her conscience and religious beliefs. It is improper for individuals, religious groups or the government to impose their beliefs concerning abortion on others. It is the Coalition's philosophy that government policies should be neutral in order to preserve the pluralistic society we all enjoy. A neutral government policy on abortion would require free access to abortion on

demand, for only then is each individual free to follow his or her own beliefs. Concern for the quality of a woman's life must be part of our government's health care policies. It is held to be socially irresponsible to limit the quality of care available to a woman on account of her economic status. In order that options will be equally available to all women, the coalition advocates federal funding of all maternity services, including diagnosis, pre-natal care, delivery and post-natal care as well as abortion, for eligible recipients.

Dan Press, Esq. (National Indian Health Board, Inc.) presented background information on the Indian Health Service and then discussed patients rights in the IHS. He suggested that the problem of patients' rights is particularly urgent with respect to Indians because they do not pay for health services and hence do not have the financial leverage to obtain the respect for their rights that is available to other health consumers. Furthermore, Indians cannot choose to purchase health care elsewhere; they are "captive consumers." It is the obligation of the IHS to implement effective grievance procedures to insure that Indians' rights as patients are respected, and to sensitize health care providers to the culture and beliefs of Indian patients. He asserted that the IHS has failed to meet these obligations. Specifically, he said IHS has made no effort to make the written bill of patients' rights operational; patients tend to be herded through treatment without explanation of the procedures or outcomes; IHS has not provided patient advocates, a necessary component of an effective grievance procedure; and IHS has merely referred in passing to the need for cultural sensitivity on the part of providers. Further, IHS has done nothing to ameliorate the

problem of insensitivity and disrespect on the part of clinicians in outside facilities who provide care to Indians under contract. The National Indian Health Board recognizes that the IHS has been forced because of inadequate funds to emphasize basic care rather than patients' rights; however, respect for human beings is essential to Indian people and to ignore it is unacceptable.

Lawrence Deyton, M.P.H. (Gay Men's V.D. Clinic) explained the problems confronting gay recipients of health care. He expressed dismay that a person's sexual preference has an effect on the quality of health care he or she receives in America today. He asserted that it is because of the general lack of acceptance and understanding on the part of health care providers that gay people are underutilizing health services. Gay clients experience intimidation, recrimination, hostility, and insensitivity when receiving health services. Gay clients have a right to good medical care without being subjected to moral judgment, and health providers ought to honor that right. He alleged that health care providers do not know how to recognize or treat the specific health problems of homosexuals; confidentiality, however, is perhaps the greatest problem. Medical records are often used for hiring, for security clearances, and for insurance purposes. Consequently, providers should take care to record and transmit only medically important information and exclude irrelevant and potentially damaging information. DHEW should take steps to identify and meet the specific health needs of the 20 million gay Americans and to educate health care providers regarding those needs.

Pauline Haynes (International Indian Treaty Council and Coalition of Grass-Roots Women) expressed concern over abuse in the delivery of health services to poor and third-world minority people, and in particular over abuse in the provision of sterilization. Sterilization abuse is considered a genocidal threat to poor and third-world people. Ms. Haynes offered sterilization statistics as well as personal testimony of abuse. She stated that poor, non-English speaking patients are especially vulnerable to abuse because they cannot understand the language of the consent forms and there are no patient advocates protecting their rights. She called for a six month moratorium on all federally funded sterilizations, unless the life of the woman is in danger, so that effective guidelines to prevent abuse can be implemented. She suggested that the guidelines require at least a three or four month, and perhaps a six month, waiting period, that patients have an advocate to explain their rights to them, and that the consent forms be written in the patient's preferred language.

Helen Rodriquez, M.D. (Committee to End Sterilization Abuse) urged the implementation of stringent guidelines, including minimum standards governing the consent process, to prevent sterilization abuse. Such standards should stipulate the circumstances under which consent may and may not be solicited, and include a mandatory waiting period of at least one month between the time of consent and performance of the procedure. She further requested (a) that all counseling and forms be in the patient's preferred language, (b) that there be a witness to the consent process, and (c) that as evidence of the patient's comprehension, the consent document include a statement by the patient as to the nature of the procedure to which he or she has consented.

Dr. Rodriquez expressed the need for a community based advocacy system that would function as a safeguard against the pressures to which people are subjected in health care institutions. Patient advocates should participate in the preparation of all educational material given to patients, and receive training that meets an established set of minimum standards. Finally, she recommended that a national system be devised to monitor the areas of surgery in which abuse is likely to occur, as well as to update the information regarding risks, benefits and the procedure of choice according to the latest scientific findings.

Chapter 3. Reports to the Commission

Health Policy Perspectives

An analysis of the implications of applying the basic ethical principles and guidelines for research to health care programs conducted or supported by DHEW was prepared for the Commission by Philip R. Lee, M.D., Carol Emmott, Ph.D., and Steven A. Schroeder, M.D., of the Health Policy Program, University of California, San Francisco.

The Policy Group stated that beginning with the Hippocratic exhortation to do no harm, a network of formal and informal traditions, standards and procedures governing physician-patient relationships has evolved over the centuries. By contrast, the principles and guidelines for protecting patients' rights in research are a relatively recent development. Furthermore, the research guidelines have their roots in the ethical traditions of health care delivery; therefore the ethical principles of beneficence, respect for persons, and justice underlie and are applicable to both research and practice. However, to take the research guidelines derived from these principles and attempt to apply them to practice would be a reversal of the process by which they evolved and, the Policy Group felt, would be inappropriate.

In support of this conclusion, the Policy Group observed that the Commission has generally applied six basic guidelines or standards derived from the three ethical principles. These standards include (1) soundness of research design, (2) competence of investigators, (3) explanation to subjects of the possible consequences of participating in research, (4) appropriate

selection of subjects, (5) informed consent, and (6) compensation for injuries resulting from the research. Application of these standards would assure that the anticipated benefits justify the risks, that subjects participate freely, and that if an injury occurs compensation will be provided. The guidelines are implemented in large part at the local level by institutional review.

The rapidly growing federal involvement in health care delivery has taken two basic forms: system-oriented approaches, that develop resources and provide technical assistance; and patient-oriented approaches, that either provide care directly or pay for care. The Policy Group concluded that since the research guidelines focus on interaction between individuals it would be impossible to apply them to the system-oriented approaches.

In considering possible applicability to the patient-oriented approaches, the Policy Group reviewed three categories of programs. First are programs in which DHEW employs the providers and furnishes all services; examples include the Indian Health Service and Public Health Service hospitals and clinics. Second are capacity-building programs, in which DHEW provides grant or contract support to programs that fill gaps in the private health care system; examples include Community Health Centers, Migrant Health Centers, Community Mental Health Centers, and Family Planning Clinics. Third are reimbursement programs in which DHEW pays for services delivered by the private sector; Medicare and Medicaid are included here. Based on their belief that it would be both inappropriate and unworkable for the government to establish national guidelines governing the private relationship between patient and practitioner, the Policy Group concluded that no attempt should

be made to apply the research guidelines to reimbursement programs. As for the other two types of programs, the group suggested that application of the research guidelines would be justified only if three conditions were met: (1) a problem exists that is relevant to the problem addressed by the research guidelines; (2) no comparable safeguard exists; and (3) implementation is feasible.

The Policy Group considered that the criterion of relevance is met by all the research standards except that pertaining to selection of subjects; since patients select physicians, that standard cannot be applied. With respect to the five remaining guidelines, the group concluded that safeguards exist that are not only comparable but superior to those provided by each of the research guidelines. Competence of physicians is assured by a process that includes stringent selection for admission to medical school, licensure and relicensure requirements, disciplinary review by peers, granting of hospital admission privileges, and review by clinical practice committees. This process, despite its limitations, is far more extensive and formal than any review of competence of investigators. Quality of care (analogous to sound research design) is enhanced by collegial consultation, medical audits, practice review committees, and Professional Standards Review Organizations, and backed by the threat of malpractice litigation; these safeguards were deemed by the Policy Group to be adequate without invoking the research guidelines. The standards for informed consent are a direct transfer from health care delivery and, though relevant, add little to existing protections. The requirement for compensation for injury has a counterpart in the malpractice system. Although negligence must be proved to recover under malpractice, this is appropriate since treatment

is for the benefit of the patient, as opposed to the no-fault system proposed for research, which is for the benefit of others.

The Policy Group further contended that the third criterion (feasible implementation) is not met by any of the standards. First, implementation of the guidelines would represent an unwarranted interference by government with the relationship between the patient and practitioner. Second, enforcement would require a costly bureaucracy and would interfere with patient confidentiality. Third, there is insufficient knowledge to develop protocols for each therapeutic intervention that would take into account variation in individual response.

Despite its conclusion that existing safeguards in health care delivery are more appropriate than application of the research guidelines, the Policy Group recognized that sources of abuse do exist in DHEW health care programs and remedies should be sought. They contended, however, that the federal government should not be involved in monitoring the process of informed consent; rather, the patients should have more control over the programs that serve them, and appropriations should be increased in order to improve both the quality and quantity of care.

From these conclusions, the Policy Group posed tentative answers to several key questions about health care in programs conducted or supported by DHEW. First, are there conflicts of interest between physician and patient (similar to those between researcher and subject) that require special safeguards? Such conflicts are inherent in health programs that aim at cost-control (such as HMOs) and that involve what might be termed "practice for

the benefit of others" (such as organ transplantation, immunization, or sterilization). Since these conflicts are more influenced by policy decisions than by individual interaction, limiting the federal role to the policy level rather than applying the research guidelines directly was recommended. Second, do issues of physician competence and quality of care require special safeguards in health programs supported by DHEW? Again, the Policy Group suggested that the appropriate level for federal intervention is through policy and appropriations rather than through application of research guidelines. Third, does the lack of alternative sources of care create special vulnerability? Acknowledging this to be the case, the Policy Group again recommended that effective compensatory action requires policy makers to increase the role of service recipients in controlling their health care programs (as is happening in many of them), rather than invoking research guidelines. Finally, do language and cultural differences between recipients and providers create a special vulnerability? Answering in the affirmative, the Policy Group continued to advise that enhancing the role of recipients in designing and operating the programs will be far more effective in coping with this vulnerability than applying outgrowths of the research guidelines, such as translators or bilingual consent forms. Thus, the Policy Group's responses to these four questions are that although sources of compromise of patients' rights exist, these are dealt with more effectively by providing adequate resources and by encouraging patient participation in program design and operation than by direct application of the research guidelines.

Medical Perspectives

A paper on the implications for medical practice of applying the basic ethical principles and guidelines for research to delivery of health services under programs conducted or supported by DHEW was prepared for the Commission by Robert J. Levine, M.D.

Dr. Levine noted that of the incidents leading to inclusion of this charge in the Commission's mandate, only the sterilization of the Relf sisters fell strictly within the criteria of medical practice rather than research or innovative therapy, and thus could be subsumed under recommendations developed under this charge. Even this incident, he said, is more appropriately categorized as "practice for the benefit of others. It thus falls in between the category of research (activities designed to contribute to generalizable knowledge and thus generally for the benefit of others) and the category of medical practice (activities designed solely to enhance the well-being of the individual). Dr. Levine described a number of examples of medical procedures that fall into the category of "practice for the benefit of others." These range from donation of blood or a kidney, in which there is benefit only to the recipient and no medical benefit to the donor; to vaccination, in which both the individual and society benefit; to quarantine, where only society benefits. Other examples include administration of tranquilizers to institutionalized patients, where the institution and possibly the patient benefit from improved manageability, and sterilization for genetic reasons or because the patient is mentally incompetent to function as a parent. It is important to distinguish this category, Dr. Levine said, because some protective measures employed in research may be appropriate here

but not in the rest of medical practice.

Dr. Levine accepted completely the applicability of the basic ethical principles of beneficence, justice, and respect for persons to medical practice, as well as to most human endeavors. He then analyzed six norms or guidelines developed to apply these principles to research, to determine whether they had analogous application in medical practice.

The first guideline, sound research design, he said, has no direct analogy in medical practice; the closest parallel is the standard of a reasonable expectation of success as the criterion for routine and accepted practice. The second guideline, competence of investigators, is far more formally developed in medical practice than in research. It is enforced for physicians in the medical practice setting through state licensure, professional society certification, granting of institutional privileges, and review of professional conduct by both professional societies and institutions.

Dr. Levine suggested that the third research guideline, identification of consequences (assessment of risks and benefits), applies quite differently in medical practice than in research. In research, the benefits rarely redound exclusively to the subject, while in practice both terms of the risk-benefit calculus apply strictly to the patient, who decides how much risk of physical or psychological harm he will bear for a given expectation of personal benefit. Patients receiving care in programs funded by DHEW have an advantage in this situation in that they need not enter the expense of the procedure in the risk side of the equation. Since the risks and benefits

fall only to the patient, Dr. Levine said, there is no reason to invoke a counterpart to the research review mechanism to apply to routine medical practice. He made an exception, however, in the category of "practice for the benefit of others" because the balancing of risk and benefit becomes more complex and involves more than just the patient. He recommended involving an accountability structure similar to the IRB to review practices falling within this category.

Equitable selection of subjects, the fourth guideline, has an analogy in practice not in selecting patients, Dr. Levine said, but in distributing benefits. All medical decisions should be made according to the principle "to each according to his essential need." Of special concern in DHEW programs is that the range of available treatments be essentially comparable to that available to those not dependent on DHEW for health care.

The fifth research guideline, informed consent, is directly applicable to practice, he said. Patients are entitled to the same degree of thoroughness in the consent process as are research subjects, Dr. Levine said. In contrast to research subjects, however, patients may be allowed to relinquish that entitlement and at their discretion delegate decision making authority to their physician, except in the category of "practice for the benefit of others." Dr. Levine stated that documentation of the negotiations for informed consent by a written form serves only to protect the investigator and the institution in the research context, and thus is needed in practice only to such an extent as is necessary to protect the physician and the institution.

Compensation of subjects for injury, the final research guideline, is justified in the research context because subjects participate partly for the benefit of others. Therefore Dr. Levine found no need for a similar no-fault compensation system for general medical practice which is done for the benefit of the patient. Once again, however, he made an exception for the category of "practice for the benefit of others," suggesting that for immunization and similar practices in this category a no-fault compensation system should be provided for injured patients.

Dr. Levine emphasized that perils exist in overregulation of medical practice supported by DHEW. Requirements for health professionals to perform meaningless tasks waste a valuable resource and promote disrespect for good regulations. Burdening DHEW programs with excess and unjustifiable regulations could discourage health professionals from choosing to practice in these programs, which already are experiencing recruiting problems. Another potential problem is that therapies available in DHEW programs may be limited to those given official approval by a government agency (*i.e.*, the FDA) even when a treatment that is not yet officially approved is nevertheless recognized as the therapy of choice by practitioners. Requiring every innovative therapy to be conducted as research, said Dr. Levine, and adhering rigidly to drug package inserts that make therapeutic orphans of children and pregnant women, could also be detrimental to patients dependent on DHEW for their health care.

Philosophical Perspectives

Papers on the ethical considerations in applying the basic ethical

principles and guidelines for research to health care programs conducted or supported by DHEW were prepared for the Commission by John Fletcher, PH.D., and Roy Branson, Ph.D.

Dr. Fletcher began by asking what Congress meant when it directed the Commission to consider the "appropriateness" of applying principles and guidelines developed for research to medical practice in programs supported by DHEW. He concluded that Congress did not mean to inquire whether such application was feasible administratively or institutionally, or whether it was correct to go to the research setting to find principles and guidelines for health care delivery. Rather, he inferred that Congress meant to ask a moral question: is the moral code for research appropriate for medical care? He began his analysis of this question by identifying two kinds of moral problems: (a) actions that violate rights of persons and moral rules of communities, and (b) conflicts between moral rules as to which takes priority. The physician, in order to avoid violating the rights of patients, must fulfill five moral obligations according to Dr. Fletcher: (1) to inform the patient truthfully regarding diagnosis, treatment, and prognosis, (2) to seek the patient's consent to treatment and to each significant medical procedure, (3) to act to preserve the life and well-being of the patient, (4) to maintain the confidentiality of the doctor-patient relationship, and (5) to treat patients equally on the basis of their needs.

Ethical principles serve three functions, Dr. Fletcher said. First, they furnish ideals for the critical appraisal of the correctness of moral rules (*e.g.*, do not kill, help those in need) in order to permit the improvement of morality, especially in times of rapid social change. Second,

they furnish the required higher standards for justifying moral rules. (The rules, by themselves, can tell us only what to do in specific situations; they do not tell us why the rules are valid or what to do when the rules conflict.) Third, ethical principles point even beyond themselves to an ethical spirit that shapes attitudes of self-respect and respect for others and provides common ground for resolving issues of moral and ethical conflict in a pluralistic society.

With this background, Dr. Fletcher next considered the relevance to practice of the Commission's basic ethical principles for research: beneficence, respect for persons, and justice. He concluded that these principles are basic to the morality of medical care in general and to the conduct of health service delivery programs in particular. They form a complex but balanced system of ideals to serve as the foundation for considering the major moral issues in the total system of health care, thus fulfilling the first function of ethical principles. In addition, they fulfill the second function in that they are relevant sources for validation of each of the five moral obligations of the physician to the patient: all five derive from the basic principles of beneficence, respect for persons, and justice. Further, they assist in ordering priorities when obligations conflict. The principles also fulfill the third function of pointing toward the self-respect and respect for others required to make morality possible, *i.e.*, to make one <u>want to be moral</u>.

But how, Fletcher asked, do diverse groups and individuals in an increasingly pluralistic society find enough common ground both to want to be moral

and to want to change social practices that cause harm? He suggested that this answer may lie in the concept of a "social-ethical contract" to which all members of society are a part. The fundamental premise of this contract is: "I believe it is in my interest to be moral." It follows that a government based on explicit consent of the governed must respect the fundamental values and moral convictions of the society. Government actions that violate the consent of the governed are not only unconstitutional, they also break the social-ethical contract by implying that it is not in the government's interest to be moral. Thus the government has a special obligation to conduct public programs in ways that uphold the social-ethical contract; for this purpose, the basic ethical principles developed for research have direct applicability to the delivery of health care. The obligations pertaining to research and those pertaining to medical care derive from the same moral rules and ethical principles, but are applied in settings with different purposes (*i.e.*, aiding the individual vs. advancing knowledge). Therefore, although the basic ethical principles have direct relevance, the guidelines for research should not be taken as literal points of departure for regulating the delivery of health services provided or funded by the government.

Dr. Branson directed his attention exclusively to the morally appropriate means of distributing health services to large groups. He approached this question by appeal partly to the principles of respect for persons and beneficence, but predominantly by reference to the principle of justice. He presented five positions that offer different options for resolving the problem of allocation of medical resources.

He first considered the "utilitarian" theory. According to its exponents, health care should be distributed strictly according to utility, *i.e.*, the goal of the health care system should be to achieve the highest level of attainable health for the maximum number of individuals. He noted that the most obvious shortcoming of such a theory is the possible neglect of vulnerable minority populations, whose interests might be sacrificed to those of the majority. Second, Branson discussed the "entitlement" theory, which is based on a conception of social and political rights. According to this theory, traditional forms of distributive justice are a threat to liberty because they take possessions from individuals (their financial holdings) in order to allocate them to others according to some general social pattern. Since individuals are entitled to their holdings, such a procedure is unjust according to this theory. Branson noted that the main worry about this theory centers on whether one is entitled to the natural assets created by one's native endowments and whether one is necessarily entitled to everything that derives from natural talents and abilities. He also mentioned that society itself can claim much of the responsibility for the success of certain persons (*e.g.*, physicians) because of the investment it has made in such individuals -- a fact that challenges whether such individuals are unqualifiedly entitled to their assets.

Third, Branson analyzed the "decent minimum" theory. This theory holds that luxury or highly sophisticated medical goods and services may be purchased by individuals, but wherever there exists a standard of "decent and fair" treatment, the decent minimum should be distributed to all individuals equally. The major objection to this position, according to Branson, is

that it fails to enable the poor to obtain the same level of care available to the rest of society and yet at the same time necessarily involves (through taxation) a forcible removal of some financial assets that were justly acquired by citizens.

Fourth, Branson presented the "maximum level" theory. According to its exponents, a social allocation system should be established that secures the highest possible mimimal level of health care consistent with available social resources. This means that all citizens would be given equal access to the most extensive network of health services that it is possible for society to provide -- beginning with the most disadvantaged groups and working up. Branson also mentioned some possible criticisms of this theory. For example, it is difficult to identify the "worst off" group, for the theory is usually ambiguous as to whether medical care is to be directed to the medically worst off or the economically worst off. He also noted that there are problems in the definition of "health" and with the very idea of "minimum," as understood in the phrase "maximum minimum."

Finally, Branson discussed the "equal access" theory, according to which all individuals should have equal access to health care regardless of their financial differences, and all persons with similar medical cases ought to receive equal treatment. The only relevant difference justifying differential treatment under this theory is the level of sickness; the goal is to bring the medically worst off up to the level of health enjoyed by others in society, or at least to approximate that level insofar as possible. This position has been criticized by nonegalitarians, according to Branson, largely because it contains an unrealistic depiction of social resources and because

there are insuperable problems in interpreting the notion of bringing the medically worst off up to the level of health of others in society.

Branson concluded that most of the above issues remain unresolved in contemporary ethical theory. He noted especially that it remains undetermined whether some one of the above positions must prevail or whether a theory can be developed that provides a synthesis of the various alternatives.

Sociological Perspectives

A paper on the sociological implications of applying the basic ethical principles and guidelines for research to health care programs conducted or supported by DHEW was prepared for the Commission by David Mechanic, Ph.D.

Dr. Mechanic approached this question in the context of the recent emphasis on human rights in the United States. Medicine has remained relatively untouched by this movement, he said, and is now facing an increase in public distrust and demand for accountability. He believes the basic ethical principles derived for research should apply not only to all types of health service programs supported by DHEW, but also to decisions by policymakers in DHEW and Congress on distribution of resources, which are at least as important. Further, he sees no reason for singling out DHEW health programs for application of these ethical principles. It is organizational procedures, types of professional remuneration, and patient-provider inequalities, rather than DHEW funding, he said, that are the sources of the problems that call for solutions grounded in these ethical principles.

Taking respect for persons as the primary ethical principle, Dr. Mechanic derived four applications to the context of health care delivery: (1) patients should be free of coercion and should participate in medical activities only with their informed consent, (2) patients should receive accurate information on all aspects of their care, (3) decisions on allocating medical care should be made solely on the basis of medical need and expected benefits, and (4) patients should have a mechanism for fair resolution of conflicts with providers. He then identified four major ethical problems related to this basic principle that arise in the delivery of health care. First, the professional behavior of providers often conveys a lack of respect to the patient. The profession does not police itself adequately in this regard; thus, a mechanism (other than regulations) is needed that will involve both professionals and patients in alleviating this problem.

The second major problem is the limitation of resources relative to the demand for services; the result is that some services to which the poor are entitled are unavailable, and care is often rushed and impersonal. Respect for persons does not require unlimited resources for health care; but it does require telling the truth about the rationing that occurs, and it requires that decisions on rationing be based on need and expected benefits, not on political or sociocultural criteria. Services should be distributed without regard to social status, religion, or race, and be determined only by medical judgments. Mechanic viewed efforts to limit federal funding for abortion as a violation of the basic ethical principles, and argued strongly that:

> "although exclusion of certain benefits under federal or state programs would be ethically permissible because of resource limitations or because the procedures involved are known to be worthless or harmful, there is no ethical justification for singling out recipients of government programs as ineligible for services known to have positive health benefits that are available to others in the population."

The third major problem is that values, expectations, and incentives within varying health care delivery plans are in conflict. For example, the form of physician payment (fee-for-service, capitation, salary, etc.) strongly influences the type and quality of services provided. Mechanic warned that particularly in programs that require physicians to absorb excess costs of health services, careful monitoring will be required "to insure that the burdens of rationing to achieve cost containment do not disproportionately fall on the poor and more needy groups in the population."

The fourth major problem Mechanic identified is the inequality in knowledge, status, and power between the patient and the provider. The ability to choose alternative sources of health care, which helps balance this inequality in the private system, is often absent from federally-provided health care. The imbalance is aggravated by language barriers, social distance, limited resources, salaried physicians and limited patient education, which often are present in publicly funded programs. Pressures for cost containment may lead to fixed prospective budgets or regionalization of care and tend to further restrict the choices of patients. Mechanic recognized the need to avoid waste, but urged that mechanisms be developed to protect patients' rights and assure physician accountability in health care systems that provide limited choices.

In considering such mechanisms, Mechanic pointed out that the problem areas involve behaviors that are difficult to monitor, so that specifying individual guidelines and regulations to govern them is a futile gesture that would add to the administrative and bureaucratic burden and detract from efforts to provide good care with limited resources. Instead, a mechanism is needed to reduce the inequality between patient and provider, and provide feedback to the professionals regarding the problems of the patients. He recommended an effective grievance procedure, institutionally based, visible and accessible to patients, to resolve difficulties in the process of patient care. The mechanism would be analogous to the research IRB and would act as a deterrent to abuse and to increase the patients' sense of trust. The grievance procedure could be supplemented by a patient ombudsman, who would improve communication between patients and providers and represent patient interests, and by external pressures on health care programs to provide patients with a statement of their rights.

Mechanic saw no use in applying this mechanism for grievance procedures to reimbursement programs like Medicare and Medicaid, but suggested that it be required in programs operated by DHEW and in capacity building grants. He also suggested experimenting with the mechanism before making it a general requirement.

Chapter 4. Legal Considerations

Most of the litigation involving health services supported by DHEW has involved Medicaid, a program funded largely by the federal government and administered by the states. State programs must be reviewed by DHEW for a determination by the Secretary that they conform with departmental regulations implementing the relevant portions of the Social Security Act. Most of the issues reviewed by the courts have centered on attempts by the states to control costs, generally through restrictions on eligibility or reductions in benefits. Whichever fiscal remedy states have implemented and the recipients have challenged, the courts have been faced with issues that are as much questions of social policy as they are questions of health care or economics. Complicating matters is the fact that the legislation creating Medicaid, and various subsequent amendments to the original Act, are products of political compromise; even the purpose of the legislation is obscure.[1] This means that policy decisions left to the discretion of the states, as well as those made by the Secretary, DHEW, (who has the responsibility of implementing the legislation) must be judged against an elusive standard. This difficulty has been noted by the Supreme Court as well as by lower courts attempting to determine whether state limitations are consistent with the purposes of enabling legislation.[2]

Eligibility Criteria and the Extent of Benefits

Although in the 1960s it may have appeared that health care recipients would prevail in litigation to establish their right to increased benefits or, at least, protection from restrictions on benefits or eligibility,[3] since

1970 the courts have maintained a reluctance to interfere unless actions taken by either the states or DHEW could be shown to violate specific provisions of the Social Security Act or the Constitution. The principle of judicial restraint in such matters was enunciated by the Supreme Court in Dandridge v. Williams (1970),[4] a decision in which the Court upheld the "undisputed power" of the states to set the level of benefits under Medicaid, noting that the Social Security Act afforded great latitude to each state for dispensing available funds under the program and even for determining the amount of funds to devote to the program.[5] The Court held that so long as the classifications employed by the state meet the standard of reasonableness, the federal courts have "no power to impose upon the States their views of what constitutes wise economic or social policy,"[6] because "the intractable economic and social and even philosophical problems presented by public welfare assistance programs are not the business of this Court."[7] In a companion case, the Court stated that "[I]t is, of course, no part of the business of this court to evaluate, apart from federal constitutional or statutory challenge, the merits or wisdom of any welfare programs, whether state or federal, in the large or in the particular," saying that the problems should, at least in the first instance, be under the supervision of DHEW.[8]

The principle enunciated in Dandridge has been reaffirmed in numerous cases challenging federal and state action, both legislative and administrative. Thus, for example, in New York Department of Social Services v. Dublino (1973), the Supreme Court adhered to the principle of "cooperative federalism" in holding that while Congress may impose certain work requirements

for families receiving assistance under Aid to Families with Dependent Children (AFDC), states may impose (and the Secretary, DHEW, approve) additional requirements as conditions for eligibility.[9] The only limitation is that the requirements imposed not be arbitrary or unreasonable, and that they not conflict with specific provisions of the Social Security Act.[10]

Similarly, in Jefferson v. Hackney (1972), the Court held that Texas could allocate its resources in such a way that individuals receiving categorical assistance (the aged, blind, or disabled) would receive more comprehensive medical services than those receiving assistance under AFDC.[11] Again, the Court applied the rule that so long as the state's action is not in violation of any specific provision of the Constitution or the Social Security Act, it would not interfere.[12] The standard applied in this case was that the judgments be "rational, and not invidious."[13] Furthermore, the Court rejected the plaintiffs' equal protection argument, saying that in tackling the problems of the poor and the needy, the state "may address a problem 'one step at a time' or even 'select one phase of one field and apply a remedy there, neglecting the others.'"[14]

Reiterating that broad discretion is left to the states to determine eligibility for and the extent of medical assistance, the Court in Beal v. Doe (1977) declared that states are not required to offer "unnecessary - though perhaps desirable" abortions.[15] The Court stated that the purpose of the Medicaid legislation is to furnish assistance to individuals unable to meet the costs of necessary medical services; since nothing is said in the Social Security Act about meeting costs of "unnecessary" medical services, such services need not be provided.[16]

In Townsend v. Swank (1971) the Court did sustain a challenge to an Illinois statute that restricted eligibility for assistance in a way that conflicted with specific provisions of the Social Security Act.[17] The Court held in Townsend that because the Act specifically provides[18] that children between the ages of 18 and 20 are eligible for assistance under AFDC whether they are in high school, vocational school, college or university, a state may not exclude from eligibility children 18-20 who are in college or university. Similarly,in Shapiro v. Thompson (1969) the Court declared that one-year residency requirements are unconstitutional because they abridge freedom to travel and constitute an impermissible apportionment of benefits on the basis of past tax contributions.[19] The state, it held, may not accomplish the legitimate purpose of limiting expenditures "by invidious distinctions between classes of its citizens."[20] Two years later, in Graham v. Richardson (1971), the Court held that states may not deny benefits to resident aliens.[21]

In procedural matters, the Court in Goldberg v. Kelly (1970) held that due process requires states to provide an evidentiary hearing for welfare recipients before terminating programs or benefits.[22] Moreover, since "the opportunity to be heard must be tailored to the capacities and circumstances of those who are to be heard," recipients must be permitted to appear in person and present their views orally to the official who will make the final determination regarding eligibility.[23]

Lower federal courts have followed the principle established in Dandridge and have, for the most part, declined to disturb any rule (federal or state)

regarding eligibility criteria or extent of services, except on procedural grounds or when the rules in question clearly conflict with provisions of the Social Security Act or the Constitution. Thus, in 1976 the United States Court of Appeals for the District of Columbia upheld the authority of the Secretary, DHEW, to establish (a) maximum limits of available resources that recipients may have and still qualify for benefits, and (b) the method of computing the value of such resources.[24] Although the plaintiffs in the case had insisted that the states had the right to make such decisions, the court held that the Secretary has broad authority to promulgate regulations binding on the states to the extent necessary for efficient administration of the Social Security Act, so long as the regulations are "reasonably related to the purposes of the enabling legislation."[25] However, the court also declared the regulations in question invalid because in issuing them the Secretary had violated the requirements of the Administrative Procedures Act and the department's own procedural rules. Moreover, the regulations conflicted with specific provisions of the Social Security Act regarding computation of available assets in determining eligibility for the program.

In 1972, the First Circuit Court of Appeals affirmed the decision of a district court in Maine upholding the right of the state to discontinue medical assistance to children of unemployed fathers (an optional program under the Social Security Act) so long as the Secretary, DHEW, had duly approved the state's modification of its plan.[26] Citing Dandridge, the court held that the decision was reasonably related to a legitimate state interest in solving difficult economic and social problems, and thus was acceptable.

Similarly, a district court in Connecticut upheld that state's right to supplement an amendment to the Social Security Act with its own, more stringent provisions requiring unwed mothers to cooperate with officials seeking to identify and locate the fathers of their illegitimate children in order to qualify for assistance under AFDC.[27]

A district court in Pennsylvania, on the other hand, held that the state may not limit provision of eyeglasses for the categorically needy to persons with "eye pathology," because Medicaid legislation defines eyeglasses as devices for improving vision, not just for treating "eye pathology."[28] (Pennsylvania's Medical Assistance Plan would have provided glasses for "ordinary refractory errors" only for school children.) The court noted medical evidence to the effect that eyeglasses are not even effective treatment for most pathological conditions of the eye, whereas they are appropriate treatment for refractory errors.

A federal district court in New York, in which plaintiffs who were unable to find a dentist willing to treat Medicaid patients sought to require county and state officials to establish a better fee structure, dismissed the suit for want of jurisdiction.[29] Finding no civil rights claim and no question concerning the regulation of commerce, the court said its jurisdiction must rest on a federal question arising under the law of the United States which, in turn, requires that the amount in controversy exceed $10,000. The court then held that individual members in a class action cannot aggregate their claims to reach the jurisdictional amount; thus, the suit could not be heard by that court. The decision was affirmed, without opinion, by the Second Circuit Court of Appeals,[30] despite recognized

authority that the state of the law regarding aggregation of claims is unsettled, at best.[31] If the ruling of the Second Circuit were applied widely it would be difficult, if not impossible, for Medicaid recipients to litigate any claims other than constitutional ones in the federal courts.

Experiments in Cost Containment

Medicaid recipients have had mixed success in attempts to enjoin the Secretary, DHEW, from approving state "experiments" in methods designed to alleviate the fiscal problems threatening the program. In 1972, a federal district court in California held that the Secretary could approve and the state could implement an experimental program requiring co-payment for medical services even though, as the court acknowledged, "it becomes quite clear that no recipient of categorical aid is, by the State's own figures able to pay anything for medical care - the amount of payment that could be required as reasonably related to income and resources is precisely zero."[32] Since some of the Medicaid provisions may be waived for experimental projects "likely to assist in promoting the objectives" of the program, it became important for the court to discern what those objectives might be.[33] "The immediate difficulty encountered . . . is that the 'objectives' of Title XIX are nowhere to be found."[34]

The federal court in California was able, nonetheless, to discover at least one objective for Medicaid: to broaden services and coverage in order to offer a comprehensive program for persons unable to pay for necessary medical care on their own. Since the proposed co-payment project would impose a liability of no more than $3 per month on participants, the

court held that it might be the only way the state could continue the program in the face of rising costs,[35] and this reasonably could be considered by the Secretary as likely to promote at least some of the objectives of the program. In answer to the plaintiff's contention that the experiment was poorly designed and thus could not produce valid results, the court said that "the Secretary [DHEW] cannot be held to standards of scientific precision in [the] testing process" and, since he often must make decisions based upon inadequate data and incomplete understanding of the problems involved, he "may approve experiments, therefore, which may produce only rough, inexact, partially ambiguous data."[36]

Medicaid recipients in Georgia were more successful in their challenge to a similar co-payment experiment. In Crane v. Mathews (1976) a federal district court concluded that the Secretary, DHEW, had authority to approve such an experiment; however, the court held that the project would then contitute research with human subjects and would be required, under DHEW regulations (45 CFR 46), to be reviewed by an Institutional Review Board for the protection of human subjects.[37] The board that subsequently reviewed the project found first, that the subjects would be at considerable medical risk because the $25 co-payment would probably be prohibitive for those individuals who receive an AFDC income of only $42 per month, and second, that the project was so poorly designed that valid conclusions could not be drawn.[38] It therefore refused to approve the project.

A third experiment in cost containment, approved by the Second Circuit Court of Appeals, permitted New York to initiate a pilot project in which certain AFDC recipients would be required to work in order to receive

benefits.[39] The recipients' challenge to the project was based on an allegation that the experimental conditions imposed more stringent requirements than those contained in the original 1935 Social Security Act[40] and an assertion that the Secretary, DHEW, has no authority to waive any provisions "which might result in the curtailment or denial of assistance."[41] The court affirmed the right of the Secretary to approve the proposed project as "likely to assist in promoting the objectives of designated parts of the Social Security Act."[42]

Informed Consent for Sterilization

Women receiving assistance for medical care through Medicaid have had mixed results in establishing conditions for valid consent to sterilization procedures. In Relf v. Weinberger (1974)[43] recipients prevailed in a suit to require DHEW to inform patients of their right to refuse sterilization without subsequent loss of any federal benefits to which they are entitled. Nevertheless, in 1977 the Fourth Circuit Court of Appeals said, in Walker v. Pierce, that it could perceive no reason why a physician could not establish and pursue a policy of requiring all such patients to consent to be sterilized after delivery as a condition for his delivering their third or any subsequent child.[44] Notwithstanding the decision of the D.C. Circuit in Relf, which cited "specific statutory language forbidding the recipients of federal family planning funds to threaten a cutoff of program benefits unless the individual submits to sterilization"[45] and clearly directing DHEW to protect against such coercion,[46] the Fourth Circuit Court of Appeals said it found no judicial precedent or statute inhibiting Dr. Pierce from implementing his personal philosophy with respect to Medicaid patients.[47]

Further, although the plaintiff testified that Dr. Pierce said he would have her AFDC funds cut off if she did not consent to sterilization, and that she then consented because to protest would have been futile,[48] the court concluded that her consent was voluntary (because she had signed several consent forms) and that "at no time is [Dr. Pierce] shown to have forced his view upon any mother."[49]

Furthermore, the court reversed the judgment against Dr. Pierce for discharging another Medicaid patient the day following her delivery (because she refused to consent to sterilization) on the ground that Dr. Pierce was not acting under color of state law when he treated Medicaid patients. However, the record discloses that Dr. Pierce received $60,000 from his Medicaid practice over a period of a year and a half, no other obstetrician was available to treat such patients at the county hospital, and thus Dr. Pierce appeared to be the only source from which the patients could receive the services to which they were entitled. Indeed, when the county commissioner of social services learned (through the press) of Pierce's policies, he arranged for obstetrical patients to be transported, at county expense, to a doctor in Augusta. In a dissent to this portion of this court's opinion, Judge Butzner argued that "a doctor who represents himself to the public as a qualified Medicaid practitioner assumes a state or public administrative function when he conditions the grant or denial of Medicaid benefits on requirements not connected with the patient's health."[50] Moreover, he observed, "Dr. Pierce was his patients' most important contact with the state program."[51]

Representation on Administrative Boards

In view of the adverse decisions that health care recipients have received from the courts in recent years, it is not surprising that they are beginning to focus their attention on the right to be represented on the planning boards that make many of the decisions regarding eligibility and benefits in the first place. In New York, a coalition of neighborhood representatives successfully sued for better representation on neighborhood planning boards and on the Mayor's Organizational Task Force of Comprehensive Health Planning. The Public Health Service Act requires that consumers of health services constitute a majority of the membership of area-wide health planning councils;[52] and the district court held that therefore "the Congress intended the representatives of local communities to have a private right of action to carry out the purpose of the statute."[53] The desire to participate in comprehensive health planning, said the court, is "akin to the desire to vote or serve as a public official," and the injury resulting from a denial of the right to such participation need not be economic to be actionable.[54]

By contrast, health service consumers in Texas were unable to persuade the Fifth Circuit Court of Appeals that the National Health Planning and Resources Development Act requires 50% of their planning board to be composed of members with incomes below $10,000.[55] The Act provides that membership of such boards should be "broadly representative of the social, economic, linguistic and racial populations, geographic areas of the health service area, and major purchasers of health care";[56] and the preamble states that "the consumer majority should roughly approximate, in its representational

aspects, the whole population of the health service area." However, the court rejected the consumers' interpretation in favor of a more flexible approach wherein the Secretary, DHEW, has discretion to approve the composition of such boards so long as it "roughly reflects the population distribution of the various counties in the health service area."[57] The proper standard of review in such matters, said the court, is whether the Secretary's action in approving the board was arbitrary, capricious, or an abuse of discretion, since his approval is, after all, an accommodation of competing policy alternatives. The court remanded the case to the trial court for determination of the facts according to that standard.

Conclusion

Partly because of ambiguities in the enabling legislation, and partly because of judicial reluctance to disturb legislative or administrative rules implementing that legislation, recipients of federally supported health services are unlikely to prevail in the courts unless they can demonstrate an obvious violation of due process or a clear conflict with specific provisions of relevant legislation or the Constitution. Congress could dispel some of the confusion in the courts by articulating the purpose of the various acts providing medical assistance and, perhaps, by granting federal jurisdiction for claims arising out of the relevant legislation, regardless of the dollar amount in controversy. Beyond that, it appears that the social, economic and philosophical problems surrounding federal support of health care are not amenable to resolution in the courts; they must be addressed by legislative and administrative action. Vigorous enforcement of rules requiring the

participation of health care recipients in such decision-making would provide important protection of their interests.

REFERENCES

1. R. Stevens and R. Stevens, Welfare Medicine in America, Free Press, New York, 1974, Chapter 15; The Courts and the Congress.

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3. Stevens and Stevens, p. 307.

4. 397 U.S. 471 (1970).

5. *Id.* at 478.

6. *Id.* at 485.

7. *Id.* at 487.

8. Rosado v. Wyman, 397 U.S. 397, 422 (1970).

9. 413 U.S. 405 (1973).

10. *Id.* at 420, 422.

11. 406 U.S. 535 (1972).

12. *Id.* at 541.

13. *Id.* at 546.

14. *Id.*

15. 432 U.S. 438 (1977).

16. *Id.* at 445.

17. 404 U.S. 282 (1971).

18. § 406(a)(2)(B) of the Social Security Act.

19. 394 U.S. 618 (1969).

20. *Id.* at 633.

21. 403 U.S. 365 (1971).

22. 397 U.S. 254 (1970).

23. *Id.* at 270.

24. National Welfare Rights Organization v. Mathews, 533 F.2d 637 (D.C. Cir. 1976).

25. *Id.* at 645.

26. United Low Income, Inc. v. Fisher, 340 F.Supp. 150 (S.D.Me. 1972), *aff'd per curiam*, 470 F.2d 1074 (1st Cir. 1972).

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30. 489 F.2d 752 (2nd Cir. 1974).

31. C. Wright, Law of Federal Courts, § 36 (West, 1976). See also, 14 Wright, Miller and Cooper, Federal Practice and Procedure: Jurisdiction § 3704.

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33. *Id.* at 494.

34. *Id.*

35. *Id.* at 497.

36. *Id.* at 498.

37. 417 F.Supp. 532 (N.D.Ga. 1976).

38. Clarification statement regarding Georgia Department of Human Resources, Human Research Review Board's review of the proposal entitled "Recipient Cost-Participation in Medicaid Reform," Russell J. Bent, Ph.D., Chair, July, 1976.

39. Aguayo v. Richardson, 473 F.2d 1090 (2nd Cir. 1973).

40. *Id.* at 1104, *citing* 42 U.S.C. § 609.

41. *Id.*

42. *Id.* at 1105.

43. 372 F.Supp. 1196 (D.D.C. 1974).

44. 560 F.2d 609 (4th Cir. 1977).

45. Relf, 372 F.Supp. at 1203.

46. *Id.* at 1204-1205.

47. Walker, 560 F.2d at 613.

48. *Id.* at 611.

49. *Id.* at 613.

50. *Id.* at 615.

51. *Id.*

52. 42 U.S.C. § 246(b)(2)(A).

53. New York City Coalition for Community Health v. Lindsay, 362 F.Supp. 434, 439 (S.D.N.Y. 1973).

54. *Id.* at 441.

55. Texas Acorn v. Texas Area 5 Health Systems Agency, 559 F.2d 1019 (5th Cir. 1977).

56. 42 U.S.C. § 3001-1(b)(3)(C)(i).

57. Texas Acorn, 559 F.2d at 1026.

Chapter 5. Deliberations and Conclusions

The Commission has identified three basic ethical principles that should underlie the conduct of research involving human subjects: respect for persons, beneficence and justice. These basic ethical principles are sufficiently general that they can be applied to almost any ethical domain where moral problems arise, as, for example, to business ethics, legal ethics, and political ethics. Issues about the application of these principles thus arise less over whether the principles can be applied at all than over the exactness of the parallels in the manner of their application. This report suggests the extent to which particular guidelines governing the delivery of health services should parallel those developed to protect subjects of biomedical and behavioral research. To make such a determination, it is useful first to consider the purpose of applying such guidelines to the research enterprise and the extent to which a similar purpose exists in the area of health services.

The Need for Protection

One of the central reasons for imposing constraints on the research enterprise is the recognition that by its very nature, it places investigators in a potential conflict of interest. The goal of developing generalizable knowledge may conflict with the duty to protect the subjects of research; it may interfere with the investigators evaluation of the risks and potential benefits reasonably to be anticipated. Similarly, the search for knowledge may affect decisions regarding continuation or termination of a research activity. For these reasons, the Commission has endorsed the longstanding

requirement that investigators submit their research proposals to review by individuals who are unrelated to the research and thus are able to provide an objective assessment of the justifiability of risks in view of the likelihood of achieving the anticipated benefits. Such review also provides an evaluation of the justification for asking subjects to accept certain risks, and an assessment of the adequacy and fairness of the information that will be disclosed to potential subjects for the purpose of their decision-making.

In the delivery of health services under federally funded programs, different conflicts exist. First and foremost is ambiguity within the system as to whether such services are available as entitlements or whether the recipients are in the position of supplicants. This ambiguity affects many aspects of the system. More particularly, the need to reduce both the expense and the work-load of the program may conflict with the provision of optimum care for all patients; when service providers are salaried (rather than receiving fees dependent upon the service provided, as in the private sector), the incentive may be to reduce rather than increase the amount of care per patient.

In addition, since the patients in federally funded programs often lack the options available to those who pay for their own care (*e.g.*, seeking different clinicians or facilities if they are dissatisfied with the care they are receiving), they have no leverage with which to ensure an appropriate standard of care or appropriate respect for their individuality and their particular needs. Thus, patients receiving federally supported services are vulnerable to the extent that they lack viable alternatives.

Further problems arise in federally supported health care from the need to limit services according to available funds and to allocate scarce resources among individuals within the health care system. Those who determine what services will be available and which individuals will receive scarce resources within those services may not be sensitive to the particular health needs and cultural preferences of the population being served.

Finally, as noted by the report of the Privacy Commission,* individuals receiving government assistance are particularly vulnerable with respect to the amount of data entered into their records and the availability of that data to other government agencies. One of the difficulties (not encountered in the private sector) is that in order to establish eligibility for services, individuals must submit extensive personal data to the responsible agency; and this information is exchanged among and within agencies, due to interrelationships in the administration of federally assisted programs.

Thus, it is clear that persons receiving their health care from federally funded programs are not vulnerable because of the same conflicts from which research subjects need protection; nevertheless, they are in need of protection from a different set of circumstances placing them at a disadvantage relative to persons who obtain health care from private sources. It is thus appropriate to consider the extent to which the principles and guidelines

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* Personal Privacy in an Information Society: The Report of the Privacy Protection Study Commission, July, 1977; Chapter 11: The Citizen as Beneficiary of Government Assistance, pp. 445-486.

that the Commission recommended for the protection of human subjects of research should be applied to protect recipients of federally funded health services.

The Application of Basic Ethical Principles

Respect for Persons. This principle obliges us to respect the autonomous choices of individuals; it is applied largely through the mechanism of "informed consent," *i.e.*, the requirement that persons be asked and give their permission before a particular procedure is applied to them. The idea of informed consent embraces the correlative requirement to respect the right of competent adults to withhold consent, even in situations where others might not. The moral obligation to respect the choices of autonomous individuals is just as strong in the context of health services as it is in the context of research, although there may be limited areas in service delivery in which consent may be presumed (*e.g.*, in emergencies, when the patient is unconscious and life-saving procedures must be initiated). Therefore, when informed consent is required in the delivery of health services, most of the guidelines regarding the adequacy of such consent that were recommended for the research context are directly applicable, including: (1) presenting information in language the patient can understand and in a setting conducive to good decision-making, (2) providing information that a reasonable person similarly situated would desire in order to make a choice regarding the therapy or course of treatment in question, (3) absence of duress or coercion, and (4) assurance that other benefits to which health care recipients are entitled will be provided whatever their decision regarding a proposed intervention or course of treatment.

In addition to seeking informed consent prior to the initiation of interventions, respect for persons requires that cultural differences be respected, that privacy be maintained and that confidentiality be protected. As the Privacy Commission observed, "welfare clients have as much right to respect and dignity as other groups and should be as carefully protected from unfairness stemming from record keeping as are consumers of insurance, medical care, and credit."

Beneficence. Beneficence requires that persons be protected from harm and that they be provided with justifiable benefits. In the provision of health services, this translates into maximizing benefits and minimizing harms to the extent possible with the available resources. In the research context, risks and benefits are kept in proper proportion by Institutional Review Boards (IRBs) that review research activities prior to their initiation. In the delivery of health services, standards are maintained on a post hoc basis by professional committees entrusted with quality control (*e.g.*, tissue committees, practice committees, licensure boards, PSROs, etc.). Part of the responsibility of practice committees in this context is to assure that innovative or untested practices are not applied prematurely.

Maintenance of standards and monitoring of practice are especially important when services are provided to disadvantaged patients who, as noted earlier, have no economic leverage through which to influence such matters; they cannot simply elect to be treated by a different clinician if the service provided by a particular practitioner is not up to standard. Further,

they do not have the social or economic resources to initiate malpractice suits on their own behalf if the care provided is grossly substandard. They may not even be aware of deficiencies in the provision of care, in some instances, due to a limited knowledge of what it is reasonable to expect. Therefore, the Commission has concluded that two mechanisms are necessary to protect the rights of patients in this regard: a grievance procedure, through which they can seek enforcement of their rights, and a system of professional practice committees to monitor the standard of care provided under programs supported by DHEW.

Justice. The principle of justice demands a fair distribution of burdens and benefits in society. In the context of research, this principle requires that both the burdens and benefits of research be fairly distributed and that the most vulnerable individuals not be selected as subjects. In the context of health service delivery, justice requires that both access to health services and the costs of these services be fairly distributed and that those most in need receive the most benefits. It also requires that once the government undertakes to provide a particular service, it should provide adequate service, and that to the extent possible, the choices available in the private sector be available to recipients of federally supported health services.

Many of the ethical problems encountered in health care delivery are those of resource allocation. Decisions must be made regarding what services will be available, regarding eligibility requirements for receiving such services, and regarding the allocation of scarce resources among the

class of people eligible to receive the service. As David Mechanic pointed out, for example, "The decision of policy makers. . . to pay for hemodialysis, hip replacements, and other technical procedures for the aged, but not for social care, counseling, or homemaker services, has major impact on the life opportunities of the old for independent living and involves important ethical issues."

Health policy choices must often be made whether to provide a particular service or a new technology and, if so, how extensively it is to be made available. Once this preliminary policy decision has been made and the service can be delivered, there remains the problem of determining which persons may receive it. A classic case occurred in the early days of kidney dialysis, where initially only limited numbers of individuals could obtain the new technology. Currently, organ transplantation and intensive care technologies are areas where decisions are continually made as to who shall receive the life-saving interventions and who shall not. These problems of distribution can be resolved in a principled way only by reference to a theory of justice that defines standards for the distribution of burdens and benefits.

More broadly, as seen in the previous chapter, as pressures for cost containment mount, decisions must be made as to whether to redefine eligibility criteria, thus excluding some current recipients from future benefits, or whether to eliminate some of the benefits without restricting the class of persons who are eligible to participate in the program. The initial

choice (*i.e.*, between restricting eligibility or reducing benefits) involves major social and ethical issues; once that choice is made, the further determination (*i.e.*, which recipients to eliminate from eligibility or which services to cut) involves similar difficult choices. It is of utmost importance that the recipients of health services participate in making those choices at the local, state and federal levels.

RECOMMENDATIONS

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research makes the following recommendations to Congress and to the Secretary of Health, Education, and Welfare, for legislative and administrative actions as appropriate, with respect to health services delivered under programs conducted or supported by the Department of Health, Education, and Welfare (DHEW). For the purposes of these recommendations, health services delivered under such programs include those supported by DHEW and provided (i) by the private sector, (ii) through state agencies, (iii) by grantees or contractors of DHEW, or (iv) by hospitals, clinics or personnel of DHEW.

RECOMMENDATION (1) ELIGIBLE PERSONS SHOULD BE RECOGNIZED BY HEALTH CARE PROVIDERS AS HAVING A LEGAL RIGHT TO RECEIVE THE HEALTH SERVICES MANDATED UNDER PROGRAMS CONDUCTED OR SUPPORTED BY DHEW.

Comment: The Commission has limited its discussion in this recommendation to the legal rights conferred by health programs conducted or supported by DHEW. The Commission has not addressed the broader question of moral entitlement to health care. Nevertheless, as will become clear in the following recommendations, the Commission considers that the ethical principles of beneficence, respect for persons and justice are applicable to the implementation of federally supported health service programs and should be considered in determining policies regarding program eligibility and extent of services provided.

The Commission believes that Congress should clearly state its intent that health care be provided as an entitlement to specific categories of persons. This would alleviate some of the problems that arise from the perception of both providers and recipients that the services are provided as a form of charity. It is important that recipients of federally supported health care not view themselves, or be viewed by others, as recipients of charity, in order to ensure that their rights and dignity are protected.

The difference between being a supplicant for charity and having a right to assistance is substantial. To have a right is to have a cause of action if the exercise of that right is frustrated, and to expect to be treated with respect in the exercise of such right. The confidence that comes with the knowledge that one is entitled to certain benefits enhances the ability to demand appropriate treatment if it is not forthcoming.

The right of eligible persons to receive health services can be recognized and assured by amending applicable legislation to reflect a clear purpose to that effect. The Commission notes that courts have had difficulty in resolving disputes regarding the legitimacy of administrative decisions and legislative acts governing eligibility criteria and availability of certain services under federally assisted health care programs, because of lack of clarity in the legislation creating or authorizing those programs. An unambiguous statement of the purpose of relevant legislation would provide a standard against which to determine whether an abuse of administrative discretion has occurred or a state legislature has imposed conditions that conflict with Congressional intent. This in turn would facilitate

enforcement of the rights of persons included in such programs and of the discharge of the correlative responsibilities of the providers, within the limits of their ability to provide the services mandated.

RECOMMENDATION (2) ELIGIBILITY FOR, AND THE RANGE OF, HEALTH SERVICES PROVIDED UNDER PROGRAMS CONDUCTED OR SUPPORTED BY DHEW SHOULD NOT BE LIMITED WITHOUT ECONOMIC JUSTIFICATION; TO THE EXTENT ECONOMICALLY FEASIBLE, THE SERVICES TO BE PROVIDED SHOULD BE DETERMINED ON THE BASIS OF THE HEALTH CARE NEEDS OF THE PERSONS SERVED BY SUCH PROGRAMS.

Comment: The purpose of a health care system is to maintain the physical and emotional well-being of those served by the system; it should not be manipulated to achieve unrelated social or moral goals, and arbitrary criteria, unrelated to health needs, should not be used as a basis for determining distribution. For example, eligibility criteria should not be written to exclude children of unwed mothers in order to discourage sexual promiscuity; that goal should be encouraged by the government, if at all, through other means. Similarly, standard medical procedures, such as abortion, that are available to the general population should not be denied to individuals dependent upon DHEW programs for their health care.

The most morally indefensible position in a federally supported health care system is the imposition of dominant social or moral views on a disadvantaged segment of the population under the guise of determining how to provide necessary services. Once the government decides to provide health

care, that goal should be accomplished without regard to any considerations other than health care needs and available resources. In determining the amount of funds to allocate to a particular program, the goal should be to provide services comparable to those available to persons who are able to pay for their own care.

The Commission is aware of the complexity of problems involved in determining eligibility and the extent of services to be covered, especially in view of the need to contain costs to maintain solvency. However, it urges that standards for eligibility and the provision of services be designed to provide health care for the individuals comprehended in the programs that is equivalent to that available in the private sector. Services should not be excluded without economic justification, nor should judgements regarding services be made on an individual basis for any reasons other than the health needs of the patients involved.

RECOMMENDATION (3) ADMINISTRATIVE DECISIONS REGARDING ELIGIBILITY, EXTENT OF BENEFITS AND STANDARDS FOR ALLOCATING MEDICAL RESOURCES UNDER HEALTH SERVICE PROGRAMS CONDUCTED OR SUPPORTED BY DHEW SHOULD BE MADE FOLLOWING BROAD PUBLIC REVIEW, BY A GROUP COMPOSED OF REPRESENTATIVES OF BOTH CONSUMERS AND PROVIDERS OF SUCH SERVICES, AS WELL AS LAWYERS, ETHICISTS AND SOCIAL SCIENTISTS.

Comment: Administrative decisions by federal and state governments should be made with as much awareness as possible of the impact they will have on those who will be directly affected. In the case of health ser-

vices, those most directly affected are, of course, the recipients of those services. If choices must be made between restricting those eligible to receive services or limiting the extent of services available (or reimbursable) under the program, those who will be affected by the ultimate choice should have effective participation in decision making. Their experiences should be utilized in the formulation of policy.

In addition, the service providers should be represented in order to assure that decisions which seem cost-effective and fair to the recipients will not have detrimental results. For example, it might be considered that lowering physicians' fees would be a method of containing costs without reducing services or restricting eligibility. If the fees are set too low, however, physicians may simply not participate in the program, and patients will be unable to find providers willing to care for them. Alternatively, some practitioners may provide fewer services or treat federally reimbursed patients with less concern than they provide to private patients. The participation of providers in the administrative process would forestall such unfortunate consequences. Finally, practitioners can assist in making decisions regarding appropriate and necessary services for particular patient populations and help define necessary (as distinct from optional) services according to the current practice.

One approach that might prove effective is the publication of a "human impact statement," with opportunity for public comment, prior to implementing changes in health service programs. Such a statement might

include the anticipated categories and numbers of persons whose eligibility would be altered, the health effects of eliminating certain services (and the approximate number of persons in the program who utilized such services in the current year, or preceding year), and a comparison of proposed reimbursement schedules with fees charged by providers in different parts of the country, or with schedules in effect in private reimbursement plans (*e.g.*, Blue Cross and Blue Shield). Health economists can assist in the preparation of such analyses, which will provide useful data for understanding the probable implications of alternative policy choices.

Finally, the Commission believes that DHEW administrators responsible for making decisions regarding eligibility criteria, extent of services and the like ought to have the advice of a committee with special competence to consider the ethical aspects of proposed rules, as distinct from (but related to) the purely economic, political or social aspects.

RECOMMENDATION (4) EFFECTIVE GRIEVANCE PROCEDURES SHOULD BE PROVIDED FOR RESOLUTION OF COMPLAINTS BY PATIENTS REGARDING THE DELIVERY OF HEALTH SERVICES UNDER PROGRAMS CONDUCTED OR SUPPORTED BY DHEW.

Comment: Health care facilities administered or supported by DHEW (*e.g.*, Indian Health Service hospitals and clinics, Community Health Centers) as well as facilities receiving DHEW funds through Medicare and Medicaid should provide mechanisms, such as the grievance committees al-

ready functioning in many such facilities, to consider complaints of patients or clients regarding the services received. In addition, similar committees should be established by states, conveniently accessible to all populations served, to respond to complaints regarding services rendered by private parties and reimbursed, by Medicaid and Medicare funds, either directly or through third-party intermediaries. Such committees might follow the fair hearing procedures established by the states for review of administrative practice. To enhance fairness and credibility, a substantial proportion of committee members should be unaffiliated with the health care facility or program.

In order to assure the effectiveness of such procedures, the Secretary of Health, Education, and Welfare should require that administrators of health care facilities and programs respond to the recommendations of grievance committees in a timely and appropriate manner.

RECOMMENDATION (5) TO ASSURE PRIVACY OF INDIVIDUALS RECEIVING HEALTH SERVICES UNDER PROGRAMS CONDUCTED OR SUPPORTED BY DHEW AND TO PROTECT THE CONFIDENTIALITY OF DATA:

(A) APPLICATION FORMS FOR BENEFITS UNDER SUCH PROGRAMS SHOULD IDENTIFY THE INFORMATION THAT MUST BE PROVIDED IN ORDER TO RECEIVE BENEFITS, AND SHOULD CLEARLY INDICATE:

(I) THAT ANY OTHER INFORMATION SOLICITED IS OPTIONAL, AND

(II) THE PURPOSES FOR WHICH SUCH ADDITIONAL INFORMATION IS SOLICITED;

(B) INFORMATION REQUIRED TO DETERMINE ELIGIBILITY FOR BENEFITS SHOULD NOT BE MADE AVAILABLE TO ANY INDIVIDUAL OR GOVERNMENT AGENCY (FEDERAL, STATE OR LOCAL) FOR PURPOSES UNRELATED TO THE IMPLEMENTATION OF THE PROGRAM FOR WHICH THE INFORMATION WAS PROVIDED; AND

(C) INFORMATION FROM PATIENTS' MEDICAL RECORDS SHOULD NOT BE MADE AVAILABLE WITHOUT THE WRITTEN INFORMED CONSENT OF THE PERSONS TO WHOM THE INFORMATION PERTAINS, UNLESS AT LEAST ONE OF THE FOLLOWING CONDITIONS IS SATISFIED:

(I) THE PATIENTS ARE NOT IDENTIFIED;

(II) THE DATA ARE FOR RESEARCH PURPOSES, AND AN INSTITUTIONAL REVIEW BOARD HAS DETERMINED THAT THE PATIENTS' INTERESTS ARE ADEQUATELY PROTECTED AND THE IMPORTANCE OF THE RESEARCH JUSTIFIES SUCH WAIVER OF THE CONSENT REQUIREMENTS;

(III) THE INFORMATION IS REQUIRED BY STATE REPORTING STATUTES; OR

(IV) THE INFORMATION IS NECESSARY TO MONITOR REGULATORY COMPLIANCE AND MAINTAIN STANDARDS OF CARE IN THE HEALTH SERVICE PROGRAM.

Comment: The Privacy Protection Study Commission identified a number of areas in which private information supplied by recipients of federally assisted programs is vulnerable to abuse. Such areas include the exchange of information among and within offices responsible for administering different assistance programs, and the collection of nonessential (but often sensitive) information. The Privacy Commission suggested that information required to determine eligibility be so identified, and that additional information requested for other reasons be clearly labeled as such. The Privacy Commission also suggested that the exchange of personally identifiable information among different administrative agencies not be generally permitted. The National Commission for the Protection of Human Subjects endorses and re-emphasizes these suggestions.

Medical records of persons receiving assistance from DHEW should be protected to the same extent and by the same privileges as those of private patients. In general, therefore, as recommended by the Privacy Commission, personally identifiable information from patients' records should not be released to individuals unrelated to the provision of their health care without written informed consent of the individual about whom the record pertains. (In the case of minor patients, consent should be obtained from the parent or legal guardian.)

In certain circumstances, however, personally identifiable information from medical records may be transmitted to specified individuals for epidemiological or other studies. For example, the Commission has suggested in its Report on Institutional Review Boards (IRBs) that some such information

may be given to research investigators if an IRB determines that the interests of the subjects are adequately protected and the importance of the research justifies the release of such information. In that report, the Commission adopted the recommendations of the Privacy Commission, emphasizing that an IRB must determine that disclosure of personally identifiable information is essential to accomplish the research for which such disclosure is sought. Moreover, the information released for such studies should be carefully protected against unauthorized redisclosure or use for any purpose other than that for which the data are specifically released. Finally, the Commission recommended that patients entering facilities that might release information on this basis be so informed and be given the opportunity to state in writing whether or not they consent to such use of their records.

In addition, most states have laws that require physicians and other service providers to report gunshot wounds, certain infectious diseases, suspected child abuse and the like. These statutes further a legitimate state interest that is deemed to justify the release, to specified authorities, of the relevant information. Finally. in order for appropriate monitoring of the health care programs, themselves, to take place, authorized individuals may need access to information contained in individual patients' medical records. Although this departs from the standard of applying the same protections to recipients of health care under such programs as are afforded to private patients, it is justified by the purpose of the monitoring which is to enhance the efficiency and adequacy of the program and to assure that the rights and welfare of such recipients are protected.

RECOMMENDATION (6) ALL PATIENTS RECEIVING HEALTH SERVICES UNDER PROGRAMS CONDUCTED OR SUPPORTED BY DHEW SHOULD BE GIVEN A STATEMENT EXPLAINING BOTH THEIR RIGHTS AND THEIR RESPONSIBILITIES AS RECIPIENTS OF SUCH SERVICES IN LANGUAGE APPROPRIATE TO THE POPULATION BEING SERVED. SUCH A STATEMENT SHOULD CONTAIN A CLEAR DESCRIPTION OF ELIGIBILITY REQUIREMENTS AND AN EXPLANATION OF THE PATIENTS' RIGHTS INCLUDING, AT A MINIMUM: (A) THE RIGHT TO BE FULLY AND FAIRLY INFORMED REGARDING THE RISKS AND BENEFITS OF PROPOSED PROCEDURES AS WELL AS THE RISKS AND BENEFITS OF ALTERNATIVE APPROACHES TO THE CLINICAL OBJECTIVE; (B) THE RIGHT TO REQUEST OR REFUSE ANY PROCEDURE WITHOUT LOSS OF OTHER BENEFITS TO WHICH THEY ARE ENTITLED; (C) THE RIGHT TO BE TREATED WITH COURTESY AND RESPECT; (D) THE RIGHT TO PRIVACY; (E) THE RIGHT TO SEEK REDRESS OF GRIEVANCES THROUGH AN ACCESSIBLE AND EFFECTIVE GRIEVANCE COMMITTEE; AND (F) THE RIGHT OF ACCESS TO MEDICAL RECORDS.

Comment: The primary focus of this recommendation is to dispel the traditional aura that since "charity" patients are receiving their care free, they should not ask too many questions, or they are not sufficiently intelligent or educated to understand much about their own treatment. The Commission wishes to emphasize that recipients of federally assisted or provided health services are entitled to the same information, respect and concern as are private patients. The enabling legislation should be amended to make clear that these are their rights and to require that they be so informed. Recipients of services should be aware of their responsibilities, as well. These

include the rules of the facility in which they receive their care (*e.g.*, regarding the making and breaking of appointments) as well as the requirements for program eligibility.

In circumstances under which consent is normally required in the provision of health services, information should be conveyed in language the patient can understand and in a setting conducive to good decision making. Further, the information conveyed should be that which a reasonable person similarly situated would desire in order to make a choice regarding the therapy or course of treatment in question. This would normally entail providing information about the risks and benefits of the suggested procedure, along with information about the risks and benefits of any alternative approaches to the clinical objective and the risks and benefits of undertaking no intervention at all. The patient should be free from duress or coercion, and particular care should be taken to assure that health care recipients understand that other benefits to which they are entitled will be provided whatever their decision regarding a proposed intervention or course of treatment.

The Commission warns against several possible misinterpretations of this recommendation. First, all patients have a right to tell a physician they do not wish to be fully informed, just as they have a right to complete disclosure about their condition. Further, there are times when a clinician, to protect the emotional well-being of a patient or client, may wish to withhold certain information regarding his or her condition, at least for a time. Clinicians should be allowed to exercise reasonable discretion in this regard, but a notation and justification should be entered in the patient's

record whenever information is withheld in whole or in part. Secondly, the Commission does not intend to suggest that elaborate consent forms be prepared and signed for every procedure performed in routine patient care. The Commission is interested primarily in enhancing the quality of communication and understanding between providers and recipients of health services; the process by which this is accomplished should be left to the discretion and sense of fairness of the providers and consumers. Finally, the Commission does not mean to suggest revision of the traditional codes of medical ethics; rather, it hopes to assure that recipients of federally supported care are treated fairly, which means, primarily, that they be treated with the same respect and sensitivity as private patients.

Privacy regarding health care raises the question whether patients should have access to their own medical records. The Privacy Commission, having analyzed the complex issues and competing interests involved, has recommended that patients or their designated representatives have a right to such access. Representatives are suggested for cases in which the medical-care provider feels that certain information might be injurious if made available to the patient (*e.g.*, in cases of emotional disorder or terminal illness); after the representative has reviewed the information in question, he or she would then make the decision as to the extent and manner of conveying the information to the patient. The Privacy Commission also recommended that minor patients be given access to medical records concerning treatment they have sought on their own behalf pursuant to state law permitting minors to receive certain care without the knowledge or consent of their patients. (Under such circumstances, the Privacy Commission recommended, the parents or guardians

of such minors should not have access to any information contained in such records.) Finally, the Privacy Commission recommended procedures for patients to request correction of their medical records when such records are maintained by an organization that is not a health-care provider (*e.g.*, an insurance company or an agency providing social services) as well as when the records are maintained by a health-care provider. The National Commission for the Protection of Human Subjects endorses these recommendations of the Privacy Commission.

RECOMMENDATION (7) PROFESSIONAL COMMITTEES SHOULD MONITOR PRACTICES IN ALL HEALTH SERVICE FACILITIES ADMINISTERED OR SUPPORTED BY DHEW, AND QUALITY AUDIT PROCEDURES SHOULD BE INCORPORATED INTO PROGRAMS SUPPORTED BY DHEW, IN ORDER TO ASSURE THAT, (A) THE BEST STANDARD OF CARE CONSISTENT WITH AVAILABLE RESOURCES IS PROVIDED AND MAINTAINED, AND (B) INNOVATIVE OR UNTESTED PROCEDURES ARE NOT APPLIED INAPPROPRIATELY.

Comment: The Secretary of Health, Education, and Welfare should require that professional committees be established in health service facilities supported by DHEW to review the appropriateness of procedures utilized in those facilities, according to the prevailing standard of care in common practice. Innovative or untested procedures should be subject to peer review prior to their introduction into practice. In some instances, the committee may wish to suggest that such procedures be incorporated into a research project in order to ascertain their safety and efficacy; at other times, the committee may approve the use of innovative procedures only under certain conditions, for a certain class of patients, or when performed by particular individuals.

The purpose of such a suggestion is not to discourage innovative practices, but to assure that they are introduced in such a way as to protect patients, who have a right to expect they are receiving the best available care.

The Commission is aware that recipients of federally funded health services often express the fear that they are being used as unwitting subjects for new therapies; there are a few instances in which this appears to be documented in the legislative history of this Commission. A conscientious review committee should assure that patients are made aware of the fact when new therapies are tried, and are informed of any available alternative therapies for their condition. Moreover, if patients feel they have been misled or mistreated in this regard, they should be able to take appropriate action with a grievance committee, as recommended in Recommendation (4). A facility that is supported by DHEW funds may be an appropriate setting for the introduction of innovations, but patients should always be appropriately informed and offered realistic choices with regard to their acceptance of an innovative therapy.

Although it is not feasible to monitor every treatment provided by private practitioners or facilities and reimbursed through public funds, some quality control can be maintained through audit procedures at the time of billing without interfering unduly in the practice of medicine. Existing Professional Standards Review Organizations (PSROs) could be utilized to fulfill this function, as appropriate. The Commission urges that some such procedures be utilized in programs providing reimbursement with DHEW funds. This review, along with the grievance committees suggested in Recommendation (4), should provide some measure of quality control and reassurance for recipients of health services under programs supported by DHEW.

RECOMMENDATION (8) ACTIVE SUPPORT SHOULD BE GIVEN TO PROGRAMS THAT WOULD PROMOTE (A) THE TRAINING OF INCREASED NUMBERS OF MINORITY INDIVIDUALS TO SERVE AT ALL LEVELS IN THE HEALTH PROFESSIONS AND (B) THE EDUCATION OF HEALTH PROFESSIONALS IN ETHICAL AND SOCIAL ISSUES.

Comment: Many health care recipients have suggested that the presence of more providers that come from their own racial and ethnic background would dispel much of the feeling of inequality and lack of understanding that they experience in the health care system. In addition, it is clear that health care practitioners could benefit from increased sensitivity to the social and ethical issues regularly encountered in the provision of health services. Therefore, the Commission recommends that the Secretary of Health, Education, and Welfare support programs designed to meet these goals and to encourage more equitable distribution of minority health professionals both geographically and at the top levels of their professions.

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