APPENDIX TO

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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This Appendix contains the papers, reports and other materials that were reviewed by the Commission during its deliberations of ethical guidelines for the delivery of health services by DHEW.

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PAPERS AND REPORTS PREPARED FOR THE COMMISSION

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ETHICAL PROBLEMS IN THE DELIVERY OF HEALTH SERVICES

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May, 1977

ETHICAL PROBLEMS IN THE DELIVERY OF HEALTH SERVICES: A REPORT TO THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

Foreword

In the past twenty years there has been a significant development of awareness and sensitivity to human rights in the United States. In many aspects of our social life, from minority group relationships and civil rights to such more specialized concerns as the rights of human subjects or students, significant progress has been made in defining ethical issues and the relationships between the rights of persons and the powers of the social institutions that affect their lives.

The practice of medicine has remained relatively immune to these developments in contrast to other social institutions. There is evidence of growing dissatisfaction with medical care and of increasing distrust of physicians and other health care providers. Trust is further eroded by growing impersonality of care and feelings on the part of patients that they have no control over a vital institution that affects their lives. There are more frequent demands that physicians and other health professionals be held accountable. As these pressures grow, there is danger that we move in directions that create more new problems than they solve. Hopefully, this paper will contribute to directing the discussion toward more productive alternatives.

Summary of Major Recommendations

1. The Commission should consider the benefits and costs of a requirement that all DHEW direct-service programs and other programs receiving "capacity-building grants from DHEW" establish a Practice Institutional Review Board to have the following functions:
   A. To establish and monitor a grievance procedure within the program in accord with standards for such a procedure established by DHEW;
   B. To conduct a continuing review of all "therapeutic actions" within the program taken without the consent of the patient and to insure that there are adequate provisions for review and appeal of such actions;
   C. To evaluate program practices for obtaining informed consent in therapeutic situations and to make suggestions for improved practice.
2. The Commission should encourage DHEW to develop a program of demonstrations and evaluations of alternative grievance procedures in health care settings and to provide funds for institutional experiments in this area.
3. The Commission should take a strong public position against medical care rationing based on political, sociocultural, or religious criteria. It should publicly support the principle that the medical resources subsidized by DHEW should be distributed to eligible recipients in relationship to medical need and expected medical benefits, and that the scope of services should not be restricted

on the basis of other criteria.

4. The Commission should sponsor a special study on the violation of civil liberties and other inhumane practices in nursing home care and other types of decentralized health care facilities financed directly or indirectly by DHEW.

I. The Charge

This report examines Section 202(a)(1)(c) of Public Law 93-348 in a broad perspective. The section states that

> The Commission shall consider the appropriateness of applying the principles and guidelines identified under subparagraph (A) [i.e., those that underlie the conduct of biomedical research involving human subjects] to the delivery of health services to patients under programs conducted or supported by the Secretary.

In preparing this report, I have taken the Commission's "Identification of Basic Ethical Principles" (Draft, March 3, 1976) into account, and I have also reviewed Robert Levine's statement, "On the Relevance of Ethical Principles and Guidelines Developed for Research to Health Services Conducted or Supported by the Secretary, DHEW" (May 28, 1976), and the Report from the Health Policy Program of the University of California (December, 1976). My intent, agreed upon in discussions with the staff of the Commission, is "to identify, from a sociological perspective, ethical problems that may exist in the delivery of health care services by the government, exploring such problems whether or not they are amenable to specific regulation."

This report rests on the premise that the Congress was aware of the differences between research and service and intended the Commission to examine ethical problems in health care delivery that were similar to those inherent in research. Although I relate this discussion to the three fundamental principles identified by the Commission's draft report--respect for persons, justice, and beneficence--no special effort

will be made to fit these comments within the six specific norms for research identified by the draft report. While Dr. Levine's discussion of problems in health delivery within these norms is commendable, such constraints are neither necessary nor desirable in analyzing ethical problems associated with health care delivery. Issues that are readily classifiable within these research norms will be discussed, however, and this will be made clear at the appropriate point in the discussion.

At the outset I will be explicit about my assumptions concerning the regulatory process. There are innumerable ethical problems inherent in patient care as there as in any complex human relationship in which there are inequalities in power and dependence between the persons involved. Given the vast differences in knowledge between the typical physician and patient and the exaggerated dependency associated with illness, patients are in a position in which they must trust the wisdom and integrity of those who care for them. There are many potential violations of such trust, but to enumerate them or attempt to devise specific rules to prevent them is largely an exercise in futility. Most rules are easily subverted in practice; when regulations are imposed, efforts are devoted often to meeting their bureaucratic requirements without major impact on behavior; and the proliferation of regulation itself adversely affects morale and practice. Thus, in considering the applicability of regulation to the service sector, it is necessary to weigh the magnitude of the problems and the likely gains achieved through regulation against the costs of imposing further bureaucratic rules. Health care is provided under real constraints of time, manpower, and resources, and regulation adds to the costs of service and the burdens on health care personnel. Time devoted to monitoring and enforcement of

specific rules and affirmations of compliance is time taken from other valued activities, and regulation may be counterproductive in its consequences. The imposition of any regulation, thus, should be evaluated not only in terms of its expected symbolic and practical benefits in changing behavior, reaffirming essential values and reassuring the public, but also in terms of its real costs in diverting professional energies and resources from other important activities, discouraging innovation and creativity through incentives for safe bureaucratic response, and eroding morale.

Although the identification of problems usually elicits the response that "there ought to be a rule," such rule making designed to constrain behavior or to punish violators is negative in its approach and does little to increase sensitivity or educational dialogue. Effective guidelines in an area as vast and difficult as the one under discussion would contribute to informing professionals and others as to problems they may be unaware of and to making them more cognizant of and sensitive to the strong feelings and views of others. In short, good regulation contains a strong educational component. The approach recommended in this paper is designed to achieve better checks and balances between patient and provider and through this process greater understanding and sensitivity.

II. Definitions

Section 202 (a)(1)(c) of Public Law 93-348 refers to health services under programs "conducted or supported by the secretary." This language covers a wide scope of practice involving much of the private and nonprofit sectors as well as direct government service programs. For the purposes of this discussion, the classification of programs offered by the Health

Policy Group of the University of California (pp. 10-11) is adequate:

a. Direct provision programs, such as the Public Health Service (PHS) hospitals and clinics and the Indian health service, in which DHEW employs the providers of service.

b. "Capacity-building" programs that provide grant support for health maintenance organizations, community health centers, migrant health centers, and maternal and child health and family planning services.

c. Programs that pay for services delivered through the private health care system either directly as in Medicare or through state programs as in Medicaid.

Although it may appear that the language of the legislation and the possibilities for regulation apply most directly to service programs in which government employees provide care, there is no inherent logic in singling out this group of providers. There are no data to my knowledge that would support the arbitrary distinction between direct DHEW service programs and other DHEW-supported programs involved in delivering health care. Other types of distinctions that will be specified are more pertinent. Moreover, if one wishes to continue the analogy between the research process and service programs, it should be clear that the impact of regulation of research has fallen largely on Type B programs, i.e., institutions in the nonprofit sector such as universities, medical schools, and voluntary hospitals that receive "capacity-building" grants for biomedical and behavioral investigation. In theory, the same types of regulatory mechanisms (i.e., Institutional Review Boards) that apply to research can apply as well to capacity-building programs.

III. Ethical Principles in Service Delivery

Medical practice has the potential for many ethical dilemmas. They range from such everyday concerns as the ways physicians communicate to patients, inform them about their illnesses, and explain options to profound decisions concerning the prolongation or termination of life. Moreover, these issues exist at every level of practice and administration from the individual decisions of the physician to the formulation of global health policy. Notions of health and illness, types of financing, mechanisms for remuneration, the concept of a medical care service, the definition of practitioners eligible for payment--all of these come to shape the delivery of services and their impact on patients' lives. The decision of policymakers, for example, 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. Although I believe that the allocation of resources among competing needs and expectations and the consequences of these decisions are more important than many of the more narrow ethical issues considered in this discussion, to focus on them would probably be a misinterpretation of Congressional intent. Thus, in selecting areas to examine here, I focus on specific service practices that pose major threats to the norms of respect for persons and fairness and on types of conflict of interest similar to those involved in the research process. It is my strong view, however, that the Commission cannot neglect the more global policy concerns because they have a crucial bearing on the ethical outcomes that constitute their area of assigned responsibility.

In this discussion I take as my primary ethical principle the fundamental notion of respect for every person. I use the term "respect" to refer to lack of partiality or discrimination, and in this sense the concept is different from esteem or veneration. Although the concept itself is open to varying interpretations, any use of it is based on four derivatives for which there is a broad social consensus.

a. Every patient should be free of coercion, participating in medical care, research, and educational programs only with their informed consent.

b. Every patient should receive accurate factual information, to the extent possible, pertaining to his or her care, risks involved, and rights in the medical context.

c. Within whatever economic limitations are operative, decisions concerning medical care should be made solely on the basis of medical need and expected medical benefits, and not on social, political, or religious criteria.

d. When conflicts develop between patients and providers, mechanisms should be available for a fair resolution.

IV. Sources of Ethical Problems in Health Care Delivery: Definition of the Problem

Ethical problems in service delivery arise from a variety of sources: (1) inappropriate and unprofessional behavior of providers; (2) limitations on resources relative to demand and resulting rationing pressures; (3) conflicts in values, expectations, and incentives within varying health delivery plans; and (4) inequalities between health providers and patients. The appropriate focus of analysis, therefore, is existing variations in

organizational procedures, types of professional remuneration, and patient-provider inequalities and not the distinction between DHEW service programs and the private sector. In some cases, problems associated with these factors may be more acute in DHEW service programs, but there is no reason to believe that this is systematically the case. In any case, I know of no data on which the Commission could depend that would allow reasonable assessment of the varying magnitude of certain types of problems in DHEW direct-service programs, DHEW capacity-building programs, and DHEW financing programs, or in the public, nonprofit, or private sectors. In each of these sectors problems arise related to the four factors indicated above.

1. Professional Behavior of Providers

Health professionals include persons with a wide range of human characteristics as in other comparable occupational groups. It is no surprise that patients sometimes encounter such professionals who demonstrate a lack of respect for them. Nor is the medical context free from manifest and more subtle forms of prejudice and discrimination. The behavior of health care professionals may vary from one situation to another or from one day to another, reflecting the health professional's personality, mood, or situational stresses or particular characteristics of difficult patients. To the extent that ethical problems arise from such factors or those associated with personal styles of the health professional, they are not easily regulated or modified. To the extent that more serious abuses arise because the health professional suffers from a mental illness or serious personality disorder, or because he blatantly violates the trust of his position, clearer options are available. For the most part, however, patients are relatively powerless

in the face of professional behavior that is inappropriate or in poor taste.

In theory, unethical professional behavior is contained through careful recruitment and selection of health professionals, through a long period of training and apprenticeship during which the trainee is socialized in respect to important values as well as in respect to relevant skills, and through review and supervision of performance. The fact is, however, that the long period of medical training socializes the physician to a distinctive point of view, one very different from the views of the typical patient. There are a variety of formal and informal mechanisms that exist in medical practice to detect significant departures: medical practice committees, boards, tissue committees, etc. Too much confidence is placed, however, in the existing peer review structure as a means of preventing violations of ethical principles. Nor is the value of PSRO developments, mandatory continuing education, or periodic relicensure as promising as some would hope. The tradition of exclusive self-regulation by medicine has served more to insulate the profession from outside influence than to protect the rights of patients.[1] Even with the best of intentions, doctors have a different perspective than patients and are unlikely to grasp the patient's point of view without consumer participation. With the exception of serious mental illness, alcoholism or drug addiction, or serious criminal behavior, suspensions or revocations of licenses or other serious sanctions are rare. There are few alternatives to the more drastic sanctions such as suspension of license, and this is a deterrent to applying any sanctions at all.

Although we are limited in any conclusion because of a lack of systematic data, it is apparent that there is little willingness among

physicians to control or sanction one another and some evidence that physicians with similar behavioral tendencies associate with one another.[2] Although physicians may withhold referrals to and employment from colleagues whose ethical behavior they question, such exclusion does not limit or affect in any significant way the continuation of ethical violations. Moreover, the effectiveness of long medical training as a screening device is an illusion. While medical schools attract applicants with a high level of academic competence, retention rates are extraordinarily high compared with most other types of graduate or postgraduate training and insure little "weeding out" of undesirable candidates. Similarly, although supervision and negative appraisal during internship or residency may affect the ability of the candidate to obtain the most desirable positions, such supervision and evaluation almost never exclude the candidate from medical employment. In short, the image of a highly selective screening process that insures quality and ethicality is a mirage, protecting the autonomy of the profession more than the public.

Regulation of autonomous and prestigeful professionals is extraordinarily difficult to achieve without producing undesirable side effects. Moreover, in regulating the segment of the profession most likely to engage in violations, burdens are placed inevitably on those who practice a high standard of quality and ethicality in a way that detracts from their performance. These facts support the argument that regulatory mechanisms are needed that provide checks on professional abuses without being too intrusive.

2. Limitation of Resources Relative to Demand: Rationing of Medical Care

Many violations of the principle of respect for persons arise because demand for services is large and resources are limited. Under such conditions services may not be available, and when they are available care becomes rushed, relationships between health professionals and patients become impersonal, and communications, explanations, and opportunities for asking questions and obtaining feedback are more limited. These problems are more likely to occur in relation to minority group patients or patients in lower socioeconomic circumstances because they are more likely to participate in programs that ration care strictly, while the affluent more frequently participate in programs characterized by open-ended budgeting that have greater availability of personnel and other resources. Even when payment for care is available, as in Medicare or Medicaid, the poor are more likely to reside in areas with lesser concentration of facilities and manpower, making it more difficult for them to "cash in" on their entitlements.[3]

Many public programs of health care cover certain benefits but rarely provide the necessary resources to meet all eligible needs in the population. The limited resources appropriated by public programs or available in private programs with fixed budgets set the stage for rationing, but the fact that rationing occurs is rarely explicit, and the rules that apply are almost never specified. Because resources are in limited supply, no consumer has an absolute right to services in general; he does, nowever, have a right to an allocation process that is just and that respects his person (by telling the truth).[4] More specifically, this requires that the fact that rationing occurs and the way it occurs is generally known, and that it is based on reasonable

categorization and is neither frivolous nor discriminatory.

A. The Concept of Just Rationing

Justice in rationing implies that persons who fit certain criteria be treated equally in respect to the relevant class of services. There is wide agreement that in rationing services the criteria applied should be medical. Determinations of who is to receive priority should be based on need and expected benefits and not on sociocultural or political criteria. Justice in allocation further implies that available services will be distributed so as not to impose an unfair burden on individuals because of their social status, religious or racial background, or personal characteristics unrelated to medical judgments.

Efforts made by some Congressmen, administrative officials, and state health care personnel to exclude payment for abortion under government-sponsored programs, for example, are attempts to substitute political and religious considerations for medical judgments. 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 and that have a high benefit ratio relative to costs. The arbitrary exclusion of abortion under Title 19, or under any other federal or state program, introduces political and religious rationing as a substitute for medical rationing. Moreover, it establishes two standards of access to a positive health benefit,[5] one for government recipients and another for persons in the nongovernmental sector. Such administrative action is a serious

violation of the ethical principle that available medical resources should be equitably administered in relationship to need and expected medical benefit. I believe that it would be desirable for the Commission to take a strong stand on this issue.

Services may be rationed poorly for reasons other than discrimination or frivolousness. Needy recipients frequently are less educated, less sophisticated, and less aggressive in demanding available services in both public and private programs, while those with greater skills but less need may overcome bureaucratic barriers more readily.[6] Non-fee-rationing devices can have inequitable effects in very much the same way as economic barriers.[7] Unless concerted efforts are made to ration equitably, those with greater skills and with more worldly sophistication will command a disproportionate share of resources regardless of the rationing techniques used.

At the service level, persons of varying social status may receive different benefits not because of need but because of individual attributes unrelated to the provision of medical care. Although we have no evidence that discrimination systematically occurs, it is frequently alleged that nonwhites, the poor, women, and Title 19 recipients are at risk. These impressions may stem, however, less from discrimination in the provision of services and more from problems in communication, differences in behavioral patterns surrounding illness in varying social and cultural groups, and resulting misunderstandings.[8] Whatever the cause of perceptions and experiences of inequality, it is essential that they be addressed. Discussion of specific remedies will be delayed until the later discussion of accountability.

Finally, it has been observed that certain categories of patients are treated differently on the basis of social criteria as compared with medical need. For example, it has been alleged that lesser efforts are made to resuscitate alcoholics,[9] and that services are less available to other patients with stigmatized social identities.[10] Data on such matters are extraordinarily difficult to obtain, and the magnitude of these problems is not clear.

B. Rationing and Truth Telling

In introducing new programs there tends to be considerable exaggeration as to the benefits to be expected. Such rhetoric raises expectations that are not fulfilled. The marketing of new types of medical care plans such as health maintenance organizations is an example. When such plans are marketed, they usually promise a comprehensive benefit package although there is often in reality a reluctance to provide some of the benefits advertised. Enrollment in an HMO is really an agreement between the enrollee and the plan to accept a situation of "constructive rationing," although such plans are rarely described to consumers in this way. For a lower premium, more comprehensive benefits, or both, the consumer implicitly agrees to accept the plan's judgment as to what services are necessary. The nature of this agreement is almost never made explicit, and these plans are often sold under an advertising rhetoric that distorts the situation.

In individual instances, such as in Medi-Cal in California, clear deception and falsification were evident in some HMO marketing efforts, but to dwell on these abuses misses the larger point. Even in the reputable plans, the scope of promised services is more than the plan wishes to provide, and a variety of barriers are introduced in the way

of the consumer who attempts to obtain them. For example, enrollees are told that HMOs are organized to provide care as early as possible in sickness episodes. What they are not told is that HMOs eliminate economic barriers to access but replace these with a variety of bureaucratic impediments and limitations on the resources provided that keep enrollees from using too many services.[11] While HMOs may still be the "best deals in town"--and I am inclined to believe that they are--they are too frequently marketed in a way that is misleading to the consumer. Similarly, many of the nonprofit and profit insurance plans are so complex and described in such esoteric terms that even an expert consumer cannot do serious comparison shopping.

3. Conflicts in Values, Expectations, and Incentives

In the research process, conflicts are apparent between research goals and optimal adherence to patients' rights. The research investigator naturally wishes to carry out his studies in the most effective way and in a fashion that utilizes his efforts and resources most economically. The consideration of patients' rights may require that he modify his design from scientifically optimal procedures or invest greater time in certain phases of the study to insure that ethical requirements are met. In short, these two sets of values must be balanced in some way. Violations of patients' rights often stem from the emphasis given to research values and from the investigator's wish to enhance his reputation or professional career. In the arena of service delivery, in contrast, conflicts are more likely to arise from the economic context and economic incentives implicit in the ways services are organized and professionals are paid. The pattern and mix of services provided tend to be shaped

substantially by the mode of remuneration; the prevalence of services performed reflects whether services are paid for directly and at what level of remuneration.[12]

One major difference, on the average, between direct federal service programs and those in the private sector is the way health professionals are paid. In the private sector most physicians work on a fee-for-service basis, and even when on salaries these tend to be established or modified by productivity indices that reflect the earning capacity of the doctor. Physicians in DHEW direct programs work for fixed salaries. Each form of payment poses somewhat different types of potential conflicts of interest.

In the fee-for-service sector it is usually in the physician's interest to carry out numerous technical procedures because doing so is remunerative. Such a fee structure creates incentives for the performance of discretionary services, and it is maintained that much excess surgery, overutilization of hospitals, and unnecessary diagnostic and laboratory procedures are a result of such economic incentives.[13] These tendencies toward excessive treatment are facilitated by the uncertainty of much of medical practice and the lack of clear norms as to the levels of care that are most appropriate. With the growth of third-party payment there are no incentives for the physician or patient to conserve resources. The tendency is toward using procedures, however marginally relevant, that offer any hope of contributing something to the patient's care.[14]

Although fee for service may be wasteful of resources, it offers certain advantages. When physicians are paid for each consultation, there is a greater awareness of patients' expectations and some desire on the part of the physician to satisfy the patients' needs and wishes.

The economic incentives characteristic of third-party payment of fees allow the physician to be an advocate for the patient, whatever else it may do in affecting aggregate financial costs. Because financial rewards are linked to the effort physicians devote to their work, physicians in fee-for-service practice work longer hours and make greater efforts to accommodate their patients.[15]

Although in theory salary and capitation as modes of physician remuneration offer advantages in separating professional judgment from fee considerations, in practice these forms of payment subtly change the way physicians relate to patients, particularly under conditions of high work load. Physicians on fixed remuneration usually have established hours of responsibility or develop some concept of a reasonable workweek relative to what they are paid. They work shorter hours on average than fee-for-service physicians, and they may make more effort to deal with all patient contingencies in the context of their established schedules. Under increased work load, salaried physicians are probably less responsive to patients, less concerned about patients' expectations, and more inflexible.[16] The salaried physician is less dependent on the patient's response, and this subtly affects attitudes and patterns of work. It is reasonable to infer that such conditions affect the poor more frequently than those more affluent and are more common in public facilities than in private contexts.

A major area receiving DHEW support is the development of HMOs.[17] It is anticipated that HMOs will provide services for enrolled populations with more effective cost containment than exists in the broader community. This is achieved through control over the availability of resources, such as hospital beds and specialists, and by eliminating

the economic incentives for expensive services of marginal value believed to be characteristic of fee-for-service arrangements. Other methods advocated, but not well developed or studied, include the provision of economic incentives for physicians to conserve resources by strict rationing and stricter administrative pressure on physician decision making. Given current trends, we have reason to anticipate that greater efforts will be made to ration services by putting physicians at financial risk when levels of utilization are too high. To the extent that such efforts are introduced in a serious way, they are likely to shift the physician's role from one as agent of the patient to one as bureaucratic official.[18] The physician will more directly represent the plan, and his own financial interests may be contingent on successfully denying patients' requests. It is difficult to anticipate clearly the problems and conflicts that might result, but there is a reasonable likelihood that the consequences of such rationing will fall disproportionately on the poor, the less sophisticated, and the less educated portions of our population. Many physicians probably will find it difficult to withhold services successfully from knowledgeable and aggressive consumers. It is primarily the more passive consumer who is likely to be the recipient of the strictest rationing because it is this type of consumer who is most likely to accept without challenge whatever the doctor does. At the very least this problem requires careful monitoring and continued study 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.

4. Inequalities Between Health Providers and Patients

It was previously noted that most ethical abuses affecting patients occur as a result of inequalities of knowledge, status, and power between patients and health care personnel. Patients have more power and are less vulnerable to potential abuse when they can exercise alternatives. To the extent that medical care programs restrict choice, they are less likely to assist patients in representing their own interests. In theory, patients in the fee-for-service sector can exercise choice and, if dissatisfied with their medical care, can seek care elsewhere. Although location, geographic distribution of facilities and physicians, and other factors such as the patient's dependency may inhibit exercise of such choice, the patient, if sufficiently dissatisfied, can frequently go elsewhere. Both patients and physicians are aware of this, and in this sense the patient exercises a certain degree of client control.[19] Similarly, in the case of health care plans such as health maintenance organizations or different types of insurance programs, many consumers have a dual choice allowing them to exercise options if they are dissatisfied. Dual choice provisions have a double function in not only allowing a dissatisfied consumer to change plans but also in protecting the plans themselves from dissatisfied clients who may create a variety of problems.

There are many instances--and these are frequently found in the public sector--in which patients have no effective choice. In many government programs, for example, patients who are dissatisfied with the care they receive have no market options because they cannot afford private care or because other comparable facilities are not available. This lack of choice frequently applies to tertiary care facilities as

well because such facilities are geographically more dispersed than other types of medical services. Thus, patients requiring hemodialysis, specialized cancer care, or other more complex medical services may also have few options to the facilities they use.

Problems relating to lack of choice and potential abuse are more acute in public programs for the disadvantaged because this lack of choice is frequently associated with other factors that pose potential problems. Many programs for the disadvantaged, for example, depend on physicians and other health care personnel who are salaried and who do not depend on the patient's good will for their employment or remuneration. A variety of studies have suggested that in such circumstances client control is diluted, and patients frequently feel that physicians are less interested in them and less responsive to their needs.[20] Problems are further exacerbated by the characteristic imbalance between demand and resources and the social distance and language barriers frequently existent between disadvantaged populations and those who provide care for them. Thus, programs of this type pose special, but not unique, problems of inequality of status, power, and dependence between patients and health care personnel.

Problems of cost containment are creating great pressures to use resources more efficiently, to ration resources more stringently, and to avoid duplication of facilities. Among the mechanisms either in place or advocated for the future are fixed prospective budgeting, capitation payment, and regionalization of facilities with controls over the development of new facilities. Although these measures may all have value in promoting important national goals, if successful they inevitably will restrict further the choices available to consumers of medical care,

their ability to select services in "a marketplace," and the types of controls they exercise over the professionals and institutions that serve them. Although it may be rational to limit choice that results in waste of valuable and expensive national resources, it is essential that functional substitutes be developed that protect patients' rights within such more restricted systems and that assure accountability of the health care professionals who serve them.

5. Some Other Ethical Problems

In the process of considering various ethical issues in service delivery in respect to DHEW programs, a variety of additional issues seemed important, but I am not sufficiently familiar with them or their scope to do more than identify them. Thus, in this section I simply list each with a short description of what I see as the basic problem.

A. Privacy of Medical Records

It goes without saying that medical relationships depend on confidentiality and trust and that the privacy of medical records must be protected. As medical care is delivered in more organized settings, a larger number of people have access to patients' records, thus providing greater potential for abuse. A more specific concern is the extent of protection of medical records within DHEW programs from federal investigative agencies. It is my impression on the basis of my own research experience as an epidemiologist that public programs and the nonprofit insurance programs are more careless in protecting confidentiality of personal medical information than private providers. However, I have no systematic information on this point. With more emphasis on review of records and wider access to records among persons not directly involved

in the patient's care, clear guidelines are necessary for authorized access. I believe that some of these issues are being studied by the National Commission on Medical Records.

B. Conflicts of Role Among Physicians Working in Institutional Settings

Physicians sometimes find themselves in positions in which they play the role of double agent, acting as a representative of the patient at the same time they represent some organization that may be adversary to the patient. Although the "double-agent" role is particularly clear in institutional psychiatry and military medicine, it also characterizes more subtle changes in physicians' roles in many organized settings. As previously noted, new financing methods may create pressures for physicians to serve as patient advocate and rationing agent at the same time. Such institutional conflicts exist in a variety of medical contexts, and it is not clear that the problem is any more acute in DHEW programs as compared with programs in the private and nonprofit sectors.

C. Refusal to Provide Care in Emergency Situations

It is alleged that hospitals sometimes refuse treatment to patients in need of emergency care because patients do not meet hospital financial eligibility criteria. These patients must be transferred to other treatment settings, at some possible risk to them. It is alleged that this problem is particularly relevant to Medicaid recipients who are turned away from some voluntary hospitals and referred to other institutions. Assessment of this issue is made difficult by the lack of a precise definition of an emergency. I have no way of estimating the extent of this problem.

D. Coercive Agreements

Apparently there are instances in medical practice, such as amniocentesis, in which some centers require a commitment from the patient who receives the procedure that the fetus will be aborted if found to be defective. Although such a practice might be seen as a prudent means of allocating a scarce medical resource, and although it would be wasteful for a physician to utilize any expensive or risky procedure if it was to have no discernible influence on decision making, too rigid a demand for a precommitment by the patient may constitute "undue pressure." Decision making under such circumstances may be difficult for the patient, and uncertainty and ambivalence may characterize the decision. Patients ought to be free to change their minds concerning any important decisions without being exposed to coercive pressures.

E. Violation of Patients' Civil Rights in Nursing Homes, Board and Care, and Other Sheltered Care

Federal programs, particularly Medicare and Medicaid, have contributed to a vast growth of the nursing home industry, and other federal legislation has encouraged processes of deinstitutionalization of mental hospitals. The nursing home situation is scandalous, and the civil rights of patients are routinely violated in many of these homes, to say nothing of the lack of humane care. Although nursing homes and other comparable community care facilities are not under the direct control of the federal government, these industries depend substantially on federal funds. There is probably no area in American medicine that requires more careful study and effective regulation. In my view the Commission ought to devote special study to ethical issues in nursing home care and other types of decentralized community facilities.

V. Problems in Service Delivery Relevant to the Ethical Norms for the Conduct of Research

Dr. Robert Levine in reviewing the legislative history of Paragraph (C) has found that of the four specific activities noted by the Congress only one--the sterilization of the Relf sisters--does not fall within the guidelines concerning research and innovative therapy already considered by the Commission. He suggests that the class of behaviors most appropriate to regulate under Paragraph (C) is practice for the benefit of others that is not designed solely to enhance the well-being of the individual, but meets the customary standard for routine and accepted practice (Report of May 28, p. 11).

A wide range of medical practices potentially fall within the rubric of "practice for the benefit of others." It is, however, frequently difficult to determine when the actions taken are intended to benefit the recipient, his family, or the larger community. Most commonly, the medical decisions reflect a synthesis of interests. The physician in making a treatment decision may take into account the patient's needs, the disruptiveness of his symptoms to the family, economic costs, and a variety of other factors. With the new emphasis on family medicine, doctors are being trained more explicitly to take family and community contingencies into account in decision making. Although it is probably futile to deal with this class of practice as a whole, it is prudent to focus on the ethical problems related to any therapeutic procedures that are involuntary or coercive. Such problems exist in the areas of involuntary commitment to psychiatric institutions, involuntary drug treatment, and involuntary sterilization. In recent years there has been substantial

litigation in the mental health area surrounding these types of problems. Although it might be useful for the Commission to monitor the present status of law in these areas, the issues and dilemmas in this field are exceedingly difficult. In principle, however, any "therapeutic" action taken coercively should be subject to appeal and review.

There are a variety of activities associated with the delivery of medical care that may bring no direct benefit to the donor or consentee. These include the donation of blood or organs, permission to use tissue or organs of the deceased, permission for autopsy, or participation in medical education. Discussion of a few of these examples may highlight the types of ethical issues involved in each case for which regulation might be considered.

Obtaining permission in any of the above areas involves the norm of respect for persons. In such cases as voluntary blood donation and medical education, the social value of such participation is so large and the possible risks sufficiently small to make these areas relatively noncontroversial. In respect to medical education, for example, future generations depend on adequately trained physicians who require clinical experience with patients to acquire necessary practice skills. Each generation of patients experiences a certain degree of inconvenience for future generations. Agreeing to participate in medical education, however, is a gift by the patient to the student and imposes certain simple requirements on medical education consistent with the norm of respect. These include that all patients be equally exposed to students, and that the poor and powerless do not disproportionately serve as "teaching material"; that any student or physician contacting a patient for educational purposes identify himself by name and explain the purpose of his

examination or request; and that the patient's right to refuse participation be apparent and protected. In the case of surgery, it also means that the patient be informed explicitly as to who will actually perform the surgery. There should also be limits to the extent that any seriously ill patient is subjected to repeated examinations simply because the case "is interesting." While I remain dubious about the value of specific regulation in this area, I believe that abuses of these simple principles are commonplace and deserve more attention than they have received.

Problems in practice for the benefit of others involve serious issues of consent as when requests are made of related potential donors to provide tissue or organs or when permission is sought from next of kin for organ donation or autopsy. Particular transplant groups have developed detailed procedures that protect the right to refuse and that insulate the potential donor from family pressures by providing a "medical excuse" when the donor does not wish to participate.[21] I do not know to what extent such procedures are common in transplant groups throughout the country. Moreover, there is variation in procedures used to obtain permission to use organs of the deceased from next of kin, but I know of no data on the extent of such variability. In each of the cases above, the potential consentee has a right to truthful information concerning the procedure and associated benefits and risks and to be protected from coercive methods and undue pressure. Some centers apparently deal with potential problems by having others than members of the transplant group, who are less likely to face a potential conflict of interest, seek the consent.

Autopsy permission constitutes a common problem, particularly because many persons seem to have serious reservations about giving

consent. In obtaining autopsy permission, the health professional is caught, as in so many other matters, between the norm of respect and the desire to achieve particular goals expeditiously. Autopsy permission is important for evaluation of performance and continuing education. In zealousness to achieve such permission, however, deception and psychological coercion are sometimes used. Although it is difficult to obtain any reasonable estimate of the extent of the problem, it is widely acknowledged that practices communicating disrespect for persons are commonplace, and such behavior has been documented forcefully in one major teaching hospital.[22] With some attention to the ethical problems involved in these situations, it is frequently possible to work out more appropriate consent arrangements without major sacrifice of other important interests. One approach, for example, used in some centers is to have specially trained nurses, who are more sensitive to the issues than busy residents and who can devote more time to communicating with families, obtain the consent.

Granting autopsy permission or consent to use tissue or organs of the deceased has many similarities to consent for research participation. Persons granting such consent have the right to know the true benefits and costs of the requested procedures, to be given correct information as to the procedures to be followed, and to be assured that there will be no invasions beyond those necessary to achieve clearly stated goals. Although these situations are unlike research in that they pose no medical risk, invasion of the body involves important symbolic values for many people, and in deciding to grant permission for such invasion, the consentee has a right to have his questions and concerns addressed honestly and to be free of coercion during a difficult time.

General Problems of Consent. Although the requirements for consent are less clear-cut in practice as compared with research, many observers of medical settings agree that informed consent is largely a fiction. Patients commonly sign consent forms without either reading them or receiving any reasonable explanations as to what their consent involves. Physicians and other health professionals frequently proceed in their work as if no explanations are necessary and as if it would be presumptuous for patients to question their judgment. Most patients are relatively docile and infrequently challenge these modes of behavior even when they are concerned about them. These attitudes are so characteristic of medical practice that it is highly unlikely that they can be successfully regulated without major and costly dislocations of practice patterns. While the threat of malpractice litigation may serve as a partial deterrent, it probably affects the forms of behavior (such as obtaining a signed consent) more than their substance (insuring that the patient really understands). A focused approach on improving procedures for obtaining surgical consent would be feasible. Surgical consent is the area of largest risk of serious violation and one in which special protections are essential because of the patient's inability to protect his own interests during the procedure.

VI. Approaches to Accountability for Health Professionals and Institutions in Respect to Ethical Issues

As I have illustrated in this paper, the delivery of health care involves a myriad of ethical issues that arise from global health policy decisions as well as behavior at the level of service delivery. Because these issues arise out of conflicts in values or resource limitations,

and because they may involve numerous types of behavior that are impossible to monitor effectively on a continuing basis, the attempt to specify individual guidelines and regulations to govern them is a futile gesture that will not achieve the behavior changes desired. Indeed, if anything, they are likely to add to administrative and bureaucratic burdens that detract from efforts to provide good care with limited resources.

The crux of the issue, I believe, is the inequality between provider and patient and the extent to which these inequalities are growing with changes in the organization and provision of health care. Mechanisms are necessary, therefore, that contribute to narrowing these inequalities and that provide effective feedback to administrators and professionals as to the problems and experiences of patients. In short, it is essential to develop countervailing influence by patients in the care process. Three possible mechanisms to close inequalities include (1) effective grievance procedures, (2) ombudsmen, and (3) extrainstitutional pressures. A short description of each of these approaches follows.

1. Grievance Procedures

Increasingly patients use medical institutions or are clients of programs for which there are no alternatives. Thus, if they feel their rights violated they have little recourse but to complain directly to the providers, withdraw from using services, or initiate litigation. Patients are frequently reluctant to make direct complaints, and when they do there is no assurance of responsiveness. Similarly, withdrawal from service is not a serious option. Litigation requires considerable initiative and does little to resolve the initial problem when it

occurs. Moreover, litigation is a highly formalized and time-consuming process that involves considerable costs for both the patient and the medical care system. Also, because the initiation of litigation is relatively infrequent, as in the case of malpractice suits, it results in a distorted pattern of compensation and resolution of existing problems.[23]

What is needed in any sizable program is a grievance procedure through which patients who feel wronged can make their problems and concerns known. Such a procedure would allow for relatively rapid mobilization to deal with problems early in their development, provide information to the institution concerning patients' dissatisfactions and concerns, and provide an opportunity to give feedback to patients who have unrealistic or misguided expectations. To be effective, such a grievance mechanism must be institutionally based and have strong administrative support to seek remedies to problems that are identified. Moreover, it must be structured so that it is visible to patients, so that access to patients is high, and the grievance process can be initiated without elaborate or formal preparation. For the most part, the mechanism would be used to achieve informal resolution of difficulties that arise in the patient care process, but under some conditions more formal procedures will be required. Such a grievance mechanism must include sufficient involvement of consumers or consumer representatives to insure that it does not simply deflect criticisms or problems. Moreover, procedures should be developed to allow staff to initiate grievances concerning failures and inadequacies of care in the program. Often staff are familiar with problems and abuses but have no adequate way of communicating their concerns.

Most grievances can be handled informally with little cost. When a complaint is first made it should be recorded, and some attempt made to resolve it quickly through consultation with the parties involved. When the grievance arises from real conflicts of interest or perspectives, and after an explanation the patient wishes to pursue the issue, more formalized procedures should exist for a hearing and an attempted resolution of the grievance. Although it is not my purpose here, it would not be difficult to specify the steps to follow in a grievance mechanism from rapid and informal resolutions to more formalized proceedings. The grievance mechanism could be adaptable to a wide variety of problems related to ethical concerns, and by its very existence might serve as a deterrent to at least some types of abuse. The existence of a visible grievance procedure provides some leverage for the patient in cases of abuses arising from the inequality of provider and patient.

As a regulatory approach, the grievance procedure offers opportunities for sensitizing health professionals to patients' perceptions and concerns. The existence of a viable grievance procedure itself probably acts as a deterrent on some abuses by developing checks and balances when they are absent--very much like Institutional Review Boards in the research area. Through the maintenance of records of complaints it becomes possible to pinpoint troublesome areas of care and to initiate discussion as to the ways problems can be remedied. Also, the existence of a serious grievance process contributes to the consumer's sense of trust that the program is accountable. If the institutional group responsible for the grievance procedure issued a report at varying intervals reviewing problematic areas of care, this could serve as a vehicle for institutional communication and greater awareness of the problems that exist.

In implementing a grievance procedure, attention must be given to the sponsorship of the procedure, the power of those administering the procedures to seek solutions for problems that arise, the role of patient and consumer representative members on hearing bodies, and the like. It would probably be useful for the Commission to initiate a detailed study on appropriate grievance procedures for medical settings and to consider encouraging DHEW to sponsor experimental demonstrations in the near future.

2. The Ombudsman

As institutional medical programs become more complex, the opportunities for breakdowns in communication and coordination and for misunderstandings very much increase. Many of these problems can be corrected if there is someone available who understands the context and the types of problems that commonly develop and who can communicate to the parties involved in the patient's care. Many hospitals in the United States have now instituted ombudsmen programs, although they function more often to protect the institution's image and public relations than to delve very deeply in serious violations of patients' rights. In most such programs the ombudsman has limited influence to intervene when there are serious conflicts of interest, and the value of such persons is largely to improve communication. If we can assume the good will of most health care professionals--and I believe we can--then the ombudsman, despite the limitations inherent in the role, provides an opportunity to improve communication and to prevent the escalation of misunderstandings, and can assist patients in communicating their needs to health care professionals. Like the grievance procedure, the

ombudsman contributes to reducing the inequality in sophistication in understanding the medical setting between patient and health professional and provides an alternative to more inflexible rules and regulations. The ombudsman role can be established so as to increase advocacy for institutional change, and the ombudsman can be given the authority to initiate grievance procedures when informal resolutions of problems cannot be achieved.

3. Extrainstitutional Pressures on Health Care Programs

One way of creating pressures for conformity with certain ethical standards is to state these standards as explicitly as possible in the form of a statement of patients' rights and make these readily available to patients. Thus, patients could receive written notice in the form of a pamphlet or brochure that states their rights in experimental situations, in therapy, in providing consent for surgical intervention or organ donation, in providing autopsy permission, and so on. Although the rules are unlikely to have much impact in and of themselves, they do provide patients with a clearer indication of what they can expect and provide leverage to outside consumer groups who wish to challenge existing practices when they are in violation of stated ethical standards.[24]

As Robert Levine (May 28) noted, the most important function of meticulous and formal documentation of consent is "to reduce the civil and/or criminal liability of the investigator and his institution." (p. 18) Because of the context in which consent is obtained it is less likely to provide for the patient a record of documentation of his continuing rights in the research situation. Similarly, patients in service situations often lack a clear notion of appropriate practices and have

difficulty in evaluating their feelings of dissatisfaction. A clear statement of standards in relation to frequently occurring situations, such as surgical consent, autopsy consent, and research participation, gives patients clear expectations and a realistic framework to evaluate their experiences. A clear statement of standards also provides criteria by which outside groups can document failure in institutional operations or, if necessary, use as grounds for initiating litigation.

VII. Implementation

Throughout this discussion, I have been skeptical of the rule-making process and the tendency to respond to each new problem with new regulations. In addition to being a costly process it encourages skepticism and at times contempt from those whose behavior the regulation is intended to influence. Frequently, more modest efforts, better fitted to the realities of organizational behavior, are more successful in achieving a sensitive response to the needs and interests of patients and research subjects than more specific rules and requirements for affirmation of conformity with these rules.

Throughout the discussion I have indicated that the crux of the difficulty is the inequalities between patients and providers, and that such inequalities are greatest when the patient has no choice of providers. This is often the case in particular DHEW programs, but true in the private sector as well when geography or the nature of the programs results in only one source of care.

Whatever the value of intervention, I see little possibility of achieving effective regulation relevant to ethical behavior in programs in which the government pays fee-for-service providers for the provision

of individual services as in the case of Medicare and Medicaid. However, using the same logic as that of the Institutional Review Board, DHEW could require that any program or institution receiving capacity-building grants from DHEW or any direct service program within DHEW develop an appropriate committee to establish and monitor a grievance procedure for that program. Further, DHEW can establish general guidelines for such a grievance procedure including such issues as access for patients, membership composition, and authority structure. The requirements might vary for institutions differing in size and complexity of operation, but these and other matters would have to be examined in greater depth.

Such an Institutional Review Board might be directed from time to time to monitor certain specified areas in which problems exist, although such requirements must be relatively modest if they are not to result in large institutional costs. Further, attention must be given to organizational entities that may be handicapped unfairly by additional administrative burdens. For example, health maintenance organizations must compete for enrollees in the same marketplace as fee-for-service practitioners and private fee-for-service group practices. When federal requirements apply to one party in a competitive situation and not to the other, they result in giving unfair advantage to the unregulated groups, whatever the original intent might have been. When, for example, as a matter of policy the federal government is attempting to shift practice from a fee-for-service pattern to a capitation pattern, additional requirements on the capitation sector may work against the larger policy interest.

In summary, any further regulatory action recommended by the Commission should be carefully considered in light of the costs of such requirements. In my view, intervention should proceed along the lines

suggested in this paper. However, I would like to see some period of experimentation and experience with varying types of grievance procedures before attempting to impose them on the vast diversity of health care programs in the United States. I think the Commission could do a great deal to encourage DHEW to stimulate such experiments so as to build a better basis for further protection of patients' rights. Through such experimentation it will be possible to define minimal standards of intervention as well as more ambitious possibilities, such as the use of ombudsmen, that could be encouraged through grant programs.

NOTES

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ON THE RELEVANCE OF ETHICAL PRINCIPLES AND GUIDELINES DEVELOPED FOR RESEARCH TO HEALTH SERVICES CONDUCTED OR SUPPORTED BY THE SECRETARY, DHEW

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May 28, 1976

"(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."

This paper is addressed to the foregoing charge to the Commission (hereafter referred to as Paragraph (C); the term, "DHEW-practice", will be used as a shorthand expression for "the delivery of health services to patients under programs conducted or supported by the Secretary." It is assumed that the reader is either familiar with or has access to several unpublished papers that were prepared for or by the Commission (1-8); these will be cited frequently.

Since the Commission has not completed its response to its charge under section 202 (a) (1) (A) (Paragraph A), it may be premature to consider the appropriateness of applying the called for principles and guidelines developed for research to DHEW-practice. This paper is based on the assumption that the existing draft (6) of the response to paragraph (A) anticipates accurately the substance of the Commission's final recommendations. A further assumption is that the draft definitions of research and practice (7) are those which will be contained in the Commission's final report. Thus, the scope of this paper is confined to those activities meeting the Commission's definition of practice which are either conducted or supported by the Secretary.

This paper first reviews the specific activities that seemed to cause the congressional concern that led to the development of paragraph (C). Of the four specific activities mentioned in the legislative history (8), according to the Commission's definitions, one is research and two are innovative therapy; these activities would be covered by the Commission's guide-

lines even if the Commission determined that its guidelines were not applicable to DHEW-practice. The fourth--though neither research nor innovative therapy--does not perfectly fit the Commission's definition of practice; it is representative of a class of activities that I shall call "practice for the benefit of others".

Next, there will be a review of the basic ethical principles which have been identified as those which should underlie the conduct of biomedical and behavioral research involving human subjects; it will be concluded that the same principles are applicable to practice. Next, there will be a detailed examination of the "ethical norms for the conduct of research" that have been identified by the Commission. It is assumed that the six norms and the discussion of the implementation procedures will form the basis of the Commission's recommendations of guidelines which should be followed to assure that research is conducted in accordance with the basic ethical principles. The norms and implementation procedures were developed for research and are based upon some attributes that are peculiar to research and not characteristic of most practice. However, it will be suggested that parts of either the same norms or some analagous norms and procedures might be appropriate for practice. There are four procedures that derive from these norms which are not appropriate for most practice: 1) A meticulous description of the proposed activity in the form of a protocol; 2) Review by an Institutional Review Board (IRB) prior to the initiation of the activity; 3) A high degree of formality in documenting the negotiations for informed consent; and 4) The development of a "no-fault" compensation system for harmed subjects. In general, the attributes of research that provide the rationale for these procedures do not obtain

in practice. However, there is a category of activity that is commonly considered practice--although it does not conform literally to the Commission's definition of practice--which shares with research generally those attributes that justify the four special procedures. This class of activities is characterized by the fact that a person (patient) is called upon to do something (assume either risk or inconvenience) at least in part for the benefit of an other or others. I shall suggest that this class (practice for the benefit of others) includes some activities to which the four procedures designed especially for research might appropriately be applied.

Finally, there are some general comments on the perils of over-regulation of DHEW-practice.

Legislative history

In order to understand what caused Congress to incorporate Paragraph (C) in the Commission's mandate, it is necessary to examine the specific cases that were brought to its attention to suggest its necessity. The two specific cases that seem instrumental in the development of this paragraph are: sterilization of the Relf sisters and use of Depo-Provera for unapproved purposes (8, at pp. 26-28). Two additional cases were presented to Congress that are germane to this discussion; however, in the legislative history, they are not linked specifically to Paragraph (C) (8, at p. 3). These are the Tuskegee syphilis study and the use of Diethylstilbesterol (DES) on college campuses.

Let us now examine each of these four activities in some detail:

1) The Tuskegee syphilis study (9): By no stretch of the imagination can this study be referred to as a health service conducted by DHEW. This

activity was research and, as such, would be covered by the guidelines to be recommended by the Commission even if there were no Paragraph (C). The specific objectionable component of this activity--the deliberate withholding of chemotherapy--was done not for the purpose of benefiting the patients but rather for the purpose of developing generalizable knowledge about the natural history of the disease.

2) Depo-Provera: Provera is a brand name for medroxyprogesterone acetate--a synthetic derivative of the naturally occurring female sex hormone, progesterone. At the time of the debates in Congress, Provera was approved by the FDA for the treatment of various types of menstrual irregularities. Depo-Provera is the brand name given to an injectable form of the drug; the main advantage of the injectable form is that it has a very long duration of action. At the time of the Congressional hearings, Depo-Provera was approved by the FDA for the treatment of cancer of the uterus and for endometriosis (abnormal growth of the lining of the uterus outside of the uterus). Its use at that time as a long-acting contraceptive for females was classified by the FDA as investigational and was being conducted under a Notice of Claimed Investigational Exemption for a New Drug (IND) (10, at pp. 42-44). During the hearings (10, at p. 56 et seq) it was stated that Depo-Provera was being administered as a contraceptive to women in the Family Planning Clinic of the Cumberland County Health Department in Tennessee; allegedly it was being administered without having first secured informed consent from its recipients. It was further alleged that the only alternatives offered for contraception were intrauterine devices (IUDs) and

sterilization. The fact that the use of Depo-Provera as a contraceptive was highly controversial is reflected in the extensive hearings. As of May, 1976, the controversy remains to be resolved.

There are two main points to be made about this case. The first is that the administration of Depo-Provera as a contraceptive was at the time classified as investigational by the FDA. This type of activity clearly falls in the category that the Commission has identified as innovative therapy (7). Such activities should be conducted in accord with the standards of research to the extent that such standards do not subvert the therapeutic purpose. Parenthetically, the fact was brought out during the hearings that the manufacturer had prepared consent forms which had not been used.

A second point that should be made about this case is that the range of alternatives allegedly offered to these women was much smaller than that generally available. Thus, in addition to Depo-Provera, IUDs and sterilization, most women have available to them oral contraceptives, diaphragms, and so on. This issue is discussed further subsequently (cf, Ethical norm number 4).

3) DES: DES is the common designation given to a drug named Diethylstilbesterol, a synthetic chemical having all of the known effects of the naturally occurring female sex hormone, estrogen. At the time of the Congressional hearings, DES was approved by the FDA for quite a variety of uses. However, the use in question was not only not approved by the FDA, there was not even an IND on file (10, at pp. 44-49). The use in question was as a post-coital contraceptive; commonly referred to as the "morning after pill". By the time of the hearings it was demonstrated to the satisfaction of all

concerned--including the Obstetrics and Gynecology Advisory Committee to the FDA--that DES was highly effective as a post-coital contraceptive when administered in a sufficient dose for 5 days beginning within 72 hours of "exposure". However, concern was expressed as to what should be done in the rare cases in which DES failed and pregnancy ensued.

This concern was largely based upon anxieties that most scientific experts assert are irrelevant to the use of DES as a post-coital contraceptive (11). In particular, in the 1940s and 1950s, DES was administered to many women during pregnancy for purposes of reducing the risk of spontaneous miscarriage. Years later it was found that the female offspring of such women had a relatively high incidence of a very rare malignant tumor of the vagina. In this case it is said that the incidence was relatively high only in comparison with the natural incidence of the tumor; the incidence in association with DES administration is no greater than 0.4 per cent. There is no cause to question that the increased incidence of this tumor was due to administration of DES. However, the association is with prolonged administration of the drug in low doses for purposes of sustaining pregnancy; further, the drug was administered during that period of pregnancy during which organs such as the vagina are forming. This is a very different thing than administration of a very much higher dose, long before organs are forming, for purposes of preventing pregnancy. There is strong evidence developed from studies done on laboratory animals that administration of DES in the very early stages of pregnancy does not lead to the development of malignant tumors in the progeny (11). Yet, it is suggested that one way in which a human fetus might be damaged owing to failure of DES as a post-coital contraceptive is that the woman might already have

been pregnant at the time of the "exposure" for which she is being treated and the fetus might be at a stage of development during which it might be vulnerable; while this seems theoretically possible, no such case has been reported.

As of 1976, the issue remains highly controversial (11). There is no way to assess the perils to the fetus of DES administered as a post-coital contraceptive in humans. The main reason for this is that its use is almost never followed by a live birth (11). In an analysis of 10,500 cases in which DES was used as a post-coital contraceptive, there were only 42 pregnancies; of these only 4 appeared to be due to failure of properly conducted therapy.

Because there is theoretical uncertainty as to whether failure of DES administered as a post-coital contraceptive might result in a damaged fetus, it is customary to recommend that if DES fails and the woman subsequently proves to be pregnant, she should have an abortion. Since almost every woman in whom DES has failed has had an abortion, there is nearly no population to study to see if it has been harmed.

The issue remains highly controversial. The controversy notwithstanding, the main point to be made about this case is that the status of DES should have been "innovative therapy" as it was for Depo-Provera and the closing statements made for the latter drug are equally applicable here. A secondary point is that the use of DES that was called to the attention of Congress was not in DHEW-practice; rather it was in private practice, particularly on college campuses.

4) Sterilization of the Relf Sisters: Of the four specific cases, this is the only one that does not conform to the Commission's definitions of either research or innovative therapy. It seems unnecessary to recount here the facts of this very famous case. But briefly, two mentally retarded children--ages 12 and 14--were surgically sterilized in a hospital under the direction of the Family Planning Clinic of the Montgomery (Alabama) Community Action Committee, an OEO funded project (10, at p. 1496 et seq). The authorization to proceed with the operation that was obtained from their illiterate mother was questioned by her attorney: She"put her mark on what we later learned was an authorization for surgical sterilization." Of historical interest is the fact that prior to the surgery the girls were treated with contraceptive injections--presumably Depo-Provera. This link to this case probably accounts for the fact that Depo-Provera was mentioned specifically in the discussion leading to Paragraph (C).

The very special contingencies of this case and the class of procedures of which it is representative remain to be resolved (12). Shortly, after this case was discussed in Congress, regulations to cover such procedures were published in the Federal Register (February 6, 1974). Shortly thereafter, the regulations were challenged in court (Relf v. Weinberger, 372 F. Supp. 1196 (1974)); the judge ruled against authorizing federal funds for sterilization procedures unless the personal consent of the patient was secured. Subsequently developed regulations (13) which are applicable to programs or projects for health services which are supported in whole or in part by federal financial assistance, make no provision for the sterili-

zation of individuals who are incapable of personally giving "legally effective informed consent". Thus, according to current federal regulation, the circumstances of the Relf case should not be repeated; there is no authorization for DHEW funds to sterilize minors or others who are legally incompetent to consent (14).

The main point to be made about this case is that it would not be covered by guidelines developed under Paragraph (A) if these guidelines were to be applied only to activities meeting the Commission's definitions of research and innovative therapy. It is representative of a class of activities for which I shall recommend procedures similar to those developed for research.

Fundamental ethical principles

In the draft of its response to paragraph (A), the Commission has identified three fundamental ethical principles which should underlie the conduct of biomedical and behavioral research (6). These are: respect for persons, justice, and beneficence. It is made clear that these three fundamental principles--which are consonant with the major traditions of Western ethical, political, and theological thought represented in the pluralistic society of the United States--relate to human relations in general rather than to the particular problems of biomedical and behavioral research. Thus, these principles should underlie--among many other human activities--the practice of medicine.

The nature of the relevance of these fundamental ethical principles to the conduct of biomedical and behavioral research on human subjects can best be explained by considering the specific norms governing the conduct of such

research. In the next section we shall consider in detail each of the six norms specified in the Commission's draft. As we examine these norms, it should be kept clearly in mind that they were developed to meet the needs of a class of activities that the Commission has defined as research. In each case it is necessary to consider carefully what specific attributes of research provide the rationale for the development of the norm. In some circumstances we find that research shares with practice those specific attributes which call for the development of these norms while in other cases it does not. Activities which do not share with research those attributes that provide the rationale for the development of these norms should not have guidelines derived from these norms applied to their conduct.

As observed in the draft (6, at p. 10), meeting the expectations called for under several of the ethical norms requires a balancing-off of considerations arising from two or more of the fundamental underlying principles. The feature of research that presents the greatest problems in this regard is that in the course of its conduct, the subject is commonly called upon to assume risk or inconvenience (4, at pp. 8-11) on behalf of others. As we examine the definitions of research and practice drafted by the Commission (7), the distinction that is most relevant to these considerations is contained in the following phrases: "Research...refers to a class of activities designed to develop or contribute to generalizable knowledge..." while "...practice...refers to a class of activities designed solely to enhance the well-being of an individual." Thus, when one asks a person to become a research subject, one asks that person to do some-

thing that is designed at least in part and, at times, exclusively to bring benefit to others; ie, to contribute to the development of generalizable knowledge. On the other hand, in the conduct of practice, the person (patient) ordinarily applies to the professional to have something done for him. As we shall see, there is a class of activities commonly called practice--although it does not conform literally to the Commission's definition of practice--in which persons are called upon to do something at least in part for the benefit of another or others.

As we examine the six specific ethical norms, the fact that this class of practice activities has much in common with research will first become apparent in consideration of ethical norm number 3. In particular, this class of practice activities presents all concerned with the complex "harm/benefit" analyses characteristic of research presenting known or unknown risks of physical or psychological harm which are virtually never encountered in practice activities other than those contained in this class. There are other similarities between this class of activities and research which will be specified. In general, it may be said that if any of the guidelines developed by the Commission in response to Paragraph (A) are applicable to DHEW-practice, the practice activities to which they might be applied may be found in this class of activities.

Practice for the benefit of others: I shall now define this category of practice and provide examples of some activities that may be found within it. Practice for the benefit of others refers to a class of activities which does not conform literally to the Commission's draft definition of practice; it departs from this definition only in that it is not "...designed solely to enhance the well-being of an individual." However, it does meet "...the customary standard for routine and accepted practice..." namely "...a reasonable

expectation of success." Thus, it does not conform to the draft definitions of either research or innovative therapy.

While the activities conducted in this category may bring direct health-related benefit to the patient, this is not necessarily the case. For example, one activity in this class--the donation of an organ (eg, kidney) or tissue (eg, blood)--brings no direct health benefit to the donor. In the example just cited, the beneficiary is a single other person who may or may not be related to the "patient". In some cases, the beneficiary may be society generally as well as the individual patient (eg, vaccination) while in others the only beneficiary may be society (eg, quarantine). In some cases, individuals are called upon to undergo psychosurgery, behavior modification, psychotherapy, or psychochemotherapy so as to be less potentially harmful to others; this is a particular problem when the individual is offered the "free choice" between the "sick-role" and the "criminal-role". In some cases the beneficiaries may include succeeding generations as when patients are called upon to undergo sterilization because they are considered either genetically defective or otherwise incompetent to be parents; the problems in this area are illustrated in the discussion of the Relf case. In some cases, one beneficiary of therapy may be an institution and there may be serious disputes over the extent to which the purpose of therapy is to benefit the "patient" or to provide administrative convenience to the institution; eg, heavy tranquillization of disruptive patients in a mental institution, treatment of hyperkinetic school-children with various stimulant and depressive drugs, and so

on.

This is not meant to be an exhaustive list; rather, it illustrates the class of activities for which it might be considered appropriate to apply to DHEW-practice some of the guidelines developed in response to Paragraph (A).

Ethical norms and implementation procedures

Let us now consider each of the six norms for the conduct of research described in the draft paper on identification of ethical principles (6, at pp. 10-20). These norms will form the basis for the Commission's recommendations of guidelines to assure that research is conducted in accord with the identified basic ethical principles. The necessity for some procedural requirements is self-evident in the discussion of some of the norms. In addition, in the Commission's draft, there is a discussion of implementation of the principles (6, at pp. 21-26). This discussion identifies as the major "accountability structure" available to assure implementation of the principles the Institutional Review Board (IRB). As we examine each of the six norms, we shall consider: 1) Is this norm relevant to the practice of medicine? 2) Might any analogous norms be stated for the practice of medicine? 3) Are the accountability structures presently available in the practice of medicine sufficient to assure implementation of the norms relevant to the practice of medicine?

1) There should be good research design; the experiments should be based on adequate laboratory and animal experimentation or other scientifically established fact.

There is no perfect analogy to this norm in the practice of medicine.

Yet, something of an analogy may be found in the Commission's draft paper on the boundaries between biomedical and behavioral research and accepted and routine practice (7, at p. 1): "The customary standard for routine and accepted practice is a reasonable expectation of success." The reasonable expectation of success standard is developed through that has been previously termed the social devices which assign such designations as accepted, approved, safe and effective, and so on (1, at p. 11 et seq). The responsibility for assigning such designations rests with the FDA for drugs and devices, and with various professional societies and hospital medical practice committees for various other procedures.

2) The investigators should be competent to do the research. By analogy, the health care professionals who undertake to deliver health services should be competent to do so. Certification and licensure in the various health professions is the responsibility of state governments. The granting of privileges to conduct various specialized procedures within an institution is the responsibility of appropriate committees within the institution; eg, medical practice committees, credentials committees, and so on (7, at pp. 3-4).

3) Under the heading, identification of consequences, there are cited passages from the Nuremberg code, Declaration of Helsinki, and DHEW regulations which have to do with the importance of weighing the risk of harm against the probability of benefit. The most problematic aspect of such calculations is that the risk of physical or psychological harm is ordinarily borne by the individual research subject while the benefits

may redound exclusively or at least in part to others. The prospective subject is almost never able to make his decision based upon a purely personal felicific calculus dealing only with the probability and magnitude of direct health-related harms as balanced against the probability and magnitude of direct health-related benefits. In recognition of the fact that the prospective subject is being asked to do something for others, he is occasionally offered economic benefits (to pay him for his time), derivative psychosocial benefits (to appeal to his altruism), and so on (2, at pp. 39-43). This presents further problems as reflected, for example, in the long debates as to the boundaries between appropriate remuneration and undue inducement (4, at pp. 41-43).

In the practice of medicine such problems are almost never seen. Almost all decisions may be based upon a personal felicific calculus. The patient decides how much statistical risk of physical or psychological harm he will assume for a given statistically-based expectation of physical or psychological benefit. Economic factors are even less an issue DHEW-practice than in privately financed practice; the patient's choice need not be based on the expense he might have to bear.

Exceptions to these distinctions between practice and research may be found in the category of activities identified as practice for the benefit of others. In this category we tend to find the more complex "harm/benefit" analyses characteristic of research. It is these more complex analyses that create the necessity for "...a balancing-off of considerations arising from two or more of the fundamental ethical principles." In the context of research, a key role in the balancing process is assigned to the IRB. I shall suggest that similar--though not identical--accountability structures should

review proposed activities classified as practice for the benefit of others. Their responsibilities will include assessment of harms and benefits of an activity from the perspectives of patients, beneficiaries and the public to assure that the rights and welfare of each are given due consideration.

4) Research subjects should be selected so that the "...benefits and burdens of research should not be distributed inequitably among different individuals or groups of people: i.e., that there should be equitable treatment of different individuals or groups, in respect both of opportunities and of protection." In considerations of delivery of health services, while one is ordinarily more concerned with just distribution of benefits than of burdens, the same principles of justice obtain. In general, all consequential medical decisions are made according to the principle, to each according to his essential need. This is particularly true in publicly funded delivery systems in which the personal finances of the individual patient are irrelevant. The special problems associated with allocation of scarce medical resources are probably beyond the scope of this discussion. I have previously surveyed the views of Ramsey, Outka, The Artificial Heart Assessment Panel of the National Heart and Lung Institute, and others, on this issue (4, at pp. 52-54).

Another problem that relates to distribution of benefits was illustrated in the discussion of the hearings on Depo-Provera (supra). That is, the range of alternative treatments made available to patients in DHEW-practice may be smaller than that generally available. In some cases this may be appropriate while in others it may not. For example, while it may be appropriate to deprive DHEW-patients of non-validated therapies, it seems

unlikely that one could justify the alleged limitation in the range of alternatives offered to Depo-Provera. I anticipate no recommendation in response to Paragraph (A) that would address this problem; the problem is peculiar to practice, not research. And yet it is a problem that the Commission might wish to consider. There is a possibility that excessively rigid interpretation of policies on the conduct and validation of innovative therapy might be peculiarly harmful to patients in DHEW-practice (cf, Perils of over-regulation).

5) Research should not proceed without the informed consent of the subject. In a previous paper (3, at pp. 40-43) a discussion was presented of various views as to whether the negotiations for informed consent to the investigator-subject relationship should meet different standards than those for the physician-patient (or any analogous professional-client) relationship. I have found no reason to depart from the conclusion reached in that paper:

> "...Patients (or other clients of professionals) are entitled to the same degree of thoroughness of negotiations for informed consent as are subjects. However, ...the patient (client) should, in general, be allowed more freedom than the subject to relinquish this entitlement. In other words, patients may be offered the opportunity to delegate decision-making authority to a physician while subjects (of any experiment bearing any consequential possibility of harm) should rarely be offered this option. The most important distinction between the negotiations for informed consent in the two contexts (research and innovative therapy as opposed to practice) is that the prospective subject must be informed--that he will be at least in part a means and perhaps only a means to another end."

In the category of "practice for the benefit of others", since the specified distinction between practice and research is absent, there is no remaining rationale for the offer to delegate decision-making authority.

Thus, the standards for the negotiations should be identical.

An earlier paper detailed the various functions of informed consent (4, at pp. 2-4) and discussed extensively the functions of documentation of the fact that informed consent had been negotiated (4, at pp. 52 et seq). A clear distinction must be made between the functions of negotiation and those of documentation. The most important function of meticulous and formal documentation of the negotiations and a retention of this document by the investigator is to serve only one of the seven specified purposes for the negotiations; viz, "to reduce the civil and/or criminal liability of the investigator and his institution." To the extent that such protection of the physician and the institution is necessary in DHEW-practice, it will be necessary to document the negotiations for informed consent. However, it must be clearly understood that we are now discussing protection of DHEW and its agents--not of the patients whom they serve. As noted earlier, (4, at pp. 76-77):

> "...the debates as to whether consent for medical practice procedures should be more or less elaborate than those for research procedures notwithstanding, in 1975, documentation of the negotiations for consent (for practice) is customarily much less formal than it is when similar procedures are done for research purposes."

Another purpose of committing to writing the information provided to the prospective subject during the negotiations for informed consent is to provide a durable reference which the subject may consult for information that is of value to him. Thus, for example, (4, at p. 16): "In some cases the prospective subject will be called upon to assume responsibility for minimizing the chance of harm. He will be asked to perform certain functions

during the course of the research to accomplish this objective." In such cases the documentation is clearly in the interests of the subject. It is customary medical practice to provide patients with written accounts of procedures they should follow to serve their own interests. Thus, patients are commonly provided with written instructions as to how they might prepare themselves for a radiological examination, how they might collect a urine specimen, complex schedules for self-administration of medications, descriptions of therapeutic diets, and so on. This sort of informing, however, is not generally viewed by the physician as part of the process of negotiating informed consent to practice.

6) Adequate provisions should be made to compensate subjects for injuries suffered in the course of research. The basis for stating this as a norm is:

> "In so far as subjects take part in research that is not directed toward their immediate benefit, considerations of justice require that they should be compensated for injuries suffered in the course of that research; and the provision of this compensation should not be made contingent on any proof of culpable negligence by the investigator...such compensation should be available...on a 'no-fault' basis...".

In an earlier paper (3, at pp. 47-51) I discussed at length my reasons for strongly supporting this concept. However, in the context of the practice of medicine the rationale for this norm "...not directed toward their immediate benefit..." does not obtain except in the category of practice for the benefit of others. In this category it might be appropriate to develop a similar system of "no fault" compensation for injury. Of interest in this regard is the recent report of the International Conference on the Role of the Individual and the Community in the Research, Development and Use of Biologicals (15):

"The basis of plans currently operating in six countries for compensating victims of injuries from immunization which is obligatory or recommended by health authorities is redress for having rendered benefit to the community by participating in a vaccination programme." ..."The view was strongly expressed that compensation of persons injured as the result of participation in field trials (of vaccines) was as important as compensation for injury from licensed products and such systems should be expanded to include research subjects."

Further, in the appended "criteria for guidelines" the report states:

"A. National and international bodies in recognizing the special characteristics of biologicals research, development and use should take into account:"

"3. Social and legislative action to be taken to provide for the needs of subjects in biologicals research and recipients of biologicals in general use who suffer disabling adverse effects." (emphasis added).

This strong call for compensation of persons harmed by administration of "licensed vaccines" (analogous to accepted or approved) is based upon the recognition that vaccination is in the public interest as well as in the interest of the individual. Thus, it is analogous to the rationale for the Commission's recommendation for compensation of injured research subjects.

Procedures for implementation of the principles

There are four procedures for implementation of the ethical principles in the context of research which are not appropriate for most practice: 1) A meticulous description of the proposed activity in the form of a protocol; 2) Review by an IRB prior to the initiation of the activities; 3) A high degree of formality in documenting the negotiations for informed consent; and 4) The development of a "no-fault" system of compensation for harmed subjects. In general, the attributes of research that provide the rationale for these procedures do not obtain in practice. Therefore, these procedures should not be recommended for the vast majority of activities in DHEW-practice. In the category defined as "practice for the

benefit of others" the attributes that justify these procedures do exist. Therefore, either these or analogous procedures should be applied to this category of DHEW-practice.

The key accountability structure in the context of research is the IRB. Its purposes and structure have been discussed extensively in an earlier paper (5). The IRB is designed specifically to review activities classified as research including innovative therapy. The membership of the IRB is selected so as to provide the expertise necessary to meet these purposes. The accountability structure designed to review practice for the benefit of others will have some but not all the duties of the IRB; accordingly, its membership should be different.

The duties of the IRB include review of proposed research to assure that the issues discussed under each of the six ethical norms are dealt with properly. In the preceding section it was pointed out that in the context of practice, there now exist adequate accountability structures to deal with the issues discussed under the first two ethical norms. Thus, the accountability structures designed for DHEW-practice will not need the scientific expertise required by the IRB. The issues they must deal with under ethical norms 3-5 require primarily a high degree of skill and authority in representing the attitudes and interests of the involved communities and institutions as well as legal and medical expertise. They should be designed accordingly.

Some accountability structures now exist for DHEW-practice. Any attempt on my part to list the structures and to analyze the extent to which they satisfy the requirements identified in this paper would necessarily

be incomplete. Therefore, I suggest that these considerations be made part of the agenda of the Colloquium on Paragraph (C) planned by the Commission for June 17-19, 1976.

Meticulous description of a proposed activity in the form of a protocol obviously is necessary to allow review by the accountability structure. The design of these protocols should be analogous to those in which research is described for IRB review (5, at pp. 22-27). The necessity for different sorts of information should be self-evident from the discussion under each of the ethical norms. It should be emphasized that these protocols do not describe the practice of a physician; this would be nearly impossible. Rather, they describe procedures that will be conducted by a physician in the context of practice for the benefit of others.

The purposes of formal documentation of informed consent were discussed in the preceding section. In the specific context of practice for the benefit of others one additional purpose is to develop a plan for the negotiations and to commit it to writing so that it can be reviewed by the accountability structure. This purpose is clearly analogous to the research context.

In considerations of the development of systems of "no-fault" compensation, some difficulties will be encountered. It will be easy to justify the development of such compensation systems for some activities classified as practice for the benefit of others. For example, in the case exemplified by immunizations which are either "...obligatory or recommended by health authorities..." compensation is easily justified. Similarly, persons should be compensated for harm produced in the course of compulsory sterilization, and so on. At the other end of the spectrum are voluntary activities done

for the benefit of someone close to the "patient"; eg, donation of a kidney to a sibling. Here the justification for compensation seems weakest. The most difficult problems will be presented by those activities in which there is serious dispute as to whether the institution or the patient is the chief beneficiary. The problems encountered in making these decisions will be similar to those presented by determining what a fair compensation system might be for harm incurred in the course of validating innovative therapy.

Extension of the guidelines developed in response to Paragraph (A) to DHEW-practice in the category defined as "practice for the benefit of others" seems to me to be responsive to the congressional concerns that led to the development of Paragraph (C). In particular, such extension would be responsive to the concerns expressed in relation to the sterilization of the Relf sisters. My chief concern is that such extension of the guidelines might lead to the development of overly bureaucratic accountability structures and needless diversion of the energies of DHEW-practitioners to trivial administrative responsibilities (cf, Perils of over regulation). In the context of research, the Commission's draft points out (6, at pp. 23-24) that the accountability structures should not be perceived as "enforcement agencies", intended to interpose fresh obstacles between the investigator and the fulfillment of his research project. The investigator can use the review machinery quite as much to clarify his own mind as he does to anticipate and avoid censure. Further, it should be one of the tasks of the IRB to identify specific research projects which can, for example, properly be exempted from certain formal

requirements. I suggest that the same conceptualization applies to the accountability structures proposed for DHEW-practice. Thus, for example, little time should be spent reviewing protocols and consent forms for plans to recruit blood donors.

Another concern expressed by Congress is that DHEW-patients might be exposed inappropriately to procedures that ought to be considered "experimental". This concern was developed particularly in the discussions of DES and Depo-Provera. The very same concerns have been addressed by the Commission in consideration of the boundaries between research and practice generally (7, at pp. 3-4). One of the key concerns is that the present accountability system is highly dependent upon the individual professional to identify his activity as research; if he so identifies it, he will then proceed to prepare a protocol and submit it to an IRB for review prior to initiation of the activity. However, there are corrective devices in the existing institutional structure. Thus, (7, at pp. 3-4):

> "...if others in the institution or community in which the practice is being applied consider either that it is research (despite the practitioner's intent or belief) or that it is a form of practice which is not sufficiently validated (either by scientific inquiry or by common practice) then it must be reviewed by the committee whose responsibility it is to monitor practice in the discipline involved. In medical practice, this function is the responsibility of the hospital board, the tissue and medical practice committees, and professional societies. It is the function and the clear duty of these bodies to identify significant deviations...and either to restrict their use, or to require that they be applied only in the context of properly designed research and under the supervision of an IRB."

In an earlier paper (5, at pp. 45-48), there is a discussion of some of the formal and informal mechanisms that exist in university hospitals which detect significant departures from routine and accepted practices. Not all of these exist in all institutions engaged in DHEW-practice. How-

ever, in most such institutions there exist medical practice committees, medical boards, tissue committees, various committees for specialized functions such as use of radioisotopes, pharmacy committees, utilization committees, and so on. DHEW-practice is under the jurisdiction of PSRO. Further, the opportunity for informal surveillance by physicians, nurses, and other health professionals should be about the same as it is in non DHEW-practice.

There remains one additional concern. That is, that patients in DHEW-practice might be excessively employed as research subjects owing to their administrative availability. I have previously suggested guidelines to minimize the probability of such inappropriate exploitation (4, at pp. 44-47).

Some perils of overregulation

I wish to emphasize that my suggestions for extension of guidelines developed under paragraph (A) to DHEW-practice represent the maximum extensions that should be considered. It is quite possible that we shall learn at the June Colloquium that some of the proposed new accountability structures either already exist or, for other reasons, will be unnecessary. In this section there will be some remarks on some of the perils of overregulation. By overregulation I mean the development of regulations which require people (eg, physicians, investigators, administrators) to perform meaningless tasks. The performance of these tasks not only does not accomplish the purposes of the regulation, it causes the performers to lose respect for good regulations (16). In a previous paper (3, at pp. 75-77) an example of an unnecessary and, in fact, counterproductive regulation is

discussed; ie the NIH requirement for full documentation of informed consent to retain for research purposes an organ or fragment thereof removed at either autopsy or surgery--even when the procedures themselves are done in accord with usual and customary medical practice.

In this section I shall first comment on the general perils of over-regulation drawing on the experience of investigators in relation to existing regulations governing research on human subjects. Then I shall focus on some specific problems associated with the conduct of innovative therapy and how they are likely to be more severely experienced in DHEW-practice than in practice generally.

Biomedical and behavioral researchers who must now submit their activities in protocol form to IRBs for review are becoming increasingly vocal in their protests about the increasing bureaucracy and requirements for full documentation of the measures they employ to safeguard the rights and welfare of subjects. The problems have been stated with particular eloquence by Ingelfinger (16), Cowan (17), Visscher (18), Baumrind (19), Wardell and Lasagna (20). It is suggested, for example, that the physician, immersed in a profusion of unimportant detail will lose sight of, and respect for the important issues; that the entire system for safeguarding the rights and welfare of subjects may collapse under the sheer weight of the bureaucracy; and that the local credibility of the IRB may be eroded in the process of attempting to implement regulations which even IRB members do not respect. It is further suggested that biomedical and behavioral researchers are beginning to get discouraged. Some are abandoning research on humans to concentrate on animal research, in vitro research, or practice. There is growing concern that we are "exporting" some sorts of research;

for example, early phase drug development increasingly is being done abroad and there is some concern that other countries may begin to think that the United States is using the rest of the world as its research subject population.

I do not know what motivates a physician who wishes only to practice--not conduct research--to work in a DHEW conducted or supported program. I assume it is difficult to recruit physicians to some DHEW positions. If it were not, Congress would not now be considering legislation designed to commit medical school graduates to service in the National Health Service Corps in exchange for subsidization of their medical education (21). Thus, it seems most unwise at this point to develop any regulations that might be considered negative incentives to National Health Service particularly in the absence of clear evidence that they would provide significant safeguards of the rights and welfare of DHEW-patients.

Senator Kennedy introduced an appropriate note of caution in the hearings leading to the development of paragraph (C) (8, at p. 27):

> "But after this experience dealing with the sterilization we added the service programs, but in a limited fashion. The phrase that we use is "whenever feasible and where appropriate". We want the Secretary to look very closely at programs like this, but we obviously need to exclude the great majority of other HEW service programs from these provisions."

As noted earlier, the fact that in response to paragraph (A) the Commission will recommend that innovative therapy be conducted in the context of research designed for its validation will contribute importantly to protecting the rights and welfare of patients. However, it should be recognized that if the guidelines are applied rigidly, they may also harm the interests of patients. Evidence for this may be found in our recent ex-

perience with drugs where the class of innovative therapy is defined sharply through regulation (infra). If the existing drug model is to be applied to other activities classified as innovative therapy, we can expect to see extensions of the same sorts of harms to the interests of patients. These harms are likely to be manifest more severely in DHEW-practice than in the private sector.

In an earlier paper (1, at pp. 11-12) I indicated cases in which in the "experience" of the practicing community a drug may become identified as the "drug of choice" in a specific situation long before this use is approved by the FDA. In some cases there may develop a substantial body of evidence appropriately accumulated, reported, and debated which seems--in the view of physicians expert in the field--to support the identification of the agent as the "drug of choice". Some examples were provided in the earlier paper; a more comprehensive list as well as an extensive analysis of the problem has subsequently been provided by Wardell and Lasagna (20).

One type of problem is presented when a drug which is approved for use in one condition becomes identified as the "drug of choice" for the treatment of another. FDA recognition of such new uses may lag many years behind their acceptance in the community of practitioners. Thus, many practitioners proceed to use these drugs in a manner inconsistent with what is written on the FDA-approved instructions on the package inserts. In medical practice this procedure of itself does not appear to harm patients. However, the real harm lies in the fact that some physicians--having lost respect for the package inserts--tend to ignore some important information they do provide. As noted earlier, sometimes the acceptance of a medication

as the "drug of choice" in the community of practitioners is based upon anecdotal reports or hearsay evidence. In these cases, departure from the package insert instructions may be dangerous to the patient. Clearly, in the interests of the public, some steps must be taken to establish the credibility of the FDA. This is, perhaps beyond the scope of the Commission's mandate.

The impact of this problem may be felt with special severity in DHEW-practice. In private practice, there is ordinarily sufficient flexibility in the environment to permit justifiable departure from instructions on package-inserts. However, it seems likely that in DHEW-practice there will be much less flexibility. DHEW is not likely to openly condone violations of policy developed by one of its own agencies. There is likely to be more rigid adherence to the instructions contained on package inserts in DHEW-practice than in practice generally. In some cases this will serve the interests of the patient. In other cases, it is conceivable that some patients might be deprived of validated therapy (technically classified as innovative therapy) that might be readily available at a private clinic merely because the physician does not want to assume the added burden of meeting FDA requirements and submitting to IRB review.

The President's Biomedical Research Panel, while recognizing that the problems of drug regulation were beyond the scope of its mandate, addressed the issue in a general way (22, at p. 19):

"At present, the FDA's most visible public function as a regulatory agency is concerned with protection of the public against hazard from new drugs, new food substitutes or additives, and new devices. The systems

available for these functions seem to be effective enough, but they also seem to work ponderously and very slowly, requiring the existence of a huge, often unresponsive bureaucracy.

"Meanwhile, there is a different kind of hazard to public health, posed by the prolonged delays and great costs of developing new and potentially useful drugs which the FDA's own protective systems have imposed. In some respects, the agency has become a formidable roadblock."

A particularly serious problem is presented by the "therapeutic-orphan" phenomenon. In an earlier paper (4, at pp. 64-68), I discussed the conflict in existing regulations that results in the fact that most drugs contain on their FDA-approved package inserts a statement to the effect that their safety and/or efficacy have not been established in children and/or pregnant women. This has also been identified as a serious problem by the President's Biomedical Research Panel (22, at p. 237). For reasons stated above this is also likely to be a particularly serious problem in DHEW-practice and may portend similar problems in innovative therapies other than drugs as the guidelines are extended. Earlier, (3, at p. 68) I suggested guidelines for the selection of subjects for a class of activities defined as "...the use of a therapeutic modality proved safe and effective for a certain disorder in one human population which is now to be tested for safety and efficacy in different sorts of persons having the same disorder." I suggested that in general the standards for selection of individuals in the new population to receive the therapeutic modality may closely approximate the standards used in the determination of therapy in the context of practice.

Summary and recommendations

A review of the legislative history of Paragraph (C) indicates that this charge was incorporated in the Commission's mandate as a consequence of congressional concern about four specific activities: 1) The Tuskegee syphilis study; 2) Administration of Depo-Provera as a contraceptive; 3) Administration of Diethylstilbesterol (DES) as a post-coital contraceptive ("morning-after" pill); and 4) Sterilization of the Relf sisters. The first activity conforms to the Commission's draft definition of research; the second and third conform to the draft definition of innovative therapy; these would be covered by guidelines developed in response to Paragraph (A) even if there were no Paragraph (C). While the fourth activity commonly is considered practice, it does not conform to the Commission's draft definition of practice. A new category of practice will be identified that should be viewed differently from the vast majority of medical practice (infra); it includes, among other things, involuntary sterilization. Closer scrutiny of activity number 2 indicates a possibility that the range of alternative treatments made available to patients in DHEW-practice may be smaller than that generally available. It is recommended that the Commission consider the development of a guideline that would minimize the possibility of illegitimate limitation of alternatives made available to patients in DHEW-practice.

The Commission's draft definitions of research and practice exclude one category of activities which is commonly considered practice. This category is termed here practice for the benefit of others. It differs from the Commission's draft definition of practice only in that it is not "...designed solely to enhance the well-being of an individual." However, it does meet

"...the customary standard for routine and accepted practice...", namely "...a reasonable expectation of success." Thus, it does not conform to the draft definitions of either research or innovative therapy. The range of activities contained in this class is discussed on pages 12-13. This class of activities differs from most practice in that it shares with research some of the specific attributes that provide the rationale for some of the ethical norms that have been developed for research. In particular, it presents the same sorts of complex "harm/benefit analyses" that are characteristic of research but not of most practice.

The Commission has identified three fundamental ethical principles which should underlie the conduct of biomedical and behavioral research. These are: Respect for persons, justice, and beneficence. It is clear that these principles should underlie--among many other human activities--the practice of medicine in general and DHEW-practice in particular.

Guidelines to assure that biomedical and behavioral research is conducted in accordance with these three principles presumably will be based upon the six ethical norms and implementation procedures drafted by the Commission. A survey of these norms and procedures indicates that most of them either are not appropriate for practice or that sufficient procedures and mechanisms are available for practice to assure that it is conducted in accord with relevant norms or their analogies.

Four procedures are identified that derive from the ethical norms which are appropriate for research but not for most practice: 1) A meticulous description of the proposed activity in the form of a protocol; 2) Review by an Institutional Review Board (IRB) prior to the initiation of the activity; 3) A high degree of formality in documenting the negotiations for informed

consent; and 4) The development of a "no-fault" compensation system for harmed subjects. In general, the attributes of research that provide the rationale for these procedures do not obtain in practice. However, in the category of "practice for the benefit of others" there are activities that share with research the attributes that justify these procedures. Therefore, the following tentative recommendations are offered:

Practice for the benefit of others should be conducted in accord with the first three procedural requirements identified for research. There should be a meticulous description of the proposed activity in the form of a protocol. There should be a high degree of formality in documenting the negotiations for informed consent. There should be a review by a suitable "accountability structure" prior to the initiation of the activity. The IRB as it is currently designed is not suitable accountability structure for this category of practice. This accountability structure will require primarily a high degree of skill and authority in representing the attitudes and interests of the involved communities and institutions as well as legal and medical expertise. It will not require the high degree of scientific expertise needed by the IRB.

Some accountability structures now exist for DHEW-practice. Any attempt on my part to list the structures and to analyze the extent to which they satisfy the requirements identified in the preceding paragraph would necessarily be incomplete. Therefore, it is further recommended that these considerations be made part of the agenda of the Colloquium on Paragraph (C) planned by the Commission for June 17-19, 1976.

Some activities conducted in the category of "practice for the benefit of others" share with research those attributes that justify the development of systems of "no-fault" compensation. Therefore, it is recommended that the systems of compensation developed in response to Paragraph (A) be extended to cover those activities in this category of DHEW-practice for which they are appropriate.

The recommendations for extension of guidelines developed under paragraph (A) to DHEW-practice represent the maximum extensions that should be considered. Overregulation of DHEW-practice is likely to be counterproductive. It might, for example, discourage young physicians from participation in the National Health Service Corps.

Finally, attention is called to the fact that in response to Paragraph (A) the Commission will recommend that innovative therapy be conducted in the context of research designed for its validation; this will contribute importantly to protecting the rights and welfare of patients. However, it should be recognized that if the guidelines are applied rigidly, they may also harm the interests of patients. Evidence for this may be found in our recent experience with drugs where the class of innovative therapy is defined sharply through regulation. If the existing drug model is to be applied to other activities classified as innovative therapy, we can expect to see extensions of the same sorts of harms to the interests of patients. These harms are likely to be manifest more severely in DHEW-practice than in the private sector.

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3

REPORT TO THE COMMISSION

FOR THE PROTECTION OF HUMAN SUBJECTS

OF BIOMEDICAL AND BEHAVIORAL RESEARCH

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REPORT TO THE COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS IN BIOMEDICAL AND BEHAVIORAL RESEARCH

Public Law 93-348, Section 202 (a):

> The Commission shall carry out the following:
>
> (1) (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...
>
> (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 (of the Department of Health, Education, and Welfare).(1)

The Health Policy Program, under contract with the National Commission, has considered Paragraph C of the Commission's charge, regarding application of the principles and guidelines developed for research involving human subjects to the delivery of health services to patients under programs conducted or supported by the Secretary of the Department of Health, Education, and Welfare (DHEW).

We conclude that, while the three principles of respect for persons, justice,and beneficence identified by the Commission as basic to the ethical conduct of research are relevant to the delivery of health services, the guidelines developed to assure adherence to these principles in the research setting should not be applied as such to the delivery of health services.

Patients are sometimes subjected to abusive practices in the course of treatment. The frequency and gravity of these abuses support the need for exploration of the problem and the need to find ways to promote adherence to the ethical principles of respect, justice, and beneficence in the therapeutic setting. We have concluded, however, that application of the research guidelines to the delivery of health services is not appropriate. Specifically, we have concluded that:

1. the problem addressed by the guideline concerning "selection of subjects" is not relevant to health service delivery;
2. problems analogous to the other guidelines are already addressed by existent safeguards in the health care setting; and
3. procedures, implementing the guidelines concerning "identification of consequences" and "informed consent", could not be effectively implemented in the health care setting.

We support completely the relevance of the principles of respect, justice, and beneficence to the delivery of health services. These principles have long been the subject of philosophical inquiry.(2) The purpose of our study, however, was to determine whether application of the principles as reflected in the research guidelines is feasible in the therapeutic setting and would contribute to protection of the rights of health care recipients. Therefore, we focused almost exclusively on application of the research guidelines and do not discuss other means of applying the principles.

The Issue and Analytical Approach

To determine whether research guidelines can or should be applied to the delivery of health services requires a broad familiarity with the health service system. The nature of health services and the varied forms of delivery

organization were considered, methods of protecting patients' rights were reviewed, and sources of abuse that do not respond to present safeguards were noted.

Americans receive health services through a wide variety of health care subsystems. These may be characterized in many ways. The organization and content of health services vary among levels of care, including primary, secondary, and tertiary. Subsystems can also be described by types of facilities, including a range of ambulatory, inpatient, and nursing home settings. The nature of health services is also influenced by location and source of funding. Significant differences berween rural and urban and public and private systems contribute to the variety of models for health service delivery. In 1973 there were over 200 million short-stay admissions to the nation's hospitals. Conditions and quality of care vary in federal, state, county, and private facilities, as do the quality and scope of services delivered in over 1 billion annual physician visits.(3)

The delivery system is regulated by a complex network of protections for patients. While the ethical principles and guidelines to assure protection of the rights of research subjects meet a critical need that has only recently come to the attention of professionals, policy makers, and the lay public, ethical standards governing the physician-patient relationship date back many centuries. Beginning with the Hippocratic standard of "Do no harm," a complex network of formal and informal traditions, standards, and procedures has emerged. Initially, ethical principles were developed at the instigation of the professions themselves, but later health care institutions, the courts, and state and federal law makers became increasingly involved.

In spite of these efforts and resultant safeguards, abuses of patient rights occur. These disturb the public, the professions, the Congress, and

members of the Commission. All are concerned about the vulnerability of those who confront the complexity of modern therapeutic choices. There is even greater concern about the autonomy of patients with special vulnerabilities, such as language barriers, which impede their informed participation in making choices about their care. We know that humane respect for patient rights is often compromised in physicians' offices as well as in large, impersonal health care institutions. We also recognize that certain medical procedures are particularly open to abuse by unethical practitioners.

In order to consider the diverse aspects which relate to the Paragraph C charge, we assembled a group of Health Policy Program (HPP) faculty and staff each of whom contributed their experience in a variety of governmental and Clinical settings. Some members of the team also have had some experience in analysis of ethical issues in research and health care.[4] Dr. Lee served as Assistant Secretary for Health and Scientific Affairs in the Department of Health, Education, and Welfare from 1965 to 1969, where Mr. Butler served as Assistant Secretary for Planning and Evaluation from 1969 to 1971. Mr. Rubel and Drs. Schroeder and Shenkin served in the Public Health Service. Drs. Lee Schroeder, and Shenkin contribute the perspective of practitioners, teachers, and administrators in a variety of clinical settings.

The HPP study group utilized Robert Levine's paper "On the Relevance of Ethical Principles and Guidelines Developed for Research to Health Services . . . "[5] and the Staff Summary of the June Conference as background for initial discussions. Consultation with several of the participants at the June meeting, including Dr. Levine, was also helpful. Michael Yesley, Lee Calhoun, Frank Pizzulli, and Duane Alexander of the Commission staff provided guidance and relevant materials. State and federal officials who were

consulted on specific questions regarding DHEW programs are listed in the Appendix.

In eight two-hour meetings as well as informal consultations, the study team explored the issues raised by application of the research guidelines. Study participants drew heavily on their governmental and clinical experience as they considered the range of DHEW programs and issues of implementation. Conflicting interests in the health care setting were discussed, along with existent safeguards on the quality of providers and care. Informed consent practices were examined, including identification of the possible consequences of therapy and patient participation in treatment choice. Special vulnerabilities of many DHEW health care recipients were considered. Methods of compensation for injuries in health care were also explored.

Within each of these areas, health care practices and the purposes they serve were compared to guidelines and procedures developed for the research setting. Conceptual differences and procedural complications were noted as we explored the possibility of applying the research guidelines in the health care setting. Sources of abuse of patient rights that are unresponsive to present safeguards were then reviewed and possible approaches to their correction discussed. Conclusions were finalized through discussion of a series of draft reports.

The results of this inquiry are presented in four sections:

Section I discusses the three purposes addressed by the research guidelines, namely, to assure that benefits justify the risks, that subjects participate freely, and that subjects are compensated for any injury.

Section II surveys the range of health programs supported by DHEW. Programs are classified as either system-oriented or patient-oriented. It is pointed out that only patient-oriented programs involve patient-provider relationships similar to those addressed by the research guidelines. Next, we discuss the fact that DHEW in its patient-oriented programs has varying degrees of control over the conditions of care. Its ability to dictate and enforce standards therefore varies between types of programs.

Section III sets forth the three criteria that we feel are essential to justify application of any or all of the research guidelines to the delivery of DHEW health services. First, the guideline(s) must be relevant to the health care setting and must address a problem analogous to the one that it was developed to solve. Second, the guideline(s) should address a problem for which there is no comparable or effective safeguard. Third, the guideline(s) should be capable of being implemented in the health care setting.

Section IV presents some questions that might be raised in response to our conclusions. The purpose of this section is to point out that while sources of abuse of the rights of DHEW health care recipients may exist, they cannot be solved using the research approach and must be addressed by other means.

Section V was not part of our original analysis. It was developed in response to the interest of some Commissioners in looking beyond the strict interpretation of the Congressional mandate to consider the ethical bases for health care delivery. Drawing on our discussions in fulfillment of the contract, we suggest five sets of issues, which involve value considerations and extensive factual inquiry. We believe these to be essential to analysis of this complex question.

Section I
Research Guidelines

The National Commission has identified six sets of issues or guidelines that pertain to treatment of human subjects in the research setting, based on the principles of respect for persons, justice, and beneficence. Guidelines have been developed prescribing proper:

1. research design;
2. competence of investigators;
3. identification of consequences;
4. selection of subjects;
5. informed consent procedures; and
6. compensation for injuries. (6)

These guidelines address aspects of the subject-investigator relationship in order to assure that:

1. benefits expected from research justify the risk assumed by subjects;
2. subjects participate freely; and
3. subjects are compensated for any injury that might occur.

Research guidelines regarding "investigator competence" and "research design" are intended to promote the quality of research and to assure that the advance of knowledge and potential benefit to future patients justifies the risks to research subjects. The process for "selection of subjects" is intended to assure that the risk of research is not imposed on specific groups or on those who are merely "administratively available" on hospital wards. Free participation of research subjects is also promoted by "identification of the consequences" of participation, or provision of the information necessary for the subjects to give "informed consent." The Commission has also stated that systems for no-fault "compensation for

injuries" should exist to assure that additional burdens are not placed on subjects who assume risks for the benefit of future patients.

It should be emphasized that the guidelines call for local institutional review of research projects. They provide for third-party oversight of subject-investigator interaction to assure that subjects are not abused in their assumption of risk for public benefit. Oversight of the individual interaction at the local level is an essential feature of the guidelines.

Section II
DHEW Health Programs

In the past twenty years, the range of federal health programs has grown steadily. The federal government has assumed major responsibility for:

1. the development of health care resources, including new knowledge generated by research, health manpower education and training, facilities construction, health planning, and the organization of health services;

2. the provision or payment for hospital and ambulatory services and long-term care; and

3. the prevention or control of diseases and accidents.

Federal outlays for medical and health-related activities for fiscal year 1976 were estimated at $42.5 billion, as reflected in Table 1.(7)

TABLE 1

Table K-2. FEDERAL OUTLAYS FOR MEDICAL AND HEALTH-RELATED ACTIVITIES BY CATEGORY (in millions of dollars)

	Outlays			
	1975 actual	1976 estimate	TQ estimate	1977 estimate
Development of health resources, total	5,108	5,721	1,356	5,933
Health research	2,459	2,826	717	3,048
Training and education	1,384	1,477	322	1,217
Construction	949	1,082	240	1,309
Health planning and statistics	316	336	83	409
Provision of hospital and medical services, total	30,450	35,416	9,169	38,681
Direct Federal services	5,567	6,046	1,490	6,285
Indirect services	24,883	29,370	7,679	32,396
Prevention and control of health problems, total	1,232	1,349	337	1,270
Total, health programs	36,790	42,486	10,862	45,935

Of this total, $31.7 billion will be spent by DHEW, and over 80 percent of these funds will be spent for health services to patients.

DHEW health programs can be classified as either:

1. system-oriented, or
2. patient-oriented.

System-oriented programs are aimed at resource development, regulation, and technical assistance. They include such programs as those of the National Center for Health Services Research, the National Center for Health Statistics, the Food and Drug Administration, and the Center for Disease Control. They do not involve the direct provision of or direct payment for care. Although system-oriented programs influence the nature of all health services, their impact is indirect, responsible parties cannot be identified,and effects on individual patients cannot be established.

Because the research guidelines focus on the direct interaction between subjects and investigators, they can be applied only where there is an analogous interaction between patients and health care providers.

We thus conclude that the research guidelines can be applied only to health programs involving direct patient-provider interaction and are not applicable to system-oriented programs.

Patient-oriented programs can be categorized by the degree to which there is federal responsibility for the conditions of the delivery of services. The three major types include:

1. Direct-provision programs, such as Public Health Service (PHS) hospitals and clinics, and the Indian Health Service (IHS), where DHEW employs the providers of services.

2. "Capacity building"[8] programs which provide grant support for Health Maintenance Organizations, Community Health Centers, Migrant Health Centers, Community Mental Health Centers, and maternal and child health and family planning services, in order to fill needs that are inadequately met through the private delivery system.

3. Programs which pay for services delivered through the private health care system, such as Medicare for the elderly and Medicaid for the poor.

Two major questions arise in considering which patient-oriented programs are amenable to the research guideline approach. The first relates to the proper role of government. To establish and enforce national ethical guidelines governing the private relationship between patient and practitioner raises serious questions of political philosophy. The second relates to the degree of government control over the conditions of treatment. Even if it were considered proper for the federal government to dictate a comprehensive set of ethical standards governing the health services purchased through the private health care system, its ability to enforce such standards is limited. Dictating standards that cannot be enforced promotes confusion, cynicism, inefficiency, and disrespect for law.

We therefore conclude that application of the research guidelines should not be considered in programs which pay for services through the private delivery system. Application of the guidelines should be considered only in DHEW direct-provision programs or in "capacity-building" programs.

Direct-provision programs and "capacity-building" programs were developed to fill gaps in the private delivery system and are distinguished from the private system in ways that might justify intervention to protect patient rights.

The degree of federal control over the conditions of care, however, varies between the direct-provision programs and the "capacity-building" programs. Only within the direct-provision programs is DHEW able to dictate most details of service delivery and only within these programs is governmental liability assumed.(9)

Section III
Criteria for Application of the Research Guidelines in Health Service Delivery

Criteria must be established to determine whether the research guidelines are applicable to DHEW direct-service programs or "capacity-building" programs.

We believe application of research guidelines to the delivery of health services could be justified only when the following criteria are met:

1. a problem exists which is relevant to that addressed by the research guideline;
2. no comparable safeguard exists; and
3. application or implementation of the research guidelines is feasible.

We conclude that all six of the research guidelines fail to meet one or more of the above criteria, as summarized below.

Criterion 1: Are the Research Guidelines Relevant to the Health Care Setting?

Health care and research differ markedly in purpose. Subjects may benefit by participation in research projects, but the main purpose is the anticipated benefit to future patients. This conflict of interest demands that safeguards be placed on subjects' rights. The central purpose of health care, however, is benefit to the individual patient. Although other purposes may be served as well, they are secondary to patient benefit.

Despite this basic difference, there are direct or indirect analogies in the health care setting to five of the six issues addressed by the research guidelines. Guidelines concerning "investigator competence" and "research design" translate into issues of provider competence and

quality of care. Guidelines setting out proper "identification of consequences," "informed consent," and "compensation for injuries" also have their counterparts.

Only "selection of subjects" addresses an issue that is irrelevant to the health care setting. This research guideline is intended to encourage more equitable distribution of the risks of research, the benefits of which will be shared by all. Potential recipients of DHEW health programs could be said to be "selected" by the policy makers who create the programs. They are "selected" as needing special government benefits. Unlike research subjects, however, they are not selected to assume risks that may or may not serve them. The risks inherent in standard therapy are assumed only when the expected benefit to the patient merits it. Furthermore, patients seek care as they perceive their own need. Providers of care do not instigate the delivery of services as investigators instigate research participation. For these reasons, we believe that the "selection" processes through which individuals become patients and research subjects are conceptually different and that this guideline cannot be properly or constructively applied to the health care setting.

Criterion 2: Are There Comparable Existent Safeguards in the Health Care Setting?

Conceptually, there are many similarities in the research guidelines and in the norms and legal standards presently governing the relationship between providers of medical care and their patients. The important question then becomes: Does application of the research guidelines and the procedures expected to implement them improve upon existent safeguards?

The guideline relating to "investigator competence" is analogous to provider quality which is regulated by the health profession and the government in a variety of ways.

The long tradition of exclusive self-regulation in medicine began to shift to state regulation of professional licensure beginning in New York in 1760.[10] Although the need for relicensure and more stringent oversight of practitioners is currently being considered, a highly organized and relatively standardized system exists to assure the quality of doctors, nurses, dentists, and other health professionals available to the American public.

Attempts to guarantee the quality of health care providers are focused at a variety of levels. Admission standards control acceptance to professional schools. Professional licensure is based on standards of education and testing requirements. Several states are currently considering the addition of mandatory continuing education and periodic relicensure of professionals. Censure or disciplinary action for unprofessional practice is carried out in accord with state and local laws. Peer representation on licensure boards is being supplemented with lay participation in some states, such as California. Criteria for granting hospital privileges provide additional controls, as do clinical practice review committees, activities of local medical societies, and informal referral practices.

Providers of services under federal grant support must meet all local standards for licensure. Members of the Commissioned Officers Corps of the PHS, however, are exempt from licensure requirements.[11]

The guideline relating to "research design" is roughly analogous to quality of care in health services. Here, a complex system of safeguards exists in therapeutic settings, including a tradition of collegial consulta-

tion and newer approaches such as medical audits and practice review mechanisms developed for Professional Standards Review Organizations (PSROs). Other innovations in this area can be expected as research into methods of quality assessment and monitoring suggest additional approaches to quality review. The malpractice system, intended to compensate patients injured through negligence, also acts as a quality incentive.

We conclude that the research guidelines relating to "investigator competence" and "research design" pertain to problems germane to health care delivery, but their application would not improve upon existent safeguards. Safeguards on the quality of providers and quality of care are in fact more standardized and explicit than the mechanisms of peer review prescribed for the research setting.

The research guidelines relating to "identification of consequences" and "informed consent" derive from similar standards in health care settings.

Patient consent is assumed in all therapy, although it has been documented primarily for surgical procedures which impose the greatest risks on patients. Recently, however, the doctrine of explicit informed consent has been extended to other therapies involving significant risk. Although the theoretical standard of consent to treatment began approximately 60 years ago, the emphasis on description of consequences and informed participation of patients in treatment decisions is a more recent phenomenon. Encouraged by malpractice law, there has been increasing emphasis on providing patients with adequate information on the consequences of therapy so that they are able to exercise informed discretion in treatment choices. The research norms dictating the nature of the interaction between subjects and investigators in regard to informed consent thus

address problems germane to the delivery of health services, but do not add to existing therapeutic practice.

The final research guideline involving "compensation for injury" has an obvious counterpart in the health care sector. Both private and public settings provide compensation for injury that results from the negligence of practitioners. Recipients of care in DHEW "capacity building" programs are provided redress through the private malpractice system. The government assumes liability for the direct provision of care by its employees in fulfillment of their official responsibilities. Under the Tort Claims Act and federal regulations, recipients of services in PHS or IHS hospitals and clinics or from National Health Service Corps providers are thought to have avenues of redress similar to those provided in the private system.

The theoretical basis and specific grounds for medical liability, however, differ from those in research injury compensation. Research subjects are to be compensated for damage from research participation regardless of the role of negligence in injury. Although there have been indications that the traditional need to prove negligence in malpractice claims is changing, negligence in some form remains the standard. The approach to compensation prescribed for the research setting is designed to balance the risk assumed by subjects. Much like the provision of pensions and other benefits for veterans, subjects are provided no-fault compensation for injuries sustained for the benefit of future patients. It is appropriate for research institutions to compensate the few subjects injured through participation in research projects. The situation in the health care setting differs in that each treatment is for the benefit of the individual patient. Response to accepted treatment cannot always be anticipated or successful results achieved for a variety of reasons.

To compensate all whose therapy has been unsuccessful would be inappropriate and financially impossible. Thus, although "compensation for injury" has its analogue in the health care setting, existent safeguards are more appropriate to health service delivery.

Criterion 3: Is It Possible to Implement and Administer the Research Guidelines in the Health Care Setting?

In Section II, we discussed general questions about government establishment and enforcement of national ethical guidelines governing the relationship between patient and private practitioner. We noted that questions of political philosophy must be addressed before imposing an extensive system of surveillance on the relationship between the patient and private practitioner. Questions regarding the government's ability to enforce standards were also raised.

Major questions or concerns arise in considering the procedures that would be required to implement the guidelines regarding "identification of consequences" and "informed consent." As noted in the preceding sections, these guidelines are clearly germane to the delivery of services and, in fact, have their basis in the ethical traditions of health service delivery. We noted that these research guidelines, therefore, fail to contribute to the ethical bases of health care delivery.

The procedures that would be necessary to implement these guidelines, however, do constitute a decided departure from health care practices. Through formal transmission of information and documentation of informed consent, the guidelines and their implementing procedures meet the criteria of relevance and improvement or enlargement upon existentsafeguards. However, strict application of the research procedures regarding "identification of consequences" and "informed consent" fail to meet the test of feasible implementation.

The goal of research is to limit the variation in procedures in order to measure cause and effect. Variation can be prescribed in a protocol and all relevant information formally summarized in a consent form. The volume of research consent forms is not prohibitive because a limited number of subjects participate in research.

Virtually all of the more than 200 million Americans, however, receive health services, and most receive services regularly. Many therapies involve a number of medical procedures. Strict application of the research procedures in this vast health care setting is infeasible for a variety of reasons.

First, the cost and inconvenience of a bureaucratic mechanism for documenting each exchange between health care recipients and providers could impose new ethical problems. Interference with emergency treatment and therapy needed by impaired patients could deny or delay access to care. Such surveillance would impinge on the confidentiality of the therapeutic relationship as well as significantly increase the cost of care.

Second, the bureaucratic structure and information transmission and storage system required to document consequences and informed consent in all therapeutic choices surpass present technology.

Finally, even if ethical, economic, bureaucratic, and technical problems could be resolved, the knowledge base is not available for development of widely accepted protocols for most therapeutic decisions. Even where therapeutic regimens are established, patient differences frequently require variation to relate care to special needs. Thus, application of the research procedures regarding "identification of consequences" and "informed consent" fails to satisfy the final criterion of feasibility on economic, bureaucratic, and scientific grounds.[12]

Section IV

Are There Problems to be Solved in the Health Care Setting?

With the exception of the guidelines concerning "selection of subjects", we believe the research guidelines address problems relevant to problems in the therapeutic setting. However, we concluded that these problems are more appropriately addressed by existent safeguards and that implementing procedures for the "identification of consequences" and "informal consent" guidelines could not be applied in the health care setting. This conclusion is not meant to imply that patients' rights are never compromised in DHEW health programs. Potential sources of abuse exist and remedies should be sought.

The federal role in health care delivery has grown significantly during the last two decades. Safeguards utilizing the research approach, particularly regarding "identification of consequences" and "informed consent," would significantly expand the federal role in health service delivery. We believe such a major extension of federal responsibility in prescribing and monitoring specific details of therapeutic relationships to be premature. Many opportunities for improvement in patient protections are available within the present purview of federal policy. Patients can be provided more power to control the DHEW programs that serve them. Further increases in appropriations and other program changes can improve the quality of providers and services available.

Questions that can be raised in response to our conclusion highlight persistent ethical problems in health care delivery and possible solutions that are available within present policy approaches.

> Question Number 1:
> Research safeguards are necessary because of the conflict between the subject's interest in avoiding risk and the need to impose risk to advance knowledge. Do provider or public interests also exist that may compete with the interests of individual health care recipients and require the institution of special safeguards?

Although health practitioners are professionally bound to serve their patients' interests, other motivations can influence therapeutic decisions. In any delivery system, competing interests are diverse, hard to predict or infer, and individual decisions impossible to control. Economic interests are inevitable. Fee-for-service remuneration can encourage the delivery of unneeded services. The reverse incentives can encourage limitations on care in Health Maintenance Organizations.

Nonmonetary provider interests can also be factors in decision making. Heavy use of tranquilizers can lessen the stress on ward personnel in mental hospitals. Care delivered in teaching hospitals often imposes burdens on patients in order to educate future professionals.

Perceived public or social interests can also influence therapeutic decisions. From the kidney donation that serves the interests of another individual to the indirect societal benefits derived from immunization, psychosurgery, or sterilization, complex motivations can compete with individual patient interest.

It seems reasonable to suggest that research guidelines be applied to the class of treatments serving broader public or social interests, described by Levine as "practice for the benefit of others." Much like the conflicting purposes that require research regulation, indications for these therapies often include purposes other than direct patient needs.

We believe, however, that treating these therapies as a class through application of a given set of guidelines is not advisable. Almost all therapies serve diverse interests. Implementing this approach would require identifying those therapies that impose a sufficient conflict between patient and

other interests to merit special safeguards. Such a categorical approach to regulation would permit continual reevaluation of the therapies to be included and could encourage unnecessary or counterproductive extension of the concept.

Furthermore, the patient groups and ethical problems in therapies classified as "practice for the benefit of others" are sufficiently different to require unique safeguards. In addition, categorical extension of safeguards to most of the therapies cited as examples would be redundant because of recent developments. Procedures for sterilization have been carefully reviewed and stringent guidelines developed. The Commission itself has explored issues in psychosurgery. The swine flu program is currently provoking consideration of the important issues surrounding immunization programs. State legislatures, through brain death and anatomical gift acts, and professionals, through elaborate testing and review procedures, have developed safeguards against abuse of the rights of organ donors. We thus conclude that little would be gained and considerable risk assumed through categorical extension of controls on "practice for the benefit of others."

It is conceivable, however, that special conditions of DHEW practice could impose unique conflicting interests leading to abuse of patient rights. The institutional allegiance that practitioners accord their employer could impose conflicts of interest similar to those sometimes seen in occupational medicine. Policies involving the subtle abuse of the rights of recipients could be developed and employees could be required to act against their concept of patient interest.

Governmental authority, however, is delegated on the good faith assumption that officials act in the public interest. Although conceptions of that interest vary and policies can be established that compromise strict patient interests, such abuse is a product of the legislative or executive policy process. The research approach, which focuses on individual interactions, would be ineffective in assuring that policy goals do not compromise the rights of patients in DHEW programs.

Question Number 2:
Do the questions of quality of providers and care addressed by the research guidelines as "investigator competence" and "research design" present problems requiring special safeguards in DHEW health care settings?

Most direct provision and "capacity building" health service programs are designed to fill needs that are inadequately addressed through the private health care system. Because of physical isolation or a limited economic base, private practitioners have not been attracted to meet the needs of recipient groups.

Questions can be raised regarding the success of these programs in providing recipients with the quality of health care providers and range of services generally available to private health care recipients. Such problems, however, can be addressed effectively within the present purview of federal policy. The government has recently sought through financial and other inducements to increase its competitive advantage in attracting qualified practitioners. Progress appears to have been made toward equalizing the quality of practitioners in public and private systems.

The range of services provided in isolated hospitals and clinics serving small populations is inevitably limited by cost-effectiveness considerations.

Although most programs have contingency plans for referral of patients to larger centers or to private practitioners for specialized services, the discrepancy between the therapeutic options available to private and public health care recipients is often pronounced. Once again, improvement in the quality of care available to recipients of care in DHEW programs can be better achieved through existent policy channels than through application of the research guidelines.

Question Number 3:
Does the lack of other sources of health services impose a special vulnerability on many recipients of DHEW health services that necessitates protection of patient rights?

The isolated settings of many DHEW health programs and the limited financial resources of recipients clearly make many of these recipients dependent on the public programs for needed health services. With no other place to go, recipients cannot express displeasure by seeking care elsewhere. It must be acknowledged that most programs were created expressly due to the lack of health care options. It is incumbent on policy makers to acknowledge the vulnerability of recipients and build into these programs mechanisms to enhance the role of recipients in the decisions that determine the quality and conditions of service. "Capacity-building" programs under grant support have begun to encourage a greater consumer role in project planning, policy making, and provision of services. Recent legislation has made consumer majorities on governing boards of Community Health, Community Mental Health, and Migrant Health Centers mandatory. The IHS, under a policy of "self-determination," now allows Indians to assume total responsibility for operation of IHS facilities.

Question Number 4:
Do the language and cultural characteristics of many of the recipients of DHEW programs impose additional vulnerabilities which require special safeguards against abuse of patient rights?

Language and cultural impediments to full patient participation in treatment decisions do present opportunities for inadvertent or intentional abuse. Limits on the ability of non-English speaking health care recipients on Indian reservations, in migrant camps, and elsewhere to understand the consequences of therapeutic decisions present problems similar to those encountered in research on children or mental incompetents. In both research and therapy, advocates or guardians of these vulnerable groups are required to participate in treatment decisions. Similarly, translators or "cultural brokers" may be required in DHEW health care settings to protect the rights of patients whose ability to participate actively in therapeutic choices is limited. It is difficult to identify the instances where the cost of providing such services is warranted by the magnitude of the problem. We conclude that mechanisms to enhance the role of recipients in program design will be more effective in establishing the need for special safeguards than will mandatory bilingual consent forms or other outgrowths of the research approach.

These questions are intended to stimulate discussion. Possible sources of compromise of the rights of patients in DHEW programs merit careful consideration by policy makers and health care professionals. We believe, however, they are not amenable to the research approach which concentrates on third-party oversight of individual interactions. Protection of patients' rights in DHEW programs derives largely from decisions made at the level of program design. We conclude that the provision of adequate resources and encouragement

of patient participation in program decisions represent a more effective approach to protecting patient rights than an outgrowth of the research guidelines.

Section V
Points for Consideration in a Broader Inquiry into the Ethics of Health Service Delivery

The analysis in the preceding sections is responsive to the Congressional mandate to determine the advisability of applying research principles and guidelines to the delivery of DHEW health services. It is our opinion that if Congress wished the Commission to explore the need for additional safeguards on the rights of health care recipients, its charge to the Commission would have stated this explicitly.

As the Commission has found, the issues and problems in research are numerous and complex. However, the ethical questions that relate to the health care delivery system are considerably more so.

We believe an exploration of the ethical bases for the delivery of health services would require consideration of at least five distinct sets of questions.

First, the boundaries of the subject would have to be defined.

Should "health services" be defined to include health promotion activities, such as health education? Should health protection programs aimed at control of environmental hazards be included? Or should "health services" be defined more narrowly to include only the delivery of personal medical care? If so, should the inquiry into the ethics of health service delivery consider policy areas such as tax, transportion, and income supplementation which affect access to such services?

Within the narrower arena of health service delivery, still other choices would have to be made. The inquiry could focus on all health service

delivery or could explore ethical issues within a subset of the system. Care delivered by private practitioners might be excluded and the inquiry further limited to specific patient groups or the beneficiaries of specified federal programs. The investigation could also concentrate on certain services or medical procedures, as suggested by Levine. Complex ethical issues are inherent in these decisions. The appropriateness of various choices would have to be carefully considered.

The second set of questions would involve value considerations regarding the organizational structure and norms of conduct that would be required of the health care system to promote adherence to the principles of justice, beneficence, and respect for persons.

Issues suggested by analogies to the research guidelines might include determination of what standard of quality of practitioners and service constitutes adequate adherence to principles of respect and beneficence. Complex questions regarding patients' rights to compensation for injury would have to be explored, including the results that can be realistically expected from medicine, current trends within malpractice law, the norms for translation of injury into monetary terms, and the ability of insurance or other systems to finance compensation. Issues regarding the information required for knowledgeable participation of patients in treatment choices would have to be considered as well. Limits on the ability and desire of health care recipients to understand the scientific basis for complex medical decisions and the placebo effect, which highlights the non-scientific aspects of the therapeutic relationship, would also have to be taken into account.

It is also important to note that some of the critical ethical issues encountered in health service delivery have no analogues in the research setting. For example, does our societal notion of distributive justice require institution of national health insurance? Should the wealthy be permitted to purchase services not available to everyone?

Professionals, ethicists and policy makers have been exploring such issues for many years.[13] Societal values are fluid. Final consensus regarding health care practices that adequately reflect our ideas of respect, beneficence, and justice will never be achieved. Nevertheless, innovations in the system of protections on the rights of health care recipients should be based on at least the provisional notions of how societal values should be reflected in the health care system.

The third set of issues involves a factual inquiry into the nature of the present health care system and the effectiveness of safeguards on the rights of patients. The health care system is currently in a period of rapid change. Malpractice, quality control under PSROs, expanded efforts in health planning, and continuing debate over national health insurance represent just a few areas undergoing intense change. A large body of research is assessing these changes and building a knowledge base for future modification of the system. Any intervention aimed at protecting patients' rights must take these changes into consideration. A review of current literature would be required along with some original research into areas of special concern, such as the nature and impact of present informed consent practices and differences in the quality of care and ethical safeguards available to various population groups.

Fourth, standards required to assure adherence to the ethical principles of justice, beneficence, and respect would have to be compared to the effectiveness of existent safeguards in order to determine whether additional protections or other changes in the health care system are needed.

Finally, if innovations are indicated, a proper policy approach must be chosen. The appropriate role of government must be considered. A complex surveillance system would raise serious questions of cost, efficiency, and privacy. Short of such a system, guidelines or standards could be set out without an extensive enforcement mechanism, as in the securities market. The "institutional assurance" model might also be considered, although the "cottage" nature of ambulatory care delivery could significantly compromise this approach.

The issues outlined above are illustrative of the nuances of philosophic and factual inquiry we believe would be required to address the ethical bases for health care delivery. Our health care system and the protections for recipients of its services have been evolving for centuries. Even the smallest innovation in this complex system can have major consequences, often in areas where least expected.

It is not our responsibility to determine whether the Commission or some other body should undertake this task. It was our goal to express clearly why we believe application of the research guidelines in the health care setting would be inappropriate and to illustrate the complex issues involved in a comprehensive inquiry into the ethics of health care delivery.

Footnotes

1. Public Law 93-348.

2. See Lawrence R. Tancredi, ed., Ethics of Health Care (Washington, D.C.: National Academy of Sciences, 1974) and Robert Veatch, ed., Ethics and Health Policy (Cambridge, Massachusetts: Ballinger Publishing Company, 1976).

3. Department of Health, Education and Welfare, Health - United States 1975, pp. 307 and 293.

4. For example, HPP Discussion Paper on "Biomedical Experimentation on Prisoners..." and series on "Health Care Delivery" for the Encyclopedia of Bioethics (publication pending).

5. Bob Levine, "On the Relevancy of Ethical Principles and Guidelines Developed for Research to Health Services Conducted or Supported by the Secretary, Department of Health, Education and Welfare," (May 28, 1976).

6. National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, "Belmont Manifesto," (draft; June 3, 1976).

7. Office of Management and Budget, Special Analyses -- Budget of the United States Government -- Fiscal Year 1977, U.S. Government Printing Office, p. 192.

8. Department of Health, Education and Welfare -- Public Health Service, Forward Plan for Health, FY 197882, U.S. Government Printing Office, (August 1976), p. 41.

9. In a recent case, U.S. vs. Joseph V. Orleans, et al., the Supreme Court held that the question of grantor liability did not hinge on whether an Office of Economic Opportunity agency "receives federal money and must comply with federal standards and regulations, but whether its daily operations are supervised by the Federal Government."

   See also the Code of Federal Regulations, Title 45, Subtitle A, Part 35 and Title 28, Part 14.

10. Jeffrey Lionel Berlant, Profession and Monopoly -- A Study of Medicine in the United States and Great Britain, (Berkeley: University of California Press, 1975), p. 197.

11. Phone communication with Mr. Phillip Needle, Executive Secretary, Employee Operations Branch, Commissioned Corps Operations Division, Public Health Service.

12. See Levine's comments regarding "the perils of overregulation," p. 25.

13. Karen Davis, National Health Insurance: Benefits, Costs and Consequences, (Washington, D.C.: The Brookings Institution, 1976) and footnote 2 above.

4

THE RELEVANCE OF ETHICAL PRINCIPLES AND NORMS DEVELOPED FOR THE CONDUCT OF RESEARCH TO THE DELIVERY OF HEALTH SERVICES SUPPORTED BY THE SECRETARY, DHEW

John Fletcher, Ph.D.

The Relevance of Ethical Principles and Norms Developed for the Conduct of Research to the Delivery of Health Services Supported by the Secretary, DHEW

The National Commission for the Protection of Human Subjects of Biomedical and Behavior Research requested an essay to assist its deliberation under section 202 (a) (1) (B) (i) of the National Research Act: "to 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 essay should 'pay critical attention to the morally relevant differences and similarities between research and practice, and, between health care delivered under auspices of the Secretary and that delivered in the private sector."

I. INTRODUCTION: WHAT KIND OF QUESTION DID CONGRESS ASK?

What does the charge mean "to consider the appropriateness, etc.?" Appropriateness raises the question as to whether it is fitting or proper to take a proposed action. This can be taken to mean: would it work administratively or institutionally? Can principles and procedures designed for the ethical oversight of research really work in the institutional settings of medical care? Will the desired results be produced? It will later be argued that to give the institutional administrative point of view first priority in evaluating the issues does not do justice to the question posed by Congress.

To ask about appropriateness can also mean "is it right?" in ethical terms to apply ethical principles and guidelines generated by the

Commission (under its research charge) to health service programs? The most common ethical question concerns the rightness of a proposed action, as Toulmin noted.[1] Is the moral code that governs research the fitting code for medical care? Can the proposed step be justified by the best reasons, i.e., moral reasons?

Further, reflection on the issues raises the question whether there is a conflict of duties inherent in the notion that what one should do towards subjects in the research setting should also be done in the setting of health service programs. The two situations may be sufficiently different as to require differing definitions of moral duties. On the other hand, it may be found that the situations are sufficiently similar to warrant a unified moral approach to subjects and patients. In short, a true or false conflict of moral duties may need to be clarified and resolved.

Finally, the question of appropriateness can also mean that it may be inappropriate (unfitting, improper, wrong) for the government to continue pressing the research setting for the development of rigorous ethical oversight and to neglect to reform the quality of oversight of publically-supported health service programs. Since 1966, with the appearance of requirements for review to insure the rights and welfare of individuals in clinical research,[2] a significant governmental effort has been made to develop knowledge and techniques to minimize harm for human subjects. When one contrasts the rigor with which government addresses the ethics of research with continued reliance on an ethic of physician self-regulation in the conduct of health service programs,

the conclusion follows that there is an unfair discrepancy. The social practice needs to be changed of reliance on self-regulation by physicians to assure competence and responsible professional behavior. Changing an existing social practice raises ethical questions.

The thesis of this paper is that if one takes the moral point of view on the issues,[3] that is, if moral reasons justify taking the step, it follows that the Belmont draft principles developed for research can be constructively applied to health service programs. It will be argued that this step is justified in relation to medical care in health service programs. Further, it is shown that although the moral obligations that govern practice and research are highly similar, there are sufficient and morally relevant differences in purpose and priority to distinguish research obligations from medical obligations. A less important facet of the thesis is that even though some of the guidelines developed for research are relevant to analogous problems in health service programs, as demonstrated by Levine,[4] these guidelines should not be taken as literal points of departure for proposed regulations in the programs under study. In conclusion, the shortcomings of giving priority to the institutional-administrative point of view on the issues will be summarized.

II. WHAT ARE THE MORAL PROBLEMS AND THE MORAL OBLIGATIONS IN MEDICAL CARE?

Any complete ethical analysis ought to proceed only on a careful assessment of the facts of the case. Levine reported that alarm about four types of cases (Tuskegee syphilis study, Depo-Provera, DES, and

sterilization of the Relf sisters) probably moved Congress to request a review of applicability of research principles (p. 3). However, Congress asked that the context of review be "delivery of health services conducted or supported by the Secretary." The University of California's Health Policy Group categorized the services in three types of programs: direct-provision, capacity-building, and those that pay for private or state-provided services.[5]

No empirically reliable knowledge base exists that describes the actual shape of moral problems in these large and varied programs that encompass every dimension of medical care from prevention to treatment. Much is known about moral problems in medical care in the United States, but little is known if one wants to compare moral experience in the private sector with that in publically-supported programs. One could hypothesize that the moral problems that do exist in American medical care are experienced more frequently and to a higher degree of unremedied abuse in many of the populations served by service programs, because these populations are poor, members of minority groups, who live in medically disadvantaged areas.[6] It should be of concern to the Commission that empirical studies are lacking in this area.

The lack of a reliable knowledge base does not deter a <u>formal</u> analysis of the relevance of the Belmont draft principles to <u>types</u> of moral problems in medical care. A more complete analysis, particularly one that recommended specific remedies or regulations, should be based on reliable facts. The author favors the recommendations made by David Mechanic[7] as prudent interventions in the light of the lack of knowledge.

There are two types of moral problems in general: a) acts that violate the rights of persons and the moral rules of communities that have sanctions for these violations, and b) conflicts of moral obligations within an individual or a community that require resolution as to which obligation takes priority.

The language of "rights" is widely used today to frame the context of moral obligations.[8] A typology follows that focuses on moral problems in which the rights of patients in medical care are violated. Problems are arranged under five widely recognized rights of the patient in medical care. The moral conflicts, as well as the rights, of physicians as persons and professionals should be included for the fullest discussion of the morality of medical care. However, the intent of Congress was clearly upon the rights of patients in health service programs. Also, space considerations limit description to patients and also holds description to the minimum.

A. The Right to Know

1) Patient or representative of patient not informed about patient rights or responsibilities

2) Knowledge of current information on diagnosis, treatment, and prognosis of medical problem is withheld from patient or his/her representative

3) Knowledge is transmitted in terms or language patient has no basis for understanding

4) Name of responsible physician withheld

5) Procedure or treatment begun prior to communication of information about same, except in cases of emergencies

6) Patient not informed about relevant consequences of procedures or treatment

7) Patient not informed about significant alternative procedures or treatment

8) Patient not informed about post-discharge health requirements

B. The Right To Be Free

1) Patient is coerced into treatment or procedure (e.g., sterilization, abortion

2) Patient is involuntarily committed to an institution without due process or means of review

3) Patient's (legally defined) right to refuse treatment is denied

C. The Right to Life

1) Patient is exploited or dies through physician intent (e.g., sexual abuse, fraud, active euthanasia)

2) Patient injured or dies due to physician neglect, incompetence, or abandonment

3) Patient injured by research not bearing on treatment

4) Patient's life is sustained artificially far beyond the point of any rational basis for recovery

D. The Right to Privacy

1) Confidentiality of patient's medical records or medical history broken without consent

2) Patient made frequent or unknowing subject for teaching, consultation, or examination by physicians uninvolved with case

E. The Right of Equal Access to Health Care

1) Patient discriminated against in access to care because of race, sex, religion, or stigmatized identity

2) Patient denied medically preferred alternative treatment because of conditions named in E. 1)

3) Patient denied emergency treatment due to not meeting hospital financial eligibility criteria

These moral problems presuppose broken obligations under the always evolving medical morality[9] that should govern the conduct of physicians towards patients in this society. The central cluster of obligations includes at least the following: the physician is obligated to inform the patient truthfully about diagnosis, treatment, and prognosis, 2) to seek the patient's consent to treatment and each significant procedure or step within treatment, 3) to preserve the life and well-being of the individual patient, 4) to maintain confidentiality in the physician-patient relationship, and 5) to treat patients equally on the basis of need.

There are other obligations of a moral nature that govern the relations of physicians to one another and to society. There are moral obligations of society towards physicians and patients. Also, there are yet-evolving obligations governing society's responsibility to promote equality in health care. These obligations develop in the press of the conflict and competition of the goals and desires of patients, physicians and the society that grants the physician and patient a special status in the social order. These obligations form the "constituted morality"[10] governing the interactions of patients, physicians and society in medical

care. There are sanctions legally and morally for violations of these obligations.

The constituted morality of communities or specific groups within communities are applications of more general moral rules that are based on the convictions and beliefs of the members of the society. Moral rules are judgments of principle stated either positively or negatively that are meant to apply to everyone and that function to "yield reasons which overrule the reasons of self-interest in cases when everyone's following self-interest would be harmful to everyone."[11] For example, the physician's obligation to inform the patient truthfully is an application of the general moral rule "tell the truth" - or "it is wrong to lie." The physician who lies or withholds necessary information for reasons of self-interest, e.g., for fear of being sued, not only violates a defined obligation within medical morality, but if the act were to be followed by everyone in like cases, it could clearly be shown to be harmful to everyone, and as such the act violates a moral rule.

As one moves from the broken obligations that produce the moral problems described earlier to a review of moral rules such as "killing is wrong," "harming others is wrong," "misusing social institutions is wrong," or "help others in need," "be fair," etc., medical morality can clearly be understood as application of the moral rules of this society. The understanding of moral rule used here is that the recognized exceptions to a rule are also contained in the rule, e.g., "killing is wrong, except in self-defense, etc."[12]

III. THE FUNCTIONS OF ETHICAL PRINCIPLES

Before discussion of the relevance of the Belmont draft principles, a brief analysis of the functions of ethical principles is necessary. There are three functions of ethical principles such as justice, respect for persons, beneficience, etc. First, they furnish to society ideals for critical appraisal of moral rules and the moralities of specific groups. Morality, like other human institutions, requires repair and improvement, especially in times of rapid social change. It may have been for just such a reason that Congress perceived that the current moral practices of physicians are not adequate for the complex needs of patients in health service programs.

Secondly, ethical principles furnish to society the grounds for justifying and validating the moral rules and for following the moral obligations embodied in applications of the rules. Moral rules tell us what to do in specific situations, but they do not tell us <u>why</u> the rules are valid. Nor do they tell us what to do in cases of conflict of rules that produce great moral suffering. Ethical principles furnish a higher social authority to refer questions about why one ought to act in a certain way or what to do in cases of conflict. It is considered wrong in this society to answer such questions with "well, because the rules say so," or in conflict of rule cases to refer only to one's own situational self-interest for a resolution. It is also wrong in conflict of rules cases to refer to some supra-moral authority ("God told me to do it," or "the devil told me to do it"). Ethical principles provide higher standards

to which we can appeal for reasons to back up and explain the moral reasons taught in our moralities.

Thirdly, ethical principles have a symbolic function, because as ideal concepts, they point beyond themselves to the cooperation and reciprocity that are required for the social purpose of morality to be achieved: i.e., the resolution of conflicts of interest and desires. To be moral at all, that is to overrule self-interest in cases where following it would harm others, requires that one be able to "reverse" roles in behavior and imagine what it is like to be at the "giving and receiving end of particular actions."[13] Reciprocity, the ability to give and take mutually, presumes that one can imagine the self in the other's place. Moral rules do not of themselves furnish the motivation to reciprocate. As ideal constructs, ethical principles do not furnish the self-respect or respect for others that is the presupposition of morality.[14] Thus do ethical principles point beyond themselves to sources of an "ethical spirit" that shapes attitudes of self-respect and respect for others that must be internalized in the person. The sources of inspiration are many, referred to as "post-ethical" or "meta-ethical" framework of belief about the world, human destiny, and the meaning of human existence. Because there are many and varied belief systems in a pluralistic society that influence the shaping and selection of ideal ethical principles, there is need for a "common ground" on which persons of differing beliefs can stand to cooperate in the practical tasks of reasoning about the great and small issues of moral conflict. Following the next section,

the discussion will return to the concept of a "common ground" as a social-ethical contract.

IV. THE RELEVANCE OF ETHICAL PRINCIPLES DEVELOPED FOR RESEARCH

The following reasons are offered for the relevance to medical care of the ethical principles developed for the conduct of research: these principles (respect for persons, beneficence, and justice) a) are the major sources of ideals for consideration of a change of social practice in the ethical oversight of health service programs, b) are the proper sources of appeal when medical obligations are in conflict, or when medical obligations are in conflict with obligations owed in the research setting, and c) point to the grounds for deferring any reasons of self-interest for continuing the status quo in the conduct and oversight of health service programs to the larger interests of the common good that may be served in adopting these principles as a social-ethical contract for reforming practices on the basis of the well-considered facts of the case. In short, it is claimed that these ethical principles are constitutive[15] for the morality of medical care in general and for the conduct of health service programs in particular. The argument attempts to show that the principles will fulfil their intended functions for the problem under study.

A. The Major Sources of Ideals

As the facts are gathered in a reliable comparison of moral experience in DHEW-supported health service programs with the private sector, the similarities and differences will be compared in the light

of some ideal or cluster of ideals. People of good will have a choice as to which ideal principles will shape the criteria for relevance in making ethical judgments about the meaning of comparisons. The private and the publically-supported spheres of medical care can be compared strictly in terms of one principle like justice, respect for persons or utility. According to the principle of utility, the proper purpose of any policy is to bring about the greatest balance of good over evil in the world. Utility conveys the notion that good and evil consequences should be stated in non-moral terms, be measured, and then balanced against one another in a quantitative comparison.[16] In the light of this ideal, one might well decide that the only morally relevant difference between private and publically-supported medical care was the total sum of measurable health benefits for individuals that resulted from one system as compared with the other. Ethical questions about the means to the end would not be of central interest and thus not truly worthy of analysis. One would even be predisposed to accept some losses in strict observance of moral obligations to achieve the highest sum of health benefits. For example, if it could be shown that the physician time required to seek informed consent from patients served in health service programs seriously reduced the availability of physician services to the total number of patients to be served, it follows that a minimalist approach to informed consent should be the rule.

From the ideal of personhood one should single out as the morally relevant difference between private and publically-supported medical care the degree of freedom and autonomy afforded the individual in the choices

of patients and physicians. Measuring freedom and autonomy are impossible. What one accepts as evidence are tendencies in the means used in different programs. Any tendency that reduces autonomy in favor of strict utility or coercion should be resisted. In fact, one would be predisposed to accept losses in a potentially greater sum of health benefits in order to protect individual freedom and autonomy.

In many modern debates of medical policy and practice, these two principles are juxtaposed in conflict and debate proceeds in polarized modes while practical moral problems need resolution.[17] The ethic of physician self-regulation, long tied to the ideal of respect for the individual welfare of the patient, is suspect from the standpoint of the insularity of the medical profession and its tendency not to regulate its members with rigor.[18] The arguments from utility are equally suspect in an era of increasing emphasis on human rights and loss of confidence in bearers of scientific expertise.

A strength of the Belmont draft principles is that they present a more complex and balanced system of ideals from which to consider the problem at hand as well as other major issues in the total system of health care. The three principles add richness to the considerations that one or even two do not. The moral problems of the patient, as described earlier, should be understood as part of a system of moral problems existing within the total system of medical care. Any change of social practice in the ethical oversight of health service programs will have effects on the whole health care system, and needs to be morally justified. Would a deliberate change be to the better and in the interest of all?

Let us suppose that careful and empirical comparison of patients and their experience in private care and DHEW supported health programs showed that patients in the latter group enjoyed significantly fewer health benefits and also showed statistically higher violations of the five rights listed in an earlier section. Would not these data be sufficient to appeal, on grounds of simple justice and respect for persons, for a change in ethical oversight of health service programs? The caution about "excessive" regulation in papers by Mechanic and Levine possibly reflects concern that intervention by rule-making will make a bad situation worse by demoralizing physicians and officials responsible in these situations. The issue, however, is not only the interest of physicians' good but the good of all concerned. Will shifting the locus of responsibility for ethical oversight of service programs bring about more good than bad results? Will this step restrain tendencies that violate rights and reduce direct health benefits? In short, the proposed step would need to be justified in all of its major features in the light of the ideal of beneficence, which states that we ought to do good and prevent harm.

Beneficence is a complex principle which is treated in the Belmont draft as containing the principle of utility in one of its dimensions. In its other dimensions, beneficence states that we are required to do or promote good and to avoid or remove harm. The ideal of beneficence is to do good and not to do any harm[19] rather than just to balance off a greater amount of good than harm. Ideally, improving the ethical oversight of

health service programs ought not do any harm, but we know that every practical intervention does carry risk of harm, and that utility would eventually figure in any concrete changes in the system of ethical oversight.

The principles of justice and respect for persons also furnish the proper sources of ideals for consideration of changing the practice. For the most just distribution of the goods to be brought about through reform of practices of ethical oversight, a new system should be organized to be as equally beneficial to disadvantaged patients as possible. Also, a system of just distribution of responsibilities and remedies for abuse would have to be designed. Equal treatment of the responsible physicians who work in health service programs would be a relevant ideal, as well as a fair system of punishment for those found in violation of the rules. Further, any alternative to the present system would need to approximate the ideal of personhood in respect to the autonomy and freedom of physicians and patients. Coercive tendencies should be absent or at the least possible minimum.

A much more complete analysis of these three principles would be required to complete the discussion of their adequacy to provide ideals for consideration of changing present practices. It is hoped that this preliminary discussion shows that the direction is promising.

B. Principles as Sources of Appeals

1. Validation

Knowing one's obligations is one thing, wanting to carry them out is another. Occasions arise in medical conduct when physicians ask "why should I follow this rule?" or "why should I respond to a so-called right?" On these occasions, ethical principles serve to validate the obligation by backing up the general moral rule from which the particular obligation is derived. The need for validation assumes the kind of situation in which the questioner stands to gain personally by neglecting important obligations to others. The function of validation is to clarify the ethical perspective, so that the specific obligations are related to a compelling and universal social good. Reasons derived from ethical principles ought to validate the reasons furnished by medical morality unless the physician wants to ask "why should I be moral at all?" From this question we can only refer the questioner to beliefs about the nature of morality itself. Validation of obligations under question is a different procedure than the justification of morality, however, and it is the former that occupies us here. The claim is that the Belmont draft principles are relevant sources of validation for physician obligations to patients, including those in health service programs.

A brief review of the obligations stated earlier will set the direction of the argument. First, when obligations to inform the patient truthfully and to seek consent for treatment are in question, the answer is to refer to respect for persons. To withhold the truth or alternatives

for choice, without an overriding moral reason, demeans the autonomy and freedom of the other person. Secondly, the obligations ought to be fulfilled to promote the good of the patient and to prevent the harm that can come from ignorance. Uninformed and unconsenting patients cannot cooperate in their own treatment.

The obligation to preserve the life and well-being of the patient is validated by both the principles of beneficence and respect for persons. Prevention of death and reduction of suffering are the specific means of avoiding harm, but these means should be viewed under the more primary imperative to restore the patient to the pursuit of the goods of his life-plan. Yet, not simply any means of treatment or palliation should be chosen, since each person has a unique history and a particular capacity to respond to treatment. Respect for the person should condition choices of treatment.

The obligation to maintain confidentiality, when questioned, can be validated by beneficence and personhood in varying degrees of force. The avoidance of harm to a patient is the primary validation of the bond of confidentiality, in that others may act on knowledge of medical facts to penalize the patient. For example, an employer who does not know the difference between sickle cell trait and sickle cell disease may dismiss a carrier identified in mass screening projects, if confidentiality is broken between physician-screener and patient. Respect for the patient's personhood is relevant in that the physician owes confidentiality to a particular individual who has consented to the patient-physician agreement.

Finally, the obligation to treat patients equally on the basis of need is validated primarily by the principle of justice that requires that the physician distribute his knowledge, time, and skill as fairly as possible to the persons who depend upon those goods. There are varying concepts of the fairest means to do justice[20] that can each be used to validate particular choices.

2. In Cases of Conflict of Obligations

Occasions frequently arise in which two or more obligations conflict in the same situation. Should a patient with a pre-existing heart condition be fully informed about the newly diagnosed presence of cancer? Is it right to admit alcoholics or chronic smokers to preferred alternatives for treatment that will be less unavailable to deserving others? When moral uncertainty is added to the normal ambiguities and doubts of decision-making, the decision-maker suffers more. One of the purposes of ethics is to aid in the resolution of dilemmas of moral conflict by evaluating alternatives in the light of ethical principles. In such cases, one ought to clarify the facts of the conflict and then weigh the obligations in reference to ethical principles. The function of ethical principles is to provide relevant standards for ordering priorities of obligations.

A more extensive discussion would show that each of the three principles is relevant in varying degrees of force to the resolution of typical moral conflicts in the practice of medicine. At this point, it should be noted that obligations in medical care can be in conflict with obligations in research if both are proceeding in the same patient. The morally

relevant similarities and differences between research and practice can best be analyzed in cases of conflict.

The differing purposes of the two activities constitutes a morally relevant difference that ought to be weighed in conflict situations. The purpose of practice, when viewed from the standpoint of the individual patient, is to decrease symptoms or pathology in a specific individual whose health problem should be considered in the context of multiple relationships. In practice the physician does something "for" another. The purpose of research is to obtain knowledge, and the investigator does something "to" another. Both purposes are morally justified, in that the increase of the good of individuals and society is the undergirding reason for both practice and research.

Which of the two purposes has priority in case of conflict? Non-therapeutic research in sick patients provides the clearest case of conflict. The knowledge gained will not directly benefit the patient. When pursuit of knowledge conflicts with the goal of treatment a higher priority should be given to treatment in a system of values where respect for persons outweighs collective interests in such cases. On the other hand, if research needs to be done with a therapeutic intent, perhaps to save the patient's life, then the purpose of research takes priority over existing treatment. To fail to do research in such cases would be to choose the wrong priorities. Thus, the specific moral relevance of the different goals of research and practice depend upon the circumstances and the actual shape of the conflict. The good of the individual person should take precedence in cases of conflict, except in the event of a disaster where the survival of the society itself takes priority.

The activities of physicians and investigators also constitute morally relevant differences. Selection of subjects for research involves a different set of procedures and intentions than selection of patients for treatment. The interests of the investigator in the knowledge to be obtained take priority in research. The needs of the patient take priority in treatment. The moral relevance of the differences in activities applies mainly in cases where the activities are combined in the same physician-investigator and multiple conflicts of interest arise. If a physician's patients are participating in a randomized clinical trial of which he is the principal investigator, conflicts arise in which the physician-investigator must choose between which activities ought to be pursued. Once again, the conflict should be resolved by evaluating the weight of obligations in the light of ethical principles. The well-being of the patient takes priority as well as the activity of the physician.

The moral obligations that govern the conduct of investigators towards subjects have certain similarities to those of the physician towards the patient, as shown in the Levine paper. The major similarity is the consent obligation with both major features to inform truthfully and obtain consent. Obligation to select subjects in such a way as to distribute fairly the burdens and benefits of research is also similar to the obligation to treat patients equally on the basis of need. Confidentiality of the data in research, to the degree agreed upon, is similar to the confidentiality obligation in practice.

Suppose Congress had asked the ethical question somewhat more explicitly: "Should one do unto those in the research setting what one would want done unto him in treatment? Are the moral obligations similar enough to be approached uniformly? Or are the moral obligations sufficiently different to constitute two types of applied morality from the same general principles?" The answer is that some of the obligations that apply in the research setting apply in treatment and vice-versa. Yet, it would be self-defeating and morally impossible to make a rule that what one ought to do in treatment ought always to be done in research and vice-versa.[21]

To do so would defeat the order of values in the society. The life and well-being of the patient points to a higher value, in the hierarchy of values of this society, than science. To promote the good of the individual and society, specifically in terms of health, is a condition of science. Science is one means of achieving this higher good, but unless it is actively applied to benefit the individual and society a lower value tends to supplant the higher good.

For this reason, medical obligations and research obligations ought to be taught as applied from the same general set of moral rules that are structured by the functions of the same set of ethical principles. Yet, the obligations ought to be taught as two types of applied morality for settings with different purposes. There can be conflicts of obligations within the research setting alone, the medical setting alone, and when these two activities meet in the same patient and the physician-investigator. The moral rules and ethical principles will be essential to sorting out issues and weighing alternatives in each instance.

It follows from this conclusion that the guidelines for the conduct of research developed by the Commission should not be taken as literal points of departure for regulating the conduct of health service programs that have therapy as their basic intent. The principles developed for research have relevance, if the previous arguments are persuasive, and ought to be applied to the conduct of health service programs as work proceeds in evaluating the moral experience of participating physicians and patients. Any new statement of moral obligations in the setting of health service programs ought to presuppose the principles of the Belmont draft.

C. Principles as Symbolic of a Social-Ethical Contract

The posture and language of the paper, to this point, have been characterized by objectivity on the problem at hand. The language of rights and moral rules presupposes distance, conditions of impartiality and generality.

There is another side to morality, the subjective side. In the attempt to analyze, to be objective, to achieve a standpoint to evaluate moral conflicts, one must not evade the fact that the real situation morally is that there is no absolute or universal standpoint where we achieve objectivity about particular moral decisions. As Aiken noted, "Morally, we are always in the middle of things, confronted with eternally exceptionable precepts. . ."[22] We cannot transfer our own moral responsibility onto the fiction of an absolute standpoint, however useful the achievement of a degree of objectivity in the consideration of a moral conflict.

To return to an unfinished theme of an earlier section, ethical principles do not furnish the self-respect and respect for others required to make morality possible in the everyday sense of being moral: to reciprocate and cooperate. Without sources of commitment and experiences that nourish self-respect there could be no effective morality. The beliefs and social experiences we have together make a profound subjective influence on morality. If one believed that moral decisions are meaningless because there was no meaning or value to living in the first place, there would be no plausible reason for wanting to be moral. Religion and other world-views provide these sources of inspiration, but the society grows increasingly pluralistic. No one interpretation of the meaning of morality holds sway, nor ought such be the case. MacIntyre's earlier paper for the Commission described the fragmentation and disagreement that prevails in the morally pluralistic situation.

The problem is how do groups and individuals with profoundly different beliefs and world-views find enough "common ground" to want to be moral, act on their convictions, and to change social practices that cause great harm to persons?

The use of the social contract theory to explain the origin of government has long been discredited from the historical perspective.[23] There were continuing efforts, however, to use the theory to explain the relationship of citizens to government. In the last century, S. T. Coleridge argued eloquently for the idea of an "ever-originating contract," not as a fiction but as a way of defining the continuing ethical

foundation of society.[24] For Coleridge, what distinguished a political community from a band of robbers was the principle of consent that operated within the terms of moral freedom. Consent involved the recognition of the individual's personality by the community and the state, in return for which the individual agrees to the obligations of citizenship. The state must treat the citizen not merely as a means but as an end. The constitution of the state follows naturally from the contract idea and serves as the embodiment of the social contract between citizens and their society. The consent of the governed in free elections points to the deeper consent to the ethical contract between citizens and the society.

The author is interested in the fruitfulness of social-contract theory for illuminating a symbolic "common ground" - on the other side of ethical principles, but prior to the level of religious or other forms of ultimate commitment - that can unify citizens of very different belief systems for the task of ethical analysis of the moral problems in the society and deliberate change to resolve the greatest contradictions. This paper is not the place for extended exploration of the fundamentals of a theory. To set a direction for argument using the problem under study is the intention here.

The phrase "consent of the governed" is an idea that reconciles the conflicts between liberty and law. The idea is that people will freely obey the demands of a government that they had created and chosen to obey, as long as the law of a particular government remains faithful to the premises of a constitution. Some political theorists have sought

to explain political obligations only as a struggle for power and based on conflict. If one is interested in explaining political obligation as one form of moral obligation, some symbolic form is required to provide that which ethical principles cannot provide, that which can move us to put our hearts as well as minds into acting on moral reasons.[25]

The idea of a "social-ethical contract" to which all members of a society are a part is one way - necessarily symbolic - of expressing the truth that unless there is cooperation and reciprocity, morality is functionally impossible. Unless one is to believe that society is a really Hobbesian war of all against all, some other symbolic form that more truly illuminates the ethical presuppositions of institutions is required. The concept is that the explicit and political consent of the governed presupposes a social-ethical contract between all members of the society to which they give an implicit consent on each occasion of a moral decision, that is in those cases where reasons of self-interest are overruled for reasons of a larger social good. The fundamental statement of the social-ethical contract, metaphorically speaking, is "I believe that it is in my interest to be moral." Without some unspoken but symbolic agreement of this nature, one could not make sense of the cooperation and reciprocity that can be commonly observed.

If it is in the interest of all to be moral, it must be in the interest of government to keep the social-ethical contract as well as specific constitutional obligations. In this view, the latter rest upon the former. The consent of the governed thus means that the governed expect government to pay critical respect to the fundamental values and moral convictions

of the society. The term critical respect indicates that (1) there are degrees of priority in the selection of enforceable morality, (2) morality is always in process, as are all institutions, and (3) the search for truth and the search for justice are indissolubly linked.

In short, actions by government that violate the consent of the governed are not only those that are unconstitutional but those that break the social-ethical contract by conveying that it is not in the government's interest to be moral. It follows that government is accountable for actions taken in the name of the people that these actions not violate the integrity of their consent. The meaning of accountability here is that government is like an agent answerable for actions promised under contracts or agreements, and further that a responsible agent acts in the expectation of a response from the other parties to the account he will give of promised actions.[26] The health service programs under study here were designed to compensate for injustices and gaps in the private system. The moral obligation of government is so to conduct public programs or assure their conduct so that the social-ethical contract with the members of the society is upheld. An accountable government expects a response from the people to actions taken in their name and concerns itself with preparing to make an answer to that response. It should be a matter of moral concern to the Commission that at present no reliably informed answer could be given to questions posed by the public about ethical conduct of health service programs.

To summarize motivation for the argument in this section: the relevance of the ethical principles is that they point beyond themselves to

a social-ethical contract that provides motivation for wanting to be moral in the conduct and reform of health service programs.

V. Conclusion

The argument began with the claim that Congress had asked an ethical question that needed to be answered first on moral grounds. Because the necessary facts to compare private and public moral experience are unavailable, only a formal case could be made that the Belmont draft principles are applicable to health service programs. The approach was to identify the major obligations of physicians towards patients and then to test the principles in each of their intended functions in relation to the obligations.

Another way to state the purpose of the argument is that it seeks to persuade the reader that answering Congress' question first from the standpoint of the institutional relevance to practice is not the best first step in moral reasoning. To answer ethical questions, one should evaluate the question first in terms of the widest obligations and from the perspective of issues of the greatest social good. Setting self-interest aside is not the mark of Levine's paper. To the extent that Levine's work dwelt mainly on professional issues and making analogies between medical and research obligations, it did not meet the tests of a full ethical argument. On Levine's side, it must be said that to construct an ethical argument was not his main purpose. He succeeded admirably in breaking new ground in an important area of medical practice, especially in the concept of "practice for the benefit of others."

A final word must be said about the efficacy of the "social-ethical contract." In the final sense, even symbolic forms are not truly adequate to move persons to be moral. We are free or not to commit ourselves to symbolic forms and allow them to move us to action. The self is more than its commitments, and as Aiken persuasively shows, the fundamental "character of the moral situation" itself is that we may choose in every new situation not to abide by past loyalties.[27] Thus, the argument finally comes to rest in the fundamental human freedom of the moral situation.

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ETHICAL ISSUES IN HEALTH CARE

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As the National Commission considers the appropriateness of applying to the delivery of health services the principles and guidelines it identifies as underlying the conduct of biomedical and behavioral research involving human subjects, it should be helpful to outline how those principles have been related to health care. One important characteristic of analyses of health care delivery is that they often deal with the distribution of services to large groups of people. It is not surprising that when health care is considered, questions of morality often concern allocation of medical resources among the health needs of groups in society. Such problems of macro-allocation (as distinct from micro-allocation, the distribution of scarce resources among individuals within a group) are what theories and principles of distributive justice are designed to address. Respect for person and beneficence are moral principles relevant to health care and they will be discussed in this paper, but primarily as they help define and modify distributive justice.

It is useful to begin by noting the broadest definition of justice: Justice is rendering to each his due. Distributive justice is the form of justice concerned with distributing among persons the benefits and burdens that are their due. Abstractly stated, distributive justice requires persons to be treated alike unless there are relevant differences among them. Aristotle observed that "all men hold that justice is some

kind of equality," and some have proceeded to claim that equality is the controlling principle of distributive justice. (Bedau, p. 171) When understood to mean that every person ought to enjoy an equal level of well-being, including health, important implications flow for the organization of health care. We will later note several ways in which equality among persons has been related to health care, but we will first look at a position that interprets distributive justice in terms of utility or beneficence, and examine one that places respect for autonomous persons at the center of a theory of distributive justice. The concrete macro-allocation question raised for each position is whether or not to develop the artificial heart.

Utilitarian

For some analysts a health care system is just if it produces the greatest possible balance of benefits over harms. The Belmont paper calls such a consideration a form of beneficence. In traditional ethical terms, it means that health care should be distributed according to utility. Understood in this way, the goal of health care is to achieve for the majority the highest level attainable of infant survival, years of life expectancy, and total work days free from hospitalization. Joseph Fletcher is convinced that just such maximizing of the number of recipients of health care and optimizing of the quality of that care is what distributive justice requires. In other words, distributive justice means "seeking the greatest good (health) for the greatest number possible." (Fletcher, pp. 107-108)

Others who have argued that ethical considerations demand that health care maximize the majority's level of health are more careful about how the few should be treated; how specifically respect for persons modifies the calculus of utility. Clark C. Havighurst, in his comments on the ethics of government funding of an artificial heart program, assumes that the decision as to whether to proceed should be settled by calculating benefits and costs. If the potential benefits from public or private projects exceed potential costs, they should be approved without concern for compensation of the actual losers. Still, he believes that within practical limits justice may require that those who are harmed by the actions benefitting the majority receive compensation. (Havighurst, p. 249)

Another advocate of this position proposes that society design the most comprehensive, as well as discerning and impartial cost/benefit analysis possible. Tom Beauchamp, like Havighurst, believes that health care programs, such as development and distribution of the artificial heart, would be defensible if (but only if) they were justified by a cost/benefit analysis. However, he concedes that sometimes it would not always be permissible to follow the dictates of such a calculus. Indeed, he would invoke broader considerations of justice, not merely in terms of compensation, but as a "threshold" consideration. (Beauchamp, pp. 20, 27-29)

Criticisms of this position arise from criticism of the theory of utilitarianism. Even if the health of the majority of society were benefitted by a health care system that slighted the care of such minorities as the aged, children, the disabled and the dependent poor,

would it be a just health care system? Critics insist that it is not obvious that minority populations should be allowed to die early in order to improve the society's success in decreasing average morbidity, or even mortality, rates. How is the worth of these vulnerable populations to be determined? Surely not simply on the basis of their benefit to the health or well-being of society. Arrangements for compensating those minority populations harmed in benefitting the health of the majority cannot be substituted for the demands of distributive justice. Justice must govern initial distribution of medical and health care benefits.

Some critics declare that distributive justice cannot be accommodated to utilitarianism since whatever sophisticated form it might take, it depends on computing the sum of the benefits produced, rather than the justice of how the benefits are distributed to individuals. (Miller, 1976, p. 39)

Entitlement to Health Care

While the Utilitarian position just discussed has been dismissed by some critics as not founded on distributive justice because it is grounded in utility, bringing about the balance of benefits over harms, another position that can be called the Entitlement position has been attacked for being so concerned with respect for individual persons and their autonomy that it also ignores crucial issues of distributive justice.

Robert Nozick is the leading advocate of the Entitlement position. He argues that his views do satisfy the requirements of distributive justice, but he makes it clear that his theory begins with the autonomous person. He starts his major work on the subjects by saying that individuals have rights, and there are things no person or group may do to them without violating their rights. (Nozick, p. ix) He later cites the physician as an example of a person whose rights to offer his skill for whatever personal reasons should not be violated by society's idea of how medical care can most appropriately be distributed to meet its needs. "Just because he has this skill, why should he bear the costs of the desired allocation, why is he less entitled to pursue his own goals, within the special circumstances of practicing medicine, than everyone else?" (Nozick, p. 234)

The Entitlement position can just as stoutly defend the rights of patients. As long as they acquired their wealth justly, whatever level of health care patients purchased would be just, and society would not be respecting patients as persons if it interfered by imposing its schemes for allocating health care. The position includes the proviso that an individual cannot consume an irreplacable resource (such as the single culture necessary for the only vaccine that can irradicate a plague) if the disappearance of that resource worsens the position of others to the point that they cannot be compensated. (Nozick, p. 178)

Nozick brushes aside traditional forms of distributive justice as a threat to the individual because they take possession from individuals and allocate them to others according to some overarching, social pattern. Instead of future benefits or present patterns of equality, Nozick stresses

the worth of past actions and conditions of individuals. He sometimes even refers to his position as the "historical-entitlement" view of justice, because it is on the basis of their present and past that persons are respected. The Entitlement position would say that if physicians, indeed a large number of physicians, wished to devote their entire resources, time and energy to developing and marketing an artificial heart to be sold at prices that would make them available for only a very few, primarily the wealthy, the free choice of physicians, should be respected, however little their choice contributed to improving the overall health of the society or violated some pattern of equality.

To understand criticisms of the Entitlement to Health Care position, it is necessary to look at Nozick's outline of how he moves from his assumptions to his conclusions.

1. People are entitled to their natural assets.
2. If people are entitled to something, they are entitled to whatever flows from it (via specified types of processes).
3. People's holdings flow from their natural assets.

Therefore

4. People are entitled to their holdings.
5. If people are entitled to something, they ought to have it (and this overrides any presumption of equality there may be about holdings). (Nozick, pp. 225-226)

Nozick's entitlement terminology does not allow his first premise to avoid a frontal clash with a common intuition shared by many and articulated by John Rawls: Respect for persons should not lead anyone to think that each person deserves his place in the distribution of native endowments, any more than he deserves his initial starting place in society. Indeed, for Rawls one of the most important tasks of human

justice is to overcome the results of the "natural lottery" in native assets. (Rawls, p. 104) While Nozick recognizes that there are many unjust acquisitions and transfers of possessions and assets, and would no doubt favor rectification in the form of health care for whatever physical handicaps resulted, what of those with natural liabilities, for which no discernible unjust action is responsible? Are we ready to say that these persons are entitled to their physical handicaps?

Another challenge to Nozick is directed at his second premise, particularly that people are entitled to <u>whatever</u> flows from their natural talents and abilities. His critics think that Nozick is idiosyncratic in his basic intuition that respect for individuals entitles them to do whatever they want with what they receive or acquire. In the real world, rights of individuals and groups clash. Thomas Nagel insists that no person possesses absolute entitlements like those Nozick believes in. Even if a defender of the Entitlement position were to believe that clashes among individuals claiming their rights to acquisition and transfer of holdings could generally be solved through contracts made in the marketplace of supply and demand, the question would remain as to whether medical care in particular is desired in the way consumers desire other goods. Is not the urgency and level of demand, especially in acute medical care, often the result of accident or forces well beyond the consumer's control and free choice? A proponent of a free market system of distribution of goods might still believe that the specific characteristics of medical care dictated the employment of other, more relevant modes of distribution.

Nozick's critics also attack his third premise, arguing that he does not sufficiently recognize that neither a patient's nor a physician's wealth flow simply from their natural assets. Society can claim much of the responsibility for both the advantages and disadvantages with which the individual physician and patient approach the training of physicians as well as the transfer and acquisitions of medical care. Therefore, more than Nozick acknowledges, society is justified in intervening in the distribution of health care delivery.

Rejection of one or more of these premises prevents critics from agreeing with Nozick's conclusion that a respect for autonomous persons overrides presumptions of equality. Critics can not agree that respect for persons and their autonomy means that physicians are entitled to offer services in whatever manner and for whatever price they choose, and that consumers are entitled to acquire health care at whatever level their wealth and income allow.

By contrast to the first two positions explored so far, the next three positions relating justice to health care make equality a necessary part of distributive justice, although it is the last position that attempts to be strictly egalitarian.

Decent Minimum of Health Care

Charles Fried has relied on both respect for persons and equality to specify how distributive justice requires that society provide a decent minimum of health care (and only a minimum) to its citizens. On the one hand, Fried thinks that patients who have the means to obtain

a higher level of health care than others should be free to purchase it. At least in the United States, a social system has been instituted where those who want fancy or more individualized services can get them if they are willing to pay more. The system which says that respect for autonomous persons allows variation in wealth and income is not itself morally suspect. He does not see why a sector like health care should be carved out and governed by different moral principles. (Fried, 1976, pp. 32, 33)

On the other hand, in all areas of society, "there obtains a notion of a decent, fair standard." Fried argues that the decent minimum in respect to health should be distributed equally to all members of the society. He is not entirely clear on the crucial point of whether the equality is in terms of a guarantee to all citizens of an equal decent minimum level of health, or in terms of making available a fixed amount of health care. Fried says that "the concept of a decent minimum is always relative to what is available over all, and what the best available might be." He suggests that no maternal and child care and humane surroundings of all health care are essential elements in the decent minimum provided directly by the government. (Fried, 1976, p. 32) However, he also says that he prefers assuring each person a fixed amount of money to purchase medical services as he chooses, realizing that a decent minimum of health care understood in this way would continue a system where the poor would be unable to get the level of care available to the rest of society. The advantaged, after all, could add the government allotment for health care to their already existing resources and purchase much more than the decent minimum available to the poor.

A decent minimum would certainly not provide every citizen with equal access to an artificial heart. It would allow development and purchase of artificial hearts by those who could afford it. In fact, the wealthy could justifiably include their government subsidy for health in their payment for an artificial heart.

As is the case with all mixed positions, more thoroughgoing advocates of respect for persons or equality can criticize the confusion created by compromise. A decent minimum of health care, through taxation, forcibly removes some financial assets justly acquired by persons, while failing to achieve for all citizens equality in levels of health care, let alone of health. Also, Fried is not clear what should be done for the poor who receive a fixed amount of money for health care, spend it on non-health expenses, and then discover that they have a condition that is certainly and imminently fatal, but can be treated and probably cured through standard medical procedures. Would society point out that it had respected the autonomy of persons who exhausted their money and actually refuse to provide medical treatment to such persons?

On the other hand, the position can be praised for its plausibility. It is sensitive to moral intuitions that society should not entirely neglect any of its citizens' basic needs. At the same time it recognizes limitations by restricting assistance below a level that would disrupt the entire political and economic system of society.

Maximin Level of Health Care

The Maximin Level of Health Care position attempts to be more generous than Fried's decent minimum in distributing health care in a way that does

not increase social inequality. The position is based on John Rawls' theory of justice. Rawls asks us to imagine persons in an "original position" of ignorance about variations in natural abilities or respective places in the social order, but knowing general facts about the human condition and natural and social laws. He thinks that if persons in such a position were asked to select principles governing society, they would prudently defend their interests by choosing rules whose effect on each of them would be the least damaging possible. In other words, they would choose a maximum minimum, or "maximin." Not knowing their chances of increasing or decreasing their share of primary goods, such rational agents would follow a maximum minimum approach to justice and adopt the principle that each member is entitled to "an equal right to the most extensive total system of equal basic liberties compatible with a similar system of liberty for all." Aware, however, that incentives for the more talented and productive individuals lead to benefits for every person, they would adopt a second, "difference principle," that permitted social and economic inequalities. But in a continuation of the maximin approach, inequalities would be permitted only so long as they led "to the greatest benefit of the least advantaged," and only if the inequalities were "attached to offices and positions open to all under conditions of fair equality of opportunity." (Rawls, p. 302)

Employing Rawls' theory of justice, Ronald Green argues that rational agents in the original position, confronted with how to relate justice to health care, would secure the highest minimal level of health care for themselves and their loved ones. He believes that such rational agents could consider health care a primary social good comparable to

civil rights and liberties. If they did, health care would be governed by Rawls' egalitarian first principle, and equal access, irrespective of income, to the most extensive health services the society allowed, would be approved as the position conforming to the demands of distributive justice. (Green, 1976, p. 117)

But how would maximin reasoning understand justice in circumstances where the amount of health care to be distributed was limited? Green says that a "lexical ordering" of health care is the single most important implication of contract theory for the macro-allocation issue. (Green, 1977, p. 14) He means by lexical ordering maximizing health benefits for the worst-off group, and only when substantial progress with them had been achieved should benefits be given to the next least-advantaged group, and so on until medical programs for the advantaged were undertaken.

One difficulty is identifying the worst-off group. Are they the medically or the economically least-advantaged? Green sometimes says that they are the group with the worst health; those with conditions that cause the greatest physical and mental suffering. Other times he assumes that the medically worst off are the same as the economically least advantaged, and says that a just health care system would benefit those suffering diseases that he believes are found disproportionately among the poor: arthritis, hypertension, malnutrition, and work-related injuries. (Green, 1977, pp. 31-33) The objectives of federal health programs, as described in the 1974 Catalogue of Federal Domestic Assistance (National Commission Staff Paper, Appendix B), reflects the same confusion as to whether medical care is directed to medical or economic need. Some programs concentrate on areas of the nation with scarce health services

(Family Health Centers) and critical shortages of health personnel (National Health Services Corps). Other programs focus on children in low-income areas (Health Care of Children and Youth) and areas suffering from severe economic distress (Maternal and Child Health Services).

Another problem is the definition of health. When health is said to be a primary social good and the measure of the least advantaged, does health mean a physical organism functioning as most other such organisms do? Or is the health regarded as a fundamental good equivalent to civil rights and liberties nothing less than what the World Health Organization defines as a state of complete physical, mental and social well-being? Are the least advantaged to be defined by their distance from such an inclusive understanding of health? And what would such an encompassing definition mean for the Indian Health Service and its objective of raising "to the highest possible level the health of approximately 498,000 American Indians and Alaska Natives?" (National Commission Staff Paper, Appendix B)

There does not seem to be any inherent reason why the Maximin position could not consider those needing an artificial heart among the medically least advantaged, and therefore place a high priority on developing it. As it happens, Green calls for a moratorium on development of the artificial heart. He thinks that rational agents would consider those with childhood diseases or conditions of high morbidity (great physical or mental suffering) as less medically advantaged than the likely users of the artificial heart, those beyond a "normative age" who have heart disease. In fact, if those whose lives

are prolonged suffer from strokes or cancer, the artificial heart might contribute to increasing morbidity in society. If the least advantaged are to be equated with the poorest, Green is certain that the artificial heart does not selectively benefit lower income individuals, nor is it the most effective means for treating their typical health needs. (Green, 1977, pp. 11, 12, 17)

Interpretations of Rawls other than Green might regard health care as a material good comparable to wealth, and therefore to be distributed according to Rawls' "difference principle." According to such an interpretation, a government that paid the health care of the affluent might still serve justice if by doing so a single and more effective heatlh care system benefitted most the health of the least advantaged. In this fashion calculation of how to maximize benefits would be allowed to modify equality. As we shall see, thoroughgoing egalitarians object to such reasoning.

Equal Access to Equal Levels of Health

The first part of this position stresses the first part of the formal definition of distributive justice: Persons are to be treated alike. All persons should have equal access to health care regardless of their financial, geographic or other differences. Persons with similar medical cases should receive similar treatment. Except for the sickness itself, no differences among the sick are relevant. As grounds for his position of equal access to health care, Gene Outka points to the moral perspective of equal regard for all persons, and

the fact that in general humans are equally vulnerable to accidents and illnesses for which they are not responsible.

The second part of the position (compatible with Outka's) focuses on the second part of the formal principle of justice: Persons are to be treated alike unless there are relevant differences. Level of sickness is identified by this position as the most significant relevant difference. It will not be enough for persons to receive the same amount of health care. Uniquely among those studied, this position demands that for distributive justice to be served varying degrees of medical need must be met for persons to be treated as equals. As Robert Veatch states the position, "justice requires everyone has a claim to health care needed to provide an opportunity for a level of health equal, as far as possible, to other persons' health." Some such assumption may lie behind the objective of the Migrant Health Program: "To raise the health status of migratory seasonal farm workers and their families to that of the general population." (National Commission Staff Paper, Appendix B)

Some egalitarians might find Veatch's formulation, limiting care of individuals to other persons' level of health, as too weak a view of equality. They would concede the position may be adequate for guaranteeing care of medical needs, but what of wants or desires concerning health? Should these be limited by a single level of health? David Miller believes that "because people have varied needs and wants, physical resources such as food, medicine, and education should not be assigned in equal quantities to each man, but in different proportions to different people, according to their peculiar

characteristics." He bases his position on the notion that "every man should enjoy an equal level of well-being." This level is not met by only satisfying needs, but by providing "as large a proportion of each person's further desires as resources will allow." Each person's different level of desires is measured on an individual "scale of well-being," indicating the allocation of resources which would give him the least and greatest well-being. Justice requires that each person should enjoy as high a position on his own scale of desire for well-being as every other person enjoys. (David Miller, pp. 149, 144)

Rather than trying to meet possible objections from egalitarians, the Equal Access to Equal Levels of Health position attempts to meet attacks from non-egalitarians. Veatch's saying that justice requires that health care "provide an opportunity" for equal levels of health points to notions of individual autonomy behind those who emphasize respect for persons. Individuals who repeatedly refuse to take advantage of treatments provided should not be required to improve their health.

When Veatch says that health care is to provide health equal, "as far as possible," to other persons' health, he accepts calculation of efficiency in increasing benefits as a limitation on equality. For example, treatments are not necessary for the incurably sick who cannot find any use for the resources allocated to them. While distributive justice requires extension of health care to all persons regardless of intensity of need, the Equal Access to Equal Levels of Health position allows limitations based on the distinction between need and desire. Outka suggests cosmetic surgery as an example of a

technique to which society would not be required to provide equal access. Veatch adds treatment for baldness, prenatal sex selection, personal attendance by physician traveling companions, and electrical stimulation of pleasure centers of the brain. (Outka, 1966, p. 92; Veatch, 1976, p. 141)

It is not surprising that this position has difficulty making an unequivocal judgment regarding the artificial heart. Surely those who seek an artificial heart to prolong life cannot be dismissed as desiring a trivial benefit. They could make a plausible case that they desperately need to benefit from an artificial heart if their level of health is to be equal to others. As it happens, Veatch thinks that the high costs of an artificial heart might make it impossible to restore those even more medically in need to a level of health equal to others. He thinks that his position could justify a legislature not voting to expend public money on such a project. (Veatch, 1977, pp. 16, 17)

Non-egalitarians remain unconvinced by the Equal Access to Equal Levels of Health position. Those emphasizing entitlement believe that respect for persons' autonomy is being violated if their wealth is taxed in order to provide equal levels of health to all citizens. Those who say questions of distributive justice should be decided by calculating how to maximize benefits accept the point made by strict egalitarians about the difficulty of separating needs from desires. However, they conclude that meeting even genuine health needs can never be met by finite human resources, and therefore that equality of need is a practical impossibility as a criterion for just distribution of health care. Even those who see the benefit of maximizing equality do

not believe that justice requires the impossible, and therefore reject the position that distributive justice demands that one of the benefits society must provide its citizens is equal levels of health. (Beauchamp, p. 20)

Conclusion

Convergence among the positions appears at certain points. Even those positions that choose either beneficence, or respect for persons, or equality as the essence of distributive justice do not ignore the importance of the others. For example, beneficence as understood by Havighurst and Beauchamp, is supplemented by other considerations. Equality, as developed by Outka and Veatch, is complemented by beneficence and respect for persons. On a more practical level, all the positions examined here that believe equality is significantly relevant to health care also believe that justice requires that society provide at least a minimum level of care. They continue to debate how justice might further specify such a minimum, but none argue that the minimum should include providing artificial hearts to those whom doctors declare need them.

Of course many differences persist. There is lack of agreement as to how key concepts should be defined and used. Health is a notoriously ambiguous term. Although there are variations in degree, all the positions outlined here are affected by how health is defined. None carefully restrict the meaning of the term. Also, there is no

consistent distinction made between medical and health care. The latter is usually employed in this literature, although the details of the discussion often remain focused on what other writers mean by medical care. If health care, particularly health in its more inclusive definitions, were actually meant, the task of determining what distrbutive justice requires would prove to be even more complex.

Other issues remain unresolved. Some philosophers believe that taking the moral point of view requires selecting a single perspective of distributive justice and then applying it to the facts of health care delivery. Others allow the varying nature of particular problems to dictate what position is controlling in the just distribution of health care.

Even more difficult to settle is how to relate justice to other ethical principles such as respect for persons or beneficence. However, even those who strictly limit distributive justice to equality recognize that ethical decisions often involve more than simply considering what justice requires. They acknowledge that sometimes egalitarian justice must be overruled by beneficence or respect for persons. The just act may not, all things considered, be the right act.

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II

PAPERS AND RECOMMENDATIONS FROM THE NATIONAL MINORITY CONFERENCE

6

ETHICS IN HUMAN EXPERIMENTATION IN HEALTH CARE DELIVERY

William A. Darity, Ph.D.

ETHICS IN HUMAN EXPERIMENTATION IN HEALTH CARE DELIVERY

by

William A. Darity*

INTRODUCTION

The issue of ethics in human experimentation in health care delivery is not a new concept. Concern over informed consent and the right of the individual has been discussed extensively. Also, the issue which is considered of foremost importance, is the value of human experimentation as an aspect of improving the health of the general population and the right of the individual to participate or not to participate. Advocates of a viable ethical approach realize that the actual control of definitive solutions to human experimentation is difficult. They insist, however, that a major goal of those involved in biomedical science and behavioral science research must assure that informed consent is acquired. Those of us in minority communities are not only concerned about informed consent but an assurance that coercion is not used to acquire "informed consent," and that the vulnerable low socioeconomic positions of many minorities are not used as pressure and coercion to acquire consent in human experimentation.

LEGISLATIVE ASPECTS

According to Curran, prior to the 1960's there was little "law" in the United States concerning medical research.[1] Curran cites some legal precedence in Regan's Doctor and Patient and the Law, which was revised and rewritten by C. J. Stettler and A. R. Moritz. Curran further points

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out that in the treatment of the patient there must be no experimentation.[2] He states that:

> This assumption was based on two factors: (1) that the doctor was found to act within the accepted methods of medical practice applicable to the practitioner's field of medicine, and (2) that the doctor has not sought nor received the permission of the patient to deviate from these methods.[3]

Although this was the prevailing thought, concern about the ethical issue mounted and interest grew. In 1960 the National Institutes of Health financed a program to study and to report actual practices of medical researchers and research organizations throughout the United States regarding ethical and moral problems in the use of human subjects and related medico-legal matters.[4]

Both the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) have supported sponsored research for some time. The FDA had some controls prior to 1961-62, the years of the outbreak of phocomelia (infant deformity) in Western Europe caused by the thalidomide drug. There were amendments to the drug control laws in 1962, requirements on reporting on preclinical testing, clinical pharmacology and clinical trials. This latter aspect, that is clinical trials, has important implications for minority groups.

NIH is a different type of organization than the FDA. Its responsibility is directly related to support a national program of health science research. It is staffed by well-trained and experienced scientists. The issue of academic freedom is adhered to, and decisions of publication of research findings are left in the hands of the principal investigator. Because of this philosophy, NIH did not impose regulations or guidelines

in the use of human subjects in its extramural project grants during its early years. However, NIH developed and acted under a well developed set of principles and procedures for the protection of patients and subjects involved in research studies at the Clinical Center.[5] These procedures as indicated were precursors of the present day concern.

The impetus to the present legislation was set forth when the U. S. Senate voted 81 to 6 in favor of a bill establishing a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. "The Commission is to develop guidelines for research and policies for assuring that subjects are fully protected."[6] The present bill which passed both houses, addresses itself particularly to the Commission's duties and to special study which are relevant to minority concern.[7] Of specific concern to this paper are the following charges to the Commission:

> The Commission shall carry out the following:
> (1) (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, ...
> (B) In carrying our subparagraph (A), the Commission shall consider at least the following:
> (i) The boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine.
> (ii) The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects.
> (iii) Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research.
> (iv) The nature and definition of informed consent in various research settings.
> (v) Mechanisms for evaluating and monitoring the performance on Institutional Review Boards established in accordance with section 474 of the Public Health Service Act and appropriate enforcement mechanisms for carrying out their decision ...

With regard to special study the Commission is charged with the following:

> The Commission shall undertake a comprehensive study of the ethical, social, and legal implications of advances in biomedical and behavioral research and technology. Such study shall include -
>
> (1) an analysis and evaluation of scientific and technological advances in past, present, and projected biomedical and behavioral research and services;
> (2) an analysis and evaluation of the implications of such advances, both for individuals and for society;
> (3) an analysis and evaluation of laws and moral and ethical principles governing the use of technology in medical practice;
> (4) an analysis and evaluation of public understanding of and attitudes toward such implications and laws and principles; and
> (5) an analysis and evaluation of implications for public policy of such findings as are made by the Commission with respect to advances in biomedical and behavioral research and technology and public attitudes toward such advances.[9]

INFORMED CONSENT AND VULNERABILITY OF MINORITIES

The concept of informed consent should be applied just as the term indicates; that is, an informed individual, who willingly participates in a human research project, with the awareness and understanding of potential hazard, possible lack of effective results, potential side reaction and other risks involved. The individual should be informed of the type of agency or organization and should have an understanding of the functions of the agency or organization sponsoring the research, the name and background of the principal investigator and the special contact person in cases where an emergency may arise.

The issue of informed consent is crucial for prisoners, children, the mentally ill, and for the poor. This is particularly true in the United States where minorities form a very high percentage of those incarcerated

and blacks, native Americans, and Spanish surnamed Americans form a very high percentage of those in the poor category. "By some estimates it is believed that possibly 80 percent of all human experimentation which has occurred in this country involved the poor."[10] Katz points out that

> Human experimentation can be hazardous to its subjects. Thus it is not surprising that the economically socially disadvantaged are conscripted for research to a disproportionately large extent. Throughout history the poor have been indentured for society's most disagreeable tasks, and medical science has only followed time-honored patterns of recruitment.[11]

The life situations of minorities make them more susceptible to being coerced into participating in research projects particularly since both poverty and physical numbers can have an impact on any decision which they make.[12]

There are cases which can be cited where informed consent was not provided. The most notorious of these is the "no treatment" syphilis study conducted among 600 black men who were suffering from syphilis in Tuskegee, Alabama.

> The men were given no treatment so that study could be made of the normal course of untreated syphilis in man. The study was supported by the United States Public Health Service...
>
> This study commenced in 1932 and it was not until both the national and international press published the information in late July 1972, 40 years later, that it was made known. At least 28 to 100 men are known to have died as direct result of no treatment in this study.[13]

It was not until there was both national and international press coverage that it was admitted that this large-scale human experiment had been carried out.[14] The critical issue and ethical concern was not only

that the study population was not informed in any way but in addition, earlier in the 20th century studies in Scandinavia had already provided evidence of what happens to persons who go untreated for syphilis.[15] In other words the research was not needed in any form to provide new information which would benefit the public.

Another example of the use of minorities in human experimentation is reported in a California research project. This study was conducted in Los Angeles County hospital in 1957-59. According to Randal,

> Most of the patients, then as now, were poor and either Spanish-American or black. The aim was to determine whether antibiotics given on a routine basis would improve the chances of survival for premature babies.
>
> The study showed that babies receiving no drugs or babies given only streptomycin and penicillin had the best chance of survival - 4 out of 5. The groups receiving chloramphenicol or chloramphenicol in combination with penicillin and streptomycin fared less well.[16]

Of 30 receiving chloramphenicol,18 or 60 percent died. Of 31 receiving choramphenicol in combination, 21 or 68 percent died.[17]

A follow-up study was made at the same hospital in 1959 and the study demonstrated that six more premature infants were given chloramphenicol and all six died from a constellation of symptoms which resulted in the collapse of their ciculatory system.[18] The same sequence had been noted in patients treated for typhoid fever with chloramphenicol.[19] Randal implies that the study was prolonged in order for medical statisticians to get enough significant cases.

The use of Mexican American women in a contraceptive pill experiment in Texas in 1969 is well documented. Not only were 76 patients of the 389 total in the study given placeboes, while thinking they were being

given contraceptive pills, those who became pregnant were not provided abortion services then they requested it.[20]

Gray[21] analyzed findings related to a labor-induction drug study. His interviews were carried out in the labor room. He observed that not all of the subjects in the study knew about the research in which they were participants. This was partly due to the procedures of informing patients. Their first explanation was in the hands of various private or house staff physicians who had first selected the subjects for the study. Others were informed while in the labor room.

In his study Gray found that 50 percent of the private patients knew of the research prior to admission as compared to 34% of the clinic patients. It was observed that 25 per cent of the private patients learned of the research while in the labor room compared to 16 percent of the clinic patients. And 50 percent of the clinic patients did not know when their participation began in the study as compared to 25 percent of the private patients.

When subjects were compared on a racial basis, a highly disportionate disparity emerged. Gray found that 50 percent of the white private patients became aware of the research before admission, the other 50 percent after admission; that 69 percent of the white clinic patients became aware of participation before admission and 31 percent after; and that 11 percent of the black clinic patients were aware before admission and 89 percent after admission. See Table I for these results.

TABLE I

Gray's study: Awareness of Research by Private-Clinic Status by Race (Labor-Induction Study)*

Patients	Before Admission	After Admission	(N)
White private	50% (8)	50% (8)	16
White clinic	69% (9)	31% (4)	13
Black clinic	11% (2)	89% (16)	18

*Extracted from page 68 (Table 4), Bradford H. Gray, Human Subjects in Medical Experimentation, John Wiley and Sons, Inc. 1975.

In order to assume that these differences were not due to education, Gray analyzed these data to determine if this was a factor among the clinic patients only, since there were no blacks among the private patients. He based his analysis on high school graduates or high vs. less than high school. His study showed that among white clinic patients with high school or more education, 86 percent learned about the research before admission while among blacks 25 percent learned before admission.

He observed that among those with less than high school education, 50% of the whites were informed before admission while among blacks, none were informed. Table 2, provides this information.

TABLE 2

Gray's study: When Learned of Research: Clinic Patients by Race and Education (Labor-Induction Study.)*

Subjects	Before Admission	After Admission	Total
White			
High school or more	6 (86%)	1 (14%)	7
Less than high school	3 (50%)	3 (50%)	6
Black			
High school or more	2 (25%)	6 (75%)	8
Less than high school	0 (0%)	10 (100%)	10
Total	11	20	31

*Extracted and modified for percentation from page 69 (Table 5), Bradford H. Gray, Human Subjects in Medical Experimentation, John Wiley and Sons, Inc. (1975).

In this study, the issue of real informed consent is questionable since the labor room does not seem to be the "most desirable" place to request consent to participate in any human experimental study on the use of pharmacological drugs. The request of participation of a woman could give the impression to the subject that she must participate - therefore implying a form of coercion rather than voluntary informed consent.

Gray's study clearly illustrates how clinic patients can be used in experiments and it further illustrates the differential level of informing patients when compared on a racial basis.

In addition to the racial or ethnic minority issue, low income or poverty enters into the study. The very widely read clinical field trails in Puerto Rico is a classical example. In one of these field trails there were 265 Puerto Rican wives from a low income population group. They lived in a housing development project. In analyzing the content of the structure of the study, there is no indication that totally informed consent was provided and particularly that the subjects were aware of the possible side effects from the oral contraceptive.[22] However, it was less than 13 years after the first clinical trail run that Lipsett et al, pointed out the effects of estrogens on renin substrate, angiotensin and other plasma proteins and the relationship of these effects to potential hypertension.[23]

It has also been observed that researchers will withhold information from subjects on the basis that information will create anticipation and suggestion, and therefore cause the patient or the subject to provide false information. The ethical aspect of withholding information on the grounds that it will create suggestion has been questioned and argued extensively. In order to analyze this aspect of ethics in health care and related research the author of this paper carried out a study in Charlotte, N. C. in 1961-62, to analyze what happened to patients where information on side effects were withheld by the program director with regard to the oral contraceptive. An analysis of the educational sessions revealed that the patients were only informed that they might expect "break through bleeding," from the use of the oral contraceptive. The follow-up study elicited information in which they were asked to describe to the interviewer

what really happened to them when they started taking the oral contraceptive. The patients described what happened to them as follows: drowsiness, dizziness, nausea, vomiting, headaches, weight gain, nervousness, and slight or heavy bleeding. Of the 107 women followed up, 78 or 73% claimed side reactions. (An unpublished Ph.D. dissertation by William A. Darity, Contraceptive Education: "The Relative Cultural and Social Factors Related to Oral Contraceptives," 1963).

The clinic in Charlotte, N.C. where the study was carried out, was operated by Charlotte-Mecklenburg Health Department. Approximately 85 percent of the subjects were black and all were from the low income class.

The ethical aspect of informed consent is questioned especially since there was already considerable information regarding side reaction and what could be expected. The "claimed side reactions" by subjects in the Charlotte study, were high compared to other studies. However, because of the low education level and the lack of reading, the self-description, provided by the subjects should be taken as valid and not "suggestions." Related studies showed that in a group of 551 women in Puerto Rico there was an incidence of 45 percent nausea.[24] In another study at the same time it was pointed out that there were 28 percent cases of headaches in Humacao, Puerto Rico, and an incidence of 17 percent vomiting among another group of women and weight gain among 25 percent of the women in the study.[25]

These latter studies support the issue that the patients in the Charlotte, N.C. program should have been informed about the possible side reactions. Also it is important to point out the number of studies

which were carried out among the Puerto-Rican population in Puerto Rico, which supports the concept that minorities were and still are used extensively in research projects.

These cases do not illustrate private physician involvement in health care research and how patients are used and never informed. However, the close relationship between the private physician and the pharmacology industry and their research projects should be considered and recognized as a gap that must be closed to assure ethics in human experimentation in this domain.

The cases cited further lead to some specific issues that relate to blacks and other minorities and some suggestions for special plans and steps to protect them from coercion and potential tyranny.

SPECIFIC ISSUES WHICH WARRANT PLANNING TO ASSURE PROTECTION OF MINORITIES

In discussing the findings of the labor-induction drug study, Gray observed that when education was equal, white patients were more informed. He stated:

> The main conclusion is that information about the study was better communicated by the house staff to patients who were relatively similar to themselves with respect to race and education (no involved house staff physician was black).[26]

He further points out that the explanation of variation in difference in knowledge about the research should not suggest that the subjects are responsible, as there is little doubt that it is the responsibility of the researcher or principal investigator to communicate relevant information to research participants.[27]

It is the responsibility of the principal investigator to be assured that subjects understand clearly the nature, purpose and method of the research.

Of particular concern to minorities is the manipulation of the situation to acquire participation in a study. The ethical issue is concerned with "the view that any manipulation of human behavior inherently violates a fundamental value."[28]

> To be fully human means to choose.... I therefore regard as ethically ambiguous any action that limits freedom of choice whether it be through punishment or reward or even through so perfect an arrangement of society that people do not care to choose..... First, I can try to show that the desire to choose represents a universal human need which manifests itself under different historical circumstances (not only under conditions of oppression). Second, I can point out that freedom of choice is an inescapable component of other valued states such as love, creativity, mastery over the environment.... Third, I can try to argue that valuing free individual choice is a vital protection against tyranny...[29]

The latter point of tyranny of the majority against the minority develops the basis for special arrangements and concerns for minorities in human experimentation.

Data show that in unemployment, low occupation characteristics, low income, selected health indices and poverty, black Americans and other minorities are disproportionately represented. For example, in April 1973, the ratio of unemployment for all workers was 4.8 percent. It was 4.3 percent for white workers and 8.7 for blacks and others, a differential ratio of 102 percent.[30] See Table 3. In 1974, the ratio was approximately 8 percent for all workers and over 15 percent for black and others.

In 1971 the median income for white families was $10,672, while for blacks and other minority families the income level was $6,714 or a differential deficit ratio of 59 percent.[31]

In a direct comparison between white families and black families, the median income for whites was $10,672 and for blacks $6,440 almost $250 less than when blacks are included with other minorities. This reveals that blacks have the lowest income of all minority groups in the United States. The income deficit is $4,232 and the differential deficit ratio .66 or 66%.[32]

TABLE 3

Unemployment Summary: 1970 to 1971

Subject	1970	1971 April	1973 April
Unemployment rate (percent):			
All Workers	4.9	5.8	4.8
White	4.5	5.2	4.3
Male	4.0	4.8	3.9
Female	5.4	5.9	4.9
Black and other	8.2	9.3	8.7
Male	7.3	8.1	7.9
Female	9.3	10.8	9.7
Ratio, Black and other to white	1.8	1.8	2.0
Blue-collar	6.2	7.6	5.4
White-collar	2.8	3.3	2.8
Experienced wage and salary workers	4.8	5.5	45.
Married men, wife present	2.6	3.2	2.5
White	2.4	3.1	2.3
Black and other	3.9	4.2	4.1

Source: U. S. Department of Commerce, Statistical Abstract of the United States, 1971 and 1973.

To be assured that there will be adequate attention given to minority subjects in human experimentation and research in health care delivery, and also to assure that they will not be coerced in participating, the following proposals should be considered:

a) The establishment of a Special Permanent Sub-Committee of the Commission, made up of minority professional and lay-persons who will be concerned with reviewing standards and guidelines to be sure that the minority interest, particularly, informed consent is included and is adequate.

b) Minorities in sufficient numbers with the background and depth be placed on all review committees of NIH; that such persons be reviewed and given approval by an outside group of minority professionals to assure that their crediability and interest are accepted.

c) To protect medicaid and medicare patients from unknown and unwarranted participation in human experimentation by clinics and private physicians, a statement of assurance be required on all payments and this form a part of PSRO standards and review.

d) Establish special standards and guidelines to assure that language, educational background, socio-economic status and cultural heritage, be considered and taken into account when informed consent is requested of minorities to participate in human experimentation.

e) Develop guidelines so that each research proposal will explain the population constituency, staffing patterns and approaches which will be used to assure clarification and understanding of minorities and their participation in studies.

f) In evaluating performance of research projects in which human experimentation is carried out, included will be special

standards for assuring the protection of minorities. This should ascertain how they were recruited, state and time of request for participation with signed agreements specifying time and place and contact person.

g) Other guidelines and standards focused particularly on minorities.

CONCLUSION

Human experimentation in health care delivery will continue to be carried out. This is essential in the improvement of health care. However, human dignity must be preserved through ethical standards. This is particularly true for ethnic minorities who find themselves in a disadvantaged position because of both economics and numbers. They usually use public clinics more than the majority population. In this connection special standards and guidelines, and special requirements must be established to assure that Black American, Puerto-Ricans, Mexican-Americans, Asian-Americans, and Native Americans will not be exploited and become victims of tyranny of the majority controlling researchers in human experimentation.

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7

AMERICAN INDIAN HEALTH CARE DELIVERY TODAY

Lionel H. deMontigny, M.D.

AMERICAN INDIAN HEALTH CARE DELIVERY TODAY

Lionel H. deMontigny, M. D.
Chippewa-Cree Tribal Member

Delivery of health care services to American Indian populations and the protection of these populations against abuse or experimentation poses significant problems. There are disease patterns unique to the American Indian population which needs specific research to resolve. In the past communicable disease has been a major problem. Indeed, the story of small pox and tuberculosis needs no repeating. It has been only within the last decade that the end to tuberculosis in Alaska has been a reality.

The American Indian situation is quite unique. Until the past two decades American Indian populations have been rural, isolated populations with those health problems associated with rural isolation. Migration to urban locations has been a recent phenomenon.[1] Health statistics on urban American Indian populations came into existance within the past two years and it is too fresh to make any significant projections regarding significant differences in disease patterns between reservation and urban Indian people.[2]

It is necessary to explain the unique differences that exist in the American Indian environment. American Indian people are tribal people. A tribe is really a group of relatives tied together through a system of family and religious relationships. Tribes are often thought of as being a small, homogeneous group with extensive intermarriage within that group. It would appear then, that genetic factors would be significant. But such is not the case, there is, and always has been a significant amount of intermarriage between tribal groups. Upon intermarriage, a non-tribal member is simply

absorbed into the system. Contrary to popular belief, American Indians frequently crossed oceans for trade purposes. Intermarriage with people from other continents was quite common.

Health services to American Indian people are very unique. Circumstances offer little oppurtunity for utilization of experimental drugs. At the same time there is little difficulty in utilizing any new drugs that have been tried and tested.

There are three systems of provision of medical health care to American Indians:

1) Federal, Public Health facilities

2) Private and other (Veteran's Administration etc...)

3) Traditional tribal healing methods

Provision of medical care to American Indians is deeply rooted in this nation's past. Incoming Europeans marveled at the fine stature and excellent health of the American Indians. After European colonies became established on this continent the chief source of medical care was American Indian healers. Over seventy per cent of the drugs now in the American Pharmacopoeia are American Indian in origin. Medical treatments such as sterilization and cauterization of wounds, plaster casts for broken bones, contraceptives were first used by American Indians.[3]

As time passed the American Indian was conquered. The situation became the familiar colonialistic occupation so common throughout the world where European industrial nations have expanded to. After conquering of American Indian tribal groups Americans began a systematic destruction of the Indian family and any institutions the tribes had. Traditional American Indian healers were shot or imprisioned. Children were torn from their parents and sent thousands of miles to distant boarding schools to teach them manual

skills consistant with the mental capacities of this "useless subhuman species."

Somehow the tribes survived. Children were hidden from federal police to keep them out of boarding school. American Indian language, tribal health care systems, and tribal education systems went underground. Federal police forces sent into isolated reservation areas to threaten traditional healers, somehow vanished.

The provision of medical care to tribal groups was first a responsibility of the War Department. Initially, medical teams were to treat American soldiers as Indian families were being shot. Diseases were introduced into the tribes as a more effecient method of extermination. Unfortunately, these diseases often spread to non-Indian populations. It became necessary for tribal members to have a health certificate before coming in contact with non-Indians. The importance of this legal precedence cannot be underestimated. It obligated the federal government to provide health services to Indian populations. Provision of health care was a portion of treaties made for cessation of lands. Until this time, treaties were ignored. In 1849 the responsibility for health care services was transfered to the Department of Interior. In 1955 responsibility for health services was transfered to the United States Public Health Service.

When World War I broke out, American Indian tribes refused to have their members drafted because they were not citizens and were forbidden to bear arms. Congressional leaders became incensed by American Indians' refusal to be drafted and conferred citizenship upon them in 1924. The results of this action made American Indian people eligible for the same benefits, rights, privilages, and protections that any other American citizen might have.

The net result today is a greatly strengthened tribal system. One might conclude that from the history of exploitation that American Indian tribal groups would have little resistance to those desirous of utilizing experimental drugs.

But exactly the opposite is true. Tribal institutions have gained a degree of strength not found in other communities. As early as 1935 tribes enacted rules forbiding the utilization of experimental methods of medical care. In 1965 tribes presented to the Surgeon General of the United States Public Health Service that a clear policy on experimental medical treatments and sterilization procedures.

Research needs to be done on those diseases unique to the American Indian population. Specifically:[4]

Diabetes

Obesity

Otitis media

Large Births

Alcoholism

Indications are that contributory factors are unique to the American Indian populations.

Factors that influence the resolution of these health problems and the use of any experimental procedures include:

1. A staunch resistance to the outside interference with the Indian community. Any institution, government or private will find it difficult, if not impossible to implement any kind of experimental program.[5]
2. A shortage of physicians in rural areas, including reservations. The relative unavailability of physician's services. They communities may become more receptive to outside exploitation by outside interests in an effort to obtain medical services. Rural United States is

experiencing a crisis in obtaining physicians, particularly in the Great Plains area where a majority of the Indians are located.[6]

3. Existance of a strong tribal health care system. Within the last decade traditional tribal healing institutions have experienced a strong comeback. In many Indian communities it is becoming necessary to deal with a traditional tribal institution prior to administering any kind of medical care program. The effects of this system are very healthy and positive, but does pose considerable problems for outsiders.[7]
4. Existance of strong regional and national Indian organizations that safeguard the Indian communities from experimental exploitations.[8]
5. The rapid industrialization of some Indian communities. Some Indian communities are experiencing an industrial boom. Some tribes have very valuable natural resources. These communities may be seriously disturbed and it is not possible yet to predict the outcome.[9]

Recent developments have significantly altered the methods of provision of medical care to the American Indian populations. These developments include:

1. A significantly improved educational system that allows Indian people to enter the professional fields. There are currently only fifty two American Indian physicians in the United States. But the number of

American Indian medical students has increased from seven to one hundred eight in the past two years.[10] The number of American Indian professional health administrators has increased within the last few years so that nearly every tribal or urban Indian health program now has professional Indian staff. The past five years has seen the graduation of over two hundred attorneys, whereas, there were less than twenty before. Eight of these Indian attorneys are currently employed by Health organizations serving Indian people.[11]

2. Since 1971 there has been a remarkable growth of tribal health institutions, owned,operated, and controlled by Indian people. Of the two hundred fifty tribal groups in the nation, thirty-five have functioning health departments. With the emergence of health departments, formal health codes and laws with systems of enforcement are emerging. While several tribal groups had passed laws specifically to control health hazards prior to this, systems of monitoring, inspection, and enforcement were lacking.
3. Since 1971 there has emerged Urban Indian health programs. Movement to urban locations for employment and educational opportunities has been common since the second World War. However, Urban Indian health institutions did not become common until today.

The impact of these programs may not be felt for the next few years, however, tribal groups are experiencing a much greater access to employment and educational opportunities through the existance of urban health institutions. Such groups guard very closely the provision of health services to the urban Indian. There are now seventeen urban Indian health projects in the nation. The next few years may see many more emerge.

The growth and development of American Indian Health institutions indicates a complete change in the methods by which Indian people obtain medical care. Formerly, it was necessary for Indian people to rely entirely upon Federal Indian services for care. Until 1971 there were really no significant Indian consumer organizations to safeguard the Indian people.

Presidential policy statements and key legislation has been passed pertaining to Indian self determination. A significant portion of the self determination process has been the evolution of American Indian consumer groups. Medical malpractice lawsuits are now becoming common, whereas, they were formerly unknown. Lawsuits against various departments of government pertaining to the delivery of health services are also recent developments.

While great progress has been made, only a small percentage of the need has been met. Many tribal groups and urban Indian populations have little working knowledge of their rights and privalages, through the existance of those institutions that have been developed, a much greater number of Indian people can be reached.

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8

ETHICS AND HUMAN EXPERIMENTATION:
EFFECT ON CULTURAL PATTERNS AND SOCIAL VALUES
OF SPANISH SURNAMED AMERICANS

Arturo E. Raya, Ph.D.

"IT IS UNFORGIVEABLE THAT IN A COUNTRY AS WEALTHY AND TECHNOLOGICALLY ADVANCED AS THE UNITED STATES, CHICANOS MUST CONTINUE TO SUFFER ILL HEALTH WITHOUT ACCESS TO SERVICES"

ARTURO E. RAYA

THE SUBJECT OF HUMAN EXPERIMENTATION IS SENSITIVE AND PARTICULARLY CONTROVERSIAL WITH REFERENCE TO SPANISH SPEAKING/SURNAMED AMERICANS BECAUSE OF THE EXTENT OF PARTICIPATION IN SUCH ACTIVITY BY THIS SEGMENT OF THE NATION'S POPULATION AND THE POSSIBLE CONSEQUENCES OF THIS INVOLVEMENT TO THE INDIVIDUAL AND THE COMMUNITY.

THIS PAPER WILL DISCUSS THE SUBJECT OF HUMAN EXPERIMENTATION WITH PARTICULAR REFERENCE TO ETHICS, CULTURAL PATTERNS, SOCIAL VALUES AND THE LIFE STYLE OF THE SPANISH SPEAKING POPULATION IN THIS COUNTRY.

DHEW REGULATIONS DEFINE "SUBJECT AT RISK" AS "ANY INDIVIDUAL WHO MAY BE EXPOSED TO THE POSSIBILITY OF INJURY, INCLUDING PHYSICAL, PSYCHOLOGICAL, OR SOCIAL INJURY, AS A CONSEQUENCE OF PARTICIPATION AS A SUBJECT IN ANY RESEARCH, DEVELOPMENT, OR RELATED ACTIVITY WHICH DEPARTS FROM THE APPLICATION OF THOSE ESTABLISHED AND ACCEPTED METHODS NECESSARY TO MEET HIS NEEDS, OR WHICH INCREASES THE ORDINARY RISKS OF DAILY LIFE, INCLUDING THE RECOGNIZED RISKS INHERENT IN A CHOSEN OCCUPATION OR FIELD OF SERVICE."

SUCH A DEFINITION LEADS ONE TO CONCLUDE THAT, IN FACT, THE FEDERAL GOVERNMENT IS TRULY CONCERNED WITH THINGS LIKE PROTECTION OF RIGHTS TO PRIVACY, THE NEED FOR INFORMED CONSENT, PROTECTION OF CONFIDENTIALITY OF DATA, AND PROTECTION AGAINST PHYSICAL, PSYCHOLOGICAL, SOCIOLOGICAL, OR LEGAL RISKS. THE REGULATIONS STATE THAT THE NEED FOR PROTECTION OF RIGHTS AND WELFARE, AND PROTECTION AGAINST RISKS TO THE INDIVIDUAL IS NOT LIMITED TO ACTIVITIES INVOLVING CHILDREN AND ADULTS BUT ALSO INCLUDES THE FETUS, THE ABORTUS AND THE DEAD. THAT'S EXCELLENT BECAUSE THE USE OF ORGANS AND BODY FLUIDS, AND

WRITTEN OR RECORDED INFORMATION, WHILE THEY PRESENT NO PHYSICAL RISKS TO THE SUBJECTS, MAY CREATE MEDICO-LEGAL RISKS, OR EXPOSE THE SUBJECT TO PUBLIC EMBARRASSMENT OR HUMILIATION THROUGH BREAK OF CONFIDENTIALITY AND INVASION OF PRIVACY.

WHILE SAFEGUARDING THE RIGHTS AND WELFARE OF SUBJECTS AT RISK IS PRIMARILY THE RESPONSIBILITY OF THE ORGANIZATION CONDUCTING GRANT ACTIVITIES, THE RESPONSIBILITY FOR DETERMINING THE ADEQUACY OF PROPOSED PROCEDURES MUST BE SHARED WITH THE IMMEDIATE COMMUNITY AS WELL AS REVIEW COMMITTEES AND DHEW STAFF.

PRINCIPAL INVESTIGATORS ARE REQUIRED TO: DESCRIBE THE REQUIREMENTS FOR A SUBJECT POPULATION AND EXPLAIN THE RATIONALE FOR USING IN THIS POPULATION SPECIAL GROUPS SUCH AS PRISONERS, CHILDREN, THE MENTALLY DISABLED OR GROUPS WHOSE ABILITY TO GIVE VOLUNTARY INFORMED CONSENT MAY BE IN QUESTION; DESCRIBE AND ASSESS ANY POTENTIAL RISKS AND ASSESS THE LIKELIHOOD AND SERIOUSNESS OF SUCH RISKS. IF METHODS OF RESEARCH CREATE POTENTIAL RISKS, DESCRIBE OTHER MEHTODS, IF ANY, THAT WERE CONSIDERED AND WHY THEY WILL NOT BE USED; DESCRIBE CONSENT PROCEDURES TO BE FOLLOWED, INCLUDING HOW AND WHERE INFORMED CONSENT WILL BE OBTAINED; DESCRIBE PROCEDURES (INCLUDING CONFIDENTIALITY SAFEGUARDS) FOR PROTECTING AGAINST OR MINIMIZING POTENTIAL RISKS AND AN ASSESSMENT OF THEIR LIKELY EFFECTIVENESS; ASSESS THE POTENTIAL BENEFITS TO BE GAINED BY THE INDIVIDUAL SUBJECT, AS WELL AS BENEFITS WHICH MAY ACCRUE TO SOCIETY IN GENERAL AS A RESULT OF THE PLANNED WORK; AND ANALYSE THE RISK-BENEFIT RATIO. THESE STATEMENTS BY THE INVESTIGATORS ARE, ACCORDING TO THE REGULATIONS, SUBJECT TO REVIEW, APPROVAL, AND MODIFICATION BY LOCAL COMMITTEES AS WELL AS BY DHEW.

WHILE DHEW REGULATIONS ADDRESS ONLY DHEW GRANTS AND CONTRACTS, THE NATIONAL RESEARCH ACT REQUIRES REVIEW OF BIOMEDICAL AND BEHAVIORAL RESEARCH INVOLVING HUMAN SUBJECTS CONDUCTED AT OR SPONSORED BY ANY INSTITUTION IN ORDER TO PROTECT THE RIGHTS OF HUMAN SUBJECTS. THE DHEW STATEMENT OF COMPLIANCE THEREFORE REFERS TO "PROJECTS AND ACTIVITIES" WITHOUT LIMITATION TO DHEW PROJECTS AND ACTIVITIES. NO EVALUATION, CERTIFICATION OR OTHER REPORTING PROVISIONS OF THE DHEW REGULATIONS ARE APPLICABLE TO RESEARCH SUPPORTED SOLELY BY THE INSISTUTION OR SUPPORTED BY PRIVATE, PUBLIC, OR NON-DHEW FEDERAL AGENCIES.

IN VIEW OF THE ETHICAL AS WELL AS CULTURAL, SOCIAL AND LIFE STYLE CONSIDERATIONS, RESEARCH INSTITUTIONS THAT DO NOT HAVE AN ETHICAL CODE OR HAVE NOT DEVELOPED AN IN-HOUSE CODE THAT COVERS ALL THE ABOVE, SHOULD BE REQUIRED TO FORMALLY ADOPT RELEVANT CODES. IMPLEMENTATION PROCEDURES SHOULD INDICATE HOW THE APPROPRIATE CODES ARE TO BE MADE CONVENIENTLY AVAILABLE TO INSTITUTIONAL STAFF, INVESTIGATORS AND SUBJECTS AT RISK AS WELL AS THE COMMUNITY TO BE AFFECTED BY ACTIVITIES WITH HUMAN SUBJECTS.

STATISTICS ON UTILIZATION OF PUBLIC HEALTH SERVICES SUGGEST THAT PERSONS OF SPANISH ORIGIN DEPEND LARGELY ON PUBLIC HOSPITALS (INCLUDING TEACHING HOSPITALS) AND OUTPATIENT FACILITIES TO SATISFY THEIR HEALTH NEEDS. AND, IF THEY DO, WHAT IS THE EXTENT TO WHICH THEY BECOME SUBJECTS OF RESEARCH AT SUCH FACILITIES.

EXISTING FEDERAL REGULATIONS PROVIDE SOME GENERAL, VAGUE WRITTEN GUIDELINES AND APPROVED PROCEDURES TO ENSURE NECESSARY SAFEGUARDS AND CONFIDENTIALITY OF INFORMATION. HOWEVER, IT IS ALSO UNFORTUNATELY TRUE THAT

THESE WRITTEN GUIDELINES AND PROCEDURES ARE NOT ALWAYS CAREFULLY OBSERVED. IT IS UNDERSTANDABLE TO THE MEMBERS OF LA RAZA THAT IN SOME CASES THE RULES ARE NOT OBSERVED BY INTENT, BUT IT IS UNFORGIVEABLE THAT IN OTHER CASES THEY MAY NOT BE COMPLIED WITH BY REASON OF IGNORANCE OR LACK OF UNDERSTANDING ON THE PART OF THE EXPERIMENTORS OF FUNDAMENTAL CULTURAL AND SOCIAL VALUES OF THOSE WHO MAY BECOME VOLUNTARILY OR INVOLUNTARILY INVOLVED IN RESEARCH. IN EITHER CASE THE RESULTS ARE DEVASTATING TO A LARGE SEGMENT OF THIS NATION'S POPULATION. SELF DENIAL OF CRITICALLY NEEDED HEALTH SERVICES IS ONLY ONE OF THE CONSEQUENCES.

IN ORDER TO DIMINISH THE POTENTIAL FOR ABUSE, CULTURE CONFLICT AND HUMAN DEGRADATION, SERIOUS CONSIDERATION MUST BE GIVEN AT EVERY LEVEL OF RELATED ACTION TO TO PROTECT CULTURAL, SOCIAL, RELIGOUS AND PERSONAL VALUES WHICH ARE HELD IN HIGH ESTEEM. THESE FUNDAMENTAL VALUES MUST BE GIVEN A HIGH RANK IN THE PRIORITY ORDER OF ISSUES TO CONSIDER IN ASSURING FULL PROTECTION OF HUMAN SUBJECTS. TO DO THIS REQUIRES KNOWLEDGE AND UNDERSTANDING OF LA RAZA, THE SECOND LARGEST MINORITY IN THE NATION.

IT IS ESTIMATED THAT SPANISH-SURNAMED AMERICANS NUMBER CLOSE TO TWELVE MILLION IN THE UNITED STATES AND PUERTO RICO (TABLE I). THEY ARE DISPERSED THROUGHOUT THE COUNTRY AND IN ALL RUNGS OF THE SOCIO-ECONOMIC SCALE. THEY ARE A HETEROGENEOUS GROUP WITH AS MUCH VARIANCE IN THEIR CHARACTERISTICS AS THE GENERAL POPULATION. IN FACT, SPANISH-SURNAMED AMERICANS ARE COMPRISED OF ALL COLORS, CREEDS, RELIGIONS, AND MULTIPLE ETHNIC HERITAGES. THEIR NATIONAL ORIGIN MAY BE IN MEXICO, CENTRAL AMERICA, SOUTH AMERICA, CUBA, PUERTO RICO, OR SPAIN. THE DIVERSITY OF CHARACTER-

TABLE I

Spanish Origin Population by Type of Spanish Origin for the U.S.:

March 1973, March 1974 and March 1975

(Numbers in Thousands)

Type of Spanish Origin	1973		1974		1975	
	No.	%	No.	%	No.	%
United States/Persons of Spanish Origin	10,577	100.	10,795	100.	11,202	100.
Mexican	6,293	59.5	6,455	59.8	6,690	59.7
Puerto Rican	1,548	14.6	1,548	14.3	1,671	14.9
Cuban	733	6.9	689	6.4	743	6.6
Central or South America	597	5.6	705	6.5	671	6.0
Other Spanish Origin	1,406	13.3	1,398	13.0	1,428	12.7

Sources: Series P-20, No. 264, Issued May 1974; P-20, No. 280, Issued April 1975; P-20, No. 283, Issued August 1975 (Advance Report).

NOTE: "The estimated number of persons of Spanish Origin presented in this report is comparable with the estimates of persons of Spanish Origin previously published from March 1974. CPS and the March 1973 CPS." (P-20, No. 283) Bureau of the Census.

ISTICS AMONG THIS POPULATION GROUP IS AS GREAT AS ITS SIMILARITY. THE CONCERN OF THIS PAPER IS WITH THAT SEGMENT OF THE SPANISH-SURNAMED POPULATION WHICH BECAUSE OF ITS ETHNIC, CULTURAL, AND/OR SPANISH-SPEAKING HERITAGE ENCOUNTERS DIFFICULTY ADJUSTING SATISFACTORILY TO THE DOMINANT SOCIETY IN THE UNITED STATES AND IS THUS DEPRIVED OF PHYSIOLOGICAL AND PSYCHOLOGICAL SAFEGUARDS AND ITS RIGHT TO PARTICIPATE AND RECEIVE SERVICES ESSENTIAL TO THE DETECTION AND TREATMENT OF DISEASE AND THE MAINTENANCE OF GOOD HEALTH. IN GENERAL, THE FOCUS OF THIS REPORT IS ON THOSE SPANISH-SURNAMED AMERICANS WHO ARE SPANISH-SPEAKING AND ARE IMMIGRANTS OR DESCENDANTS OF IMMIGRANTS FROM MEXICO, PUERTO RICO, CUBA, CENTRAL AND SOUTH AMERICA WHO CONTINUE TO IDENTIFY, OR ARE IDENTIFIED, WITH THE CULTURE AND HERITAGE OF THOSE COUNTRIES. THE CONCERN IS WITH THOSE SPANISH-SURNAMED AMERICANS WHO EXPERIENCE DIFFICULTY ADJUSTING TO THE "AMERICAN WAY OF LIFE" EITHER BECAUSE OF THEIR CUSTOMS AND LANGUAGE OR BECAUSE OF INSTITUTIONAL RACISM DIRECTED AT THEM BECAUSE THEY ARE IDENTIFIED AS SPANISH-SURNAMED AMERICANS.

THE LARGEST POPULATION SEGMENT OF THE SPANISH-SURNAMED AMERICANS ARE THE MEXICAN AMERICANS OR CHICANOS. THEY MAKE UP THE SECOND LARGEST MINORITY GROUP IN THE UNITED STATES WITH A POPULATION IN 1975 OF APPROXIMATELY 6,690,000. THE MAJORITY OF MEXICAN AMERICANS LIVE IN THE STATES OF CALIFORNIA, ARIZONA, COLORADO, NEW MEXICO, AND TEXAS WITH SIZABLE NUMBERS LIVING IN ILLINOIS, IOWA, INDIANA, MICHIGAN, KANSAS, UTAH, OREGON AND WASHINGTON, AND IN THE REST OF THE UNITED STATES IN SMALLER NUMBERS. THE GREATEST CONCENTRATION OF MEXICAN AMERICANS IS IN THE STATE OF CALIFORNIA WHERE THEY NUMBER 3,100,000 PERSONS OR ABOUT 15% OF THE TOTAL POPULATION. IT IS PROJECTED THAT THE MEXICAN AMERICAN POPULATION WILL BE

18.7% IN 1980 OR ABOUT ONE OUT OF EVERY FIVE CALIFORNIANS. THIS PROJECTION REFLECTS THE FACT THAT MEXICAN AMERICANS HAVE THE HIGHEST BIRTHRATE IN THE COUNTRY, EXCEEDING THAT OF THE U.S. POPULATION BY 50%. IN ADDITION, THEIR NUMBER IS INCREASED EACH YEAR BY ABOUT 40,000 IMMIGRANTS FROM MEXICO. THE PROXIMITY OF MEXICO AND THE CONTINUAL INFLUX OF IMMIGRANTS WILL PERPETUATE CULTURAL MORES AND LANGUAGE BARRIERS WHICH NEED TO BE CONSIDERED IN THE APPLICATION OF HUMAN SUBJECTS TO MEDICAL EXPERIMENTATION NOT ONLY IN CALIFORNIA, BUT IN ALL THE SOUTH-WESTERN STATES.

THE FREE FLOW OF AIR TRAVEL BETWEEN PUERTO RICO AND THE EAST COAST POSES SIMILAR PROBLEMS, PARTICULARLY IN NEW YORK WHERE ESTIMATES PLACE THE SPANISH-SPEAKING POPULATION FIGURE AT MORE THAN ONE MILLION.

THE SOCIAL AND ECONOMIC PROBLEMS OF SPANISH SPEAKING AMERICANS ARE OF LONG STANDING STANDING BUT HAVE ONLY RECENTLY BECOME THE FOCUS OF NATIONAL ATTENTION AND ACTION. SPANISH SPEAKING AMERICAN LEADERS HAVE BEEN INSTRUMENTAL IN CREATING THIS NEW AWARENESS AND UNDERSTANDING OF THEIR PEOPLE'S NEEDS. THEY STRESS THE NEED FOR MORE COMPREHENSIVE DATE ON SUCH ELEMENTAL QUESTIONS AS THE NUMBER OF PEOPLE OF SPANISH HERITAGE IN DIFFERENT PARTS OF THE COUNTRY, VITAL STATISTICS AND HEALTH DATA, EDUCATION, EMPLOYMENT STATUS, OCCUPATIONAL PROFILE, INCOME DISTRUBUTION, AND IDENTIFICATION OF THE REASONS FOR THEIR LOW ACCESS TO COMPREHENSIVE HEALTH SERVICES. THE IMPACT OF HUMAN EXPERIMENTATION ON UTILIZATION OF HEALTH CARE SERVICES NEEDS TO BE STUDIED WITH THE OBJECTIVE OF IDENTIFYING THE DEGREE TO WHICH IT SERVES AS A BARRIER TO ACCESS FOR SPANISH-SPEAKING AMERICANS.

SPANISH SPEAKING PEOPLE LIVE IN DISTINCT, CLOSELY KNIT NEIGHBORHOODS, EITHER BY CHOICE OR BECAUSE THEY CANNOT AFFORD OR ARE BARRED FROM HOUSING ELSEWHERE. MANY AMERICANS OF SPANISH BACKGROUND HAVE PERSISTENT ENGLISH LANGUAGE DIFFICULTIES WITH THE EFFECT OF DEEPENING AND PROLONGING THEIR CULTURAL ISOLATION FROM THE MAINSTREAM OF THE POPULATION. MECHANISMS FOR REDUCING THIS ISOLATION THROUGH COMMUNICATION ACROSS ETHNIC LINES IN BOTH THE JOB MARKET AND OTHER ASPECTS OF ECONOMIC AND SOCIAL LIFE, INCLUDING COMPREHENSIVE HEALTH SERVICES, HAVE BEEN GENERALLY INADEQUATE.

TO THESE DIFFICULTIES MUST BE ADDED THAT OF INADEQUATE EDUCATION AMONG BOTH MEXICAN AMERICANS AND PUERTO RICANS, ESPECIALLY IN THE OLDER AGE GROUPS. A LACK OF EDUCATION COMBINED WITH A LIMITED KNOWLEDGE OF ENGLISH FURTHER COMPOUND THE OBSTACLES TO SATISFACTORY, WELL PAID EMPLOYMENT FOR MANY SPANISH SPEAKING ADULTS.

THE SPANISH SPEAKING AMERICAN COMMUNITY IN THE UNITED STATES HAS POLITICALLY HAD MINIMAL IMPACT ON DEVELOPING METHODS TO IMPROVE ITS ACCESS TO EQUITABLE COMPREHENSIVE HEALTH SERVICES. THE SPANISH SPEAKING AMERICAN'S PROGRESS HAS BEEN MARKEDLY SLOWER THAN THAT OF THE BLACK AMERICAN, FOR EXAMPLE, WHOSE DRAMATIC STRUGGLE FOR SOCIAL, ECONOMIC AND POLITICAL GAINS HAS BEEN HIGHLY VISIBLE AND PARTIALLY SUCCESSFUL.

BRIEFLY, THE SPANISH ORIGIN POPULATION IS QUITE YOUNG (MEDIAN AGE, 21) AND IS ONE OF THE MOST FERTILE GROUPS IN THE NATION. IT IS A BILINGUAL POPULATION AND IS DISTRIBUTED AMONG THE FIFTY (50) STATES OF THE UNION. IT ALSO SUFFERS LOWER EDUCATIONAL LEVELS, CONSEQUENTLY LOWER INCOMES TOO.

MOST PERSONS OF SPANISH ORIGIN ARE EMPLOYED IN BLUE COLLAR JOBS. IN JUNE OF 1975 THEY HAD THE SECOND HIGHEST UNEMPLOYMENT RATE (13%) NEXT TO THE BLACK POPULATION (15%). THE NATIONAL HEALTH STATUS OF THE SPANISH ORIGIN POPULATION IS UNKNOWN DUE TO LACK OF MORTALITY, MORBIDITY AND HEALTH STATISTICS IN GENERAL. IT IS ESTIMATED THAT THEIR HEALTH STATUS CAN BE EXTREMELY DEPLORABLE.

THE SPANISH ORIGIN POPULATION IS THE ONLY ETHNIC GROUP IN THE UNITED STATES THAT ACTIVELY MAINTAINS THE LANGUAGE RELATED TO ITS CULTURAL ORIGIN. MOREOVER, IT IS NOT ONLY THE OLDER PEOPLE WHO CONTINUE TO USE THE LANGUAGE OF THEIR ORIGIN. SIXTY-FIVE (65) PERCENT OF THE MEXICAN ORIGIN GROUP THAT HAS MANY THIRD AND EVEN FOURTH GENERATION MEMBERS, REPORTED IN 1973 THAT THEY CURRENTLY SPOKE SPANISH AT HOME. ADDITIONALY, SIXTY-FOUR (64) PERCENT OF THOSE PERSONS WHO WERE UNDER TWENTY YEARS OF AGE SPOKE SPANISH AT HOME. IN TERMS OF THE RELATIONSHIP BETWEEN THE HEALTH CARE INDUSTRY AND ITS RESEARCH EFFORTS AND THE SPANISH ORIGIN POPULATION, LANGUAGE MAINTENANCE ON THE PART OF THIS GROUP IS A FACT THAT CANNOT BE IGNORED (TABLE II).

IN A CURRENT POPULATION REPORT PUT OUT BY THE BUREAU OF THE CENSUS IN NOVEMBER 1971, DATA FROM NOVEMBER 1969 SHOWED THAT THE SPANISH ORIGIN ETHNIC GROUP HAD MORE CHILDREN EVER BORN PER 1,000 WOMEN THAN ANY OTHER GROUP. OUT OF THE SPANISH ORIGIN ETHNICS, MEXICAN ORIGIN WOMEN "COMPRISED ONE OF THE MOST FERTILE GROUPS IN THE POPULATION OF THE UNITED STATES". ACCORDING TO THIS REPORT, THE RATE "IMPLIES A POTENTIAL DOUBLING OF THEIR NUMBERS IN ABOUT ONE GENERATION OR A TWENTY-SIX YEAR PERIOD." (TABLE III)

TABLE II

Persons of Spanish Origin Reporting Spanish Currently Spoken

At Home by Age for the United States, March 1972

Origin & Age	Total	Reporting Spanish Currently Spoken at Home	
		No.	%
Spanish Origin	9,178	6,000	65.4
Under 20 Years	4,572	2,934	64.2
65 Years & Over	322	275	85.4
Mexican	5,254	3,425	65.2
Puerto Rican	1,518	1,101	72.5
All Other Spanish Origin[1]	2,406	1,474	61.3

[1] Includes Cuban origin, Central or South American and Other Spanish Origin not shown separately.

Source: P-20, No. 250, April 1973

TABLE III

Children Ever Born Per 1,000 Women 15 to 44 Years Old By Age, Marital Status, Race and Spanish Origin for Selected Years, 1970 and 1974

(Nos. In Thousands)

Subject	Spanish Origin		All Races		White		Black	
	1974	1970	1974	1970	1974	1970	1974	1970
All Women (including Single)								
15 to 44 years old	1,744	1,919	1,472	1,616	1,452	1,584	1,610	1,851
35 to 39 years old	3,406	3,453	2,831	2,980	2,754	2,920	3,466	3,450
	3,813	3,599	3,084	2,927	3,029	2,852	3,526	3,520

Source: CPS Report P-20, No. 269, "Prospects for Americal Fertility: June 1974 (Advance Data), September 1974.

ALTHOUGH LIMITED, DEMOGRAPHIC SOCIAL AND ECONOMIC STATISTICS DEMONSTRATE THAT THERE IS A DIFFERENCE BETWEEN THE SPANISH ORIGIN POPULATION IN THE UNITED STATES AND THE REST OF THE POPULATION AND WE MUST LEARN TO UNDERSTAND THAT DIFFERENCE.

AN IMPORTANT PART OF THE DIFFERENCE IS OF A CULTURAL NATURE. THE UNITED STATES IS ESSENTIALLY EUROPEAN. EUROPEAN IN BLOOD, EUROPEAN IN CULTURE. SPANISH SPEAKING AMERICA, INCLUDING OUR SOUTHWEST, IS ONLY PARTLY EUROPEAN, PLUS AFRICAN, PLUS INDIAN, IN BLOOD AND IN CULTURE. THE MOORS OF NORTH AFRICA OCCUPIED SPAIN FOR 800 YEARS. THEY LEFT MANY THINGS IN SPAIN; THE DARK HAIR, THE DARK SKIN, THE BLACK FLASHING EYES AND THE FIERY BLOOD THAT TURNS THOSE EYES ON. BUT THEY ALSO LEFT MANY OTHER THINGS, UNDER THE SKIN, PHILOSOPHIC THINGS, RELIGIOUS THINGS, ESTHETIC THINGS.

WHEN THE HANDFUL OF SPANIARDS CAME TO THE NEW WORLD, THEY BROUGHT WITH THEM MANY PREJUDICES, BUT ONE PREJUDICE THE SPANIARDS DID NOT BRING TO THE NEW WORLD WAS RACIAL PREJUDICE. THE PROOF IS TO BE SEEN IN OUR SPANISH SPEAKING SOUTHWEST. IT IS TO BE SEEN IN MEXICO. MEXICO TODAY IS MESTIZO IN BLOOD AND IN CULTURE AND THEY ARE PROUD OF IT.

ANOTHER IMPORTANT DIFFERENCE IS TO BE FOUND IN THE WAY OF LIFE OF OUR PEOPLE. THE ANGLO-AMERICAN HAS AN EPIC SENSE OF LIFE. THE HISPANO-AMERICAN HAS A TRAGIC SENSE OF LIFE. THE EPIC SENSE OF LIFE FUNCTIONS IN A HETEROGENEOUS CULTURE. THE ANGLO-AMERICAN IS A NOBLE KNIGHT, OUT TO SLAY DRAGONS. YOU MIGHT SAY HE IS A GOOD MAN. HE STRUGGLES TO CONQUER

OBSTACLES SUCH AS POVERTY, SICKNESS, TYRANNY, CRIME, CORRUPTION, DRUG ADDICTION, ETC. THE ANGLO-AMERICAN IS A HEROIC OPTIMIST IN THE WAR BETWEEN GOOD AND EVIL AND EVERYONE KNOWS WHICH SIDE HE IS ON. HIS RELIGION WITHOUT PLAYING DOWN THE VALUE OF FAITH, STRESSES CONDUCT AS THE AVENUE TO SALVATION. HE IS A FIRM BELIEVER IN THE TENENT, "GOD HELPS HIM WHO HELPS HIMSELF." PRAGMATISM, THE PHILOSOPHY OF DOING, THE PHILOSOPHY OF GETTING THINGS DONE IS PERHAPS THE BEST THEORETICAL EXPRESSION OF THE EPIC SENSE OF LIFE.

ON THE OTHER HAND, THE HISPANO-AMERICAN HAS A TRAGIC SENSE OF LIFE, PERHAPS A TRAGIC SENTIMENT OF LIFE. HIS IS A TRAGIC SOUL, FIGHTING TO OVERCOME ITSELF. THE HISPANIC SOUL CARRIES WITHIN IT A CONFLICT BETWEEN THE VALUES OF HIS INDIAN INHERITANCE AND HIS SPANISH INHERITANCE. THEREFORE, THE BATTLE IS NOT BETWEEN GOOD AND EVIL. IT IS A BATTLE BETWEEN TWO GOODS. HIS RELIGION, WITHOUT PLAYING DOWN THE VALUE OF GOOD DEEDS, STRESSES FAITH AS THE AVENUE TO SALVATION. HIS RELIGION HAS TOLD HIM, AS IT HAS TOLD ALL CHRISTIANS, THAT THIS WORLD IS A VALLEY OF TEARS, THAT THE GOOD LIFE COMES LATER. HIS ENTIRE HISTORICAL PERSPECTIVE SUPPORTS THIS THESIS. THE BULL FIGHT, A RITUAL FULL OF GRACE, SYMBOLIZES THE TRAGIC SENSE OF LIFE. ONE MAN ALONE CARRIES HIS LIFE AND HIS DEATH ON THE POINT OF A SWORD. A WHOLE PEOPLE ON A SUNDAY AFTERNOON COME FORWARD TO DO HOMAGE TO THIS MAN ALONE, FACING HIS DEATH. IF THE ANGLO-AMERICAN HAS A RENDEZVOUS WITH DESTINY, THE HISPANO-AMERICAN HAS A RENDEZVOUS WITH DEATH. EXISTENTIALSIM, THE PHILOSOPHY OF HUMAN DISASTER AND HUMAN FAILURE IS PERHAPS THE BEST THEORETICAL EXPRESSION OF THE TRAGIC SENSE OF LIFE.

THESE ARE VIEWS OF LIFE THAT PEOPLE HAVE AND THEY HAVE TO BE UNDERSTOOD AND RESPECTED WHEN DEALING WITH THEM, BECAUSE NOT ALL PEOPLE SEE LIFE IN THE SAME WAY. WE NEED TO UNDERSTAND AND RELATE TO THE FEELINGS OF A WOMAN WHO MENTIONS THAT SHE WOULD NOT LIKE TO DIE IN A HOSPITAL WITH A PACEMAKER AND TUBES COMING OUT OF HER MOUTH OR ANYTHING. SHE SAID, "I WANT TO DIE IN MY HUSBAND'S ARMS." SHE FELT THAT DEATH WAS A GREAT EVENT IN HER LIFE AND SHE WANTED TO BE CLOSER TO THAT PERSON THAT SHE LOVED MOST. IT IS THE SAME WITH THE RITUAL OF BIRTH. IT IS THAT VIEW OF LIFE THAT MOVES A WOMAN TO SAY SHE IS AFRAID TO GIVE BIRTH TO HER CHILD IN A COUNTY HOSPITAL WHERE SHE WILL HAVE SURGERY PERFORMED ON HER THAT WILL PREVENT HER FROM HAVING OTHER CHILDREN WITH HER HUSBAND.

ANY FURTHER ATTEMPTS TOWARD THE DEVELOPMENT OR MODIFICATION OF RULES OF BEHAVIOR FOR RESEARCHERS CAN BE SUCCESSFUL ONLY TO THE DEGREE THAT THEY CONSIDER CULTURAL AND SOCIAL VIEWS OF LIFE. SPECIFICALLY, WITH REFERANCE TO THE SPANISH ORIGIN POPULATION THE FOLLOWING ARE SIGNIFICANT:

WE MAKE COLLECTIVE DECISIONS, RELATED TO THE HIGH DEGREE OF SOCIAL AND CULTURAL INTEGRATION THAT WE HAVE. THE FAMILY MUST BE DRAWN IN. THE PATIENT CANNOT BE EXPECTED TO MAKE A MEDICAL DECISION UNTIL HE OR SHE CAN CONSULT WITH FAMILY MEMBERS. IN CASES INVOLVING SENSITIVE ISSUES, FAMILY RANK MUST BE CONSIDERED WHEN ADVISING THE FAMILY IN ORDER TO INSURE THAT THE DECISION IS MADE WITH PROPER COUNSEL.

ADMISSION TO THE HOSPITAL IS A FAMILY AFFAIR. SURGICAL PROCEDURES ARE OFTEN REGARDED AS HARMFUL, DANGEROUS AND UNNECESSARY.

ELDERS ARE VERY IMPORTANT TO US. THEY ARE THE CENTER OF ATTENTION OF THE FAMILY, THE PATRIARCH OF THE COMMUNITY. ANY THOUGHT OF HUMILIATING THEM THROUGH EXPERIMENTAL SURGERY OR TREATMENT IS INCOMPREHENSIBLE.

RELIGION PLAYS AN IMPORTANT ROLE IN OUR LIFE. IT PERMEATES EVERYTHING, FROM PROCREATION AND CHILD RAISING TO MEDICINE. IT IS UNACCEPTABLE TO INDEPENDENTLY TALK TO A MEXICAN AMERICAN WOMAN OF CATHOLIC BACKGROUND ABOUT BIRTH CONTROL METHODS. WHE WILL NOT ACCEPT THE ADVICE AND WILL RESENT IT BEING MENTIONED TO HER. IT MUST BE RECOGNIZED THAT HER ACTION TO ACCEPT BIRTH CONTROL MAY BE INTERPRETED AS "LEAVING THE MORAL AND RELIGIOUS TRADITIONS".

THE CONCEPT OF MODESTY HAS GREAT SIGNIFICANCE TO CHICANO WOMEN. FOR MANY, THEIR BEING EXAMINED BY A MAN IS ENOUGH REASON FOR NOT VISITING A CLINIC OR A DOCTOR. INVOLVING MEXICAN AMERICAN WOMEN IN RESEARCH ACTIVITY RELATED TO BREAST CANCER OR CERVICAL CANCER MUST BE HANDLED DELICATELY FOR MODESTY IS ONE OF THE MOST IMPORTANT INDICES FOR JUDGING WHETHER A WOMAN IS "GOOD" OR "BAD". THIS MAY HELP TO EXPLAIN WHY WOMEN, EXPECIALLY THOSE 30 YEARS OF AGE OR OLDER, SHOW RETICENCE IN HAVING A PELVIC OR BREAST EXAMINATION.

OBESITY IS NOT UNCOMMON AMONG MEN AND WOMEN OF MEXICAN AMERICAN EXTRACTION. IT IS PARTLY DUE TO NUTRITIONAL HABITS, BUT OUR CULTURE TEACHES US THAT TO HAVE A WELL FLESHED BODY IS A SYMBOL OF BEAUTY AND IT IS OFTEN CONSIDERED A SIGN OF GOOD HEALTH AND ENCOURAGED.

FOLK MEDICINE IS STILL WIDELY PRACTICED IN THE SOUTHWEST STATES. FOLK BELIEFS MUST BE RESPECTED AND UNDERSTOOD. MANY PATIENTS WILL NOT VOLUNTARILY DIVULGE SIMULTANEOUS TREATMENT FROM A "CURANDERO".

THESE BELIEFS OR CONCEPTS OF HEALTH ARE IN NO WAY TO BE INTERPRETED AS IN CONFLICT WITH THE NEED FOR BIOMEDICAL RESEARCH OR THE NEED TO INCREASE MEDICAL KNOWLEDGE. SPANISH SPEAKING AMERICANS ARE NO STRANGERS TO THE HISTORY OF SCIENTIFIC AND MEDICAL ACHIEVEMENT. THEY HAVE PARTICIPATED IN AND CONTRIBUTED TO THE GROWTH OF MEDICAL INTELLIGENCE IN THE AMERICAS.

ONLY IN RECENT YEARS HAVE ANTHROPOLOGISTS BEGUN TO RECOGNIZE THE MAJOR SCIENTIFIC AND MEDICAL ACHIEVEMENTS OF THE AZTEC, MAYAN AND INCA CIVILIZATIONS OF MEXICO AND OF PERU, AS WELL AS THE ISLAND PEOPLE OF THE CARIBBEAN. THESE ACHIEVEMENTS EQUAL OR SURPASS THOSE OF MEDITERRANEAN AND EUROPEAN CIVILIZATIONS. THESE CIVILIZATIONS HAD A HIGHLY ORGANIZED, RATIONAL MEDICAL SYSTEM.

THE AZTECS AND INCAS HAD LARGE DRUG FORMULARIES WITH EFFECTIVE REMEDIES FOR A VARIETY OF ILLNESSES LONG BEFORE THE SPANISH CONQUEST. IN ADDITION, THESE PEOPLE HAD DOCTORS, EVEN SPECIALISTS, DIVIDED IN A FASHION SIMILAR TO OUR INTERNISTS AND SURGEONS. THEY SUTURED WOUNDS, SET FRACTURES, APPLIED SPLINTS DEVELOPED RUBBER SYRINGES AND PRESCRIBED DIETARY REGIMENS. THEIR SURGEONS DID AMPUTATIONS AND PERFORMED DELICATE NEUROSURGERY, ESSENTIALLY WHAT WE NOW CALL THE CRANIOTOMY, THAT IS, OPENING THE SKULL TO RELEASE PRESSURE OR TO CLEAN A WOUND. THESE SURGEONS, WITH TOOLS FROM WHICH MODERN ONES ARE IN MANY CASES DERIVED, HAD A SUCCESS RATE OF FIFTY PERCENT. THERE IS EVEN EVIDENCE OF MIDWIFERY FOR CHILDBIRTH.

IT CAN BE CONCLUDED THAT THE CONTROVERSY ABOUT HUMAN EXPERIMENTATION AND THE SPANISH SPEAKING POPULATION IN THIS COUNTRY IS BASED NOT SO MUCH ON INCOMPATIBILITY AS ON THE DEVELOPMENT AND APPLICATION OF SAFEGUARDS THAT ARE CLEAR AND UNDERSTANDABLE AS WELL AS HUMANISTIC.

A REVIEW OF RECENT LITERATURE AVAILABLE AT A HIGHLY RESPECTED SCHOOL OF MEDICINE IN CALIFORNIA REVEALED LITTLE REFERENCE TO THE IMPACT OF HUMAN EXPERIMENTATION ON MINORITY POPULATIONS AND ALMOST NO MENTION OF EFFECT ON CULTURE, LANGUAGE, RELIGION, SOCIAL VALUES OR LIFE STYLE OF THE SPANISH SURNAMED/SPEAKING.

THIS SERVES TO SUBSTANTIATE OTHER FINDINGS AND DETERMINATIONS THAT THERE IS NEED FOR SPECIFIC DIRECTION TO MEDICAL EXPERIMENTERS, WHETHER THEY BE INDIVIDUAL OR INSTITUTIONAL, TO CONFORM WITH GUIDELINES THAT ENSURE RELATED ACTIVITIES ARE NOT OFFENSIVE AND DAMAGING; TO INSURE ADEQUATE SAFEGUARDS FOR PROTECTION OF HUMAN SUBJECTS IN ALL STUDIES; TO ENSURE THAT PROCEDURES FOR OBTAINING INFORMED CONSENT INCLUDE BICULTURAL AND BILINGUAL COMMUNICATION WITHOUT COERCION, IMPLIED THREATS OR SUBTERFUGE; AND TO ENSURE THAT THERE IS FULL DISCLOSURE TO THE INDIVIDUAL AND THE COMMUNITY OF RESEARCH OBJECTIVES AND IMPLICATIONS TO THEM.

THE ELEMENT OF FULL DISCLOSURE CARRIES WITH IT THE NEED FOR FULL AND MEANINGFUL COMMUNICATION. IT IS NOT ENOUGH TO HAVE FORMS PRINTED IN THE SPANISH LANGUAGE OR TO PROVIDE INTERPRETERS WHO WILL TRANSLATE ENGLISH VERSIONS OF REGULATIONS INTO SPANISH. COMMUNICATION MEANS PARTICIPATION BY THE PROFESSIONAL TO THE FULL EXTENT THAT SUCH COMMUNICATION IS REQUIRED BY THE HUMAN SUBJECT OF RESEARCH.

WITHOUT SUCH SAFEGUARDS IT IS NOT UNEXPECTED THAT ACCUSATIONS ABOUT CALLOUS TREATMENT, INSENSITIVITY AND OUTRIGHT ABUSE ARE MADE WITH APPARENT JUSTIFICATION IN MANY CASES.

IT IS REPORTED THAT THOUSANDS OF WOMEN, MOST OF THEM FROM LOW-INCOME, MINORITY GROUPS HAVE BEEN VICTIMIZED BY UNREGULATED "VOLUNTARY" STERILIZATION PROGRAMS IN SOME OF THE NATION'S MOST PRESTIGIOUS HOSPITALS. SUCH ABUSES, ACCORDING TO A LOS ANGELES PHYSICIAN-RESEARCHER, HISTORICALLY HAVE FOUND FERTILE CLIMATES IN THE NATION'S GIANT, CORE-CITY TEACHING COMPLEXES WHERE MEDICINE IS HIGH-VOLUME, ALMOST IMPERSONAL, AND PRACTICED ON PATIENTS WHO ARE GENERALLY POOR, FRIGHTENED AND UNEDUCATED.

IT IS WITHIN THIS ENVIRONMENT THAT THE POSSIBILITY EXISTS FOR WOMEN, WHILE IN THE THROES OF CHILDBIRTH, TO BE CAJOLED, PRESSURED AND SOMETIMES COERCED INTO CONSENTING TO SURGICAL STERILIZATION. IT IS ALSO IN THIS ENVIRONMENT THAT WOMEN CAN BE SUBJECTED TO EXPERIMENTATION WITH NEW METHODS OF CONTRACEPTION, THE USE OF ORAL CONTRACEPTIVES AND RELATED RESEARCH WITHOUT THEIR FULL KNOWLEDGE OR CONSENT.

ANOTHER DHEW ACTIVITY CURRENTLY THE SUBJECT OF COMMUNITY SCRUTINY IS THE PSYCHOLOGICAL SCREENING PROGRAM. IT CONTINUES TO BE PROMOTED BY FEDERAL OFFICIALS DESPITE SKEPTICISM AMONG PSYCHOLOGISTS, PSYCHIATRISTS, CIVIL RIGHTS ADVOCATES AND MINORITY GROUP MEMBERS.

SPANISH SPEAKING AMERICANS ARE CONCERNED BECAUSE OF EARLIER EXPERIENCES WITH SIMILAR PSYCHOLOGICAL EVALUATIONS WHICH RESULTED IN THEIR CHILDREN

BEING PLACED IN SPECIAL EDUCATION CLASSES AND LABELED AS MENTALLY DEFICIENT, RETARDED, BRAIN DAMAGED OR LEARNING DISABLED. CHICANOS STILL BELIEVE THAT INAPPROPRIATE TESTS, STANDARDIZED ON WHITE AND MIDDLE CLASS CHILDREN WERE USED TO REMOVE LIMITED OR NON-ENGLISH SPEAKING CHILDREN FROM THE REGULAR SCHOOL CLASSES.

THE FEAR TODAY IS THAT THE SCREENING WILL BE DONE QUICKLY AND BADLY BY POORLY TRAINED OR CULTURALLY AND ETHNICALLY PREJUDICED TESTERS. MOREOVER, THE SCREENING MAY BE DONE BY NON-SPANISH SPEAKING TESTERS WHO WILL BE UNABLE TO CLEARLY TRANSLATE THE WRITTEN WORDS AND EXPRESSIONS TO THE CHILD BEING INTERVIEWED. SOME OF THE DEVELOPMENTAL SCREENING FORMS ARE COMPLICATED WITH LITERAL TRANSLATIONS LEAVING MUCH TO BE DESIRED (EXHIBIT A). AS A RESULT, INESTIMABLE DAMAGE MAY BE INFLICTED ON CHILDREN WHOSE MAJOR "ABNORMALITY" IS THEIR CULTURAL AND ETHNIC HERITAGE.

ATTEMPTS TO CORRECT HUMILIATING EXPERIENCES AND INJUSTICES THAT EXIST IN THE CONDUCT OF EXPERIMENTATION WITH HUMAN SUBJECTS AS IT RELATES TO THE SPANISH-SPEAKING POPULATION HAVE MET WITH LIMITED SUCCESS. AN EXAMINATION OF THE RECENT HISTORY OF ACCUSATIONS AND INVESTIGATIONS INDICATES THAT PUBLIC HEALTH AGENCIES AND TEACHING HOSPITALS HAVE BEEN THE PRIMARY FOCUS OF ACTIVITY. IN SOME COMMUNITIES PROFESSIONAL STAFFS AND SPANISH-SPEAKING COMMUNITY LEADERS HAVE OPENLY DISCUSSED THE SHORTCOMINGS OF SUCH ACTIVITIES AND IN SOME CASES SIGNIFICANT IMPROVEMENTS HAVE RESULTED. THE GENERAL RULE, HOWEVER, CONTINUES TO BE THAT NO

DENVER DEVELOPMENTAL SCREENING TEST
STO = STOMACH
SIT = SITTING
PERCENT OF CHILDREN PASSING
25
50
75
90
May pass by report
Test from
Footnote No.
see back of form
Date
Name
Birthdate
Hosp. No.
EXHIBIT A
PERSONAL-SOCIAL
FINE MOTOR-ADAPTIVE
LANGUAGE
GROSS MOTOR
MONTHS
YEARS
REGARDS FACE
SMILES RESPONSIVELY
SMILES SPONTANEOUSLY
@ 100% gross at birth
FOLLOWS TO MIDLINE
EQUAL MOVEMENTS
FOLLOWS PAST MIDLINE
HANDS TOGETHER
RESPONDS TO BELL
VOCALIZES NOT CRYING
LAUGHS
SQUEALS
STO LIFTS HEAD
STO HEAD UP 45°
STO HEAD UP 90
SIT. HEAD STEADY
ROLLS OVER
INITIALLY SHY WITH STRANGERS
PLAYS PAT-A-CAKE
PLAYS PEEK-A-BOO
WORKS FOR TOY OUT OF REACH
RESISTS TOY PULL
50%
FEEDS SELF CRACKERS
PULL TO SIT NO HEAD LAG
SITS WITHOUT SUPPORT
STO CHEST UP ARM SUPPORT
STANDS HOLDING ON
PULLS SELF TO STAND
GETS TO SITTING
DRINKS FROM CUP
INDICATES WANTS (NOT CRY)
REACHES FOR OBJECT
SIT, LOOKS FOR YARN
SIT, TAKES 2 CUBES
BAKES RAISIN ATTAINS
PASSES CUBE HAND TO HAND
THUMB-FINGER GRASP
NEAT PINCER GRASP OF RAISIN
DADA OR MAMA, NON-SPECIFIC
TURNS TO VOICE
DADA OR MAMA, SPECIFIC
WALKS HOLDING ON FURNITURE
BEAR SOME WEIGHT ON LEGS
STANDS MOMENTARILY
STOOPS & RECOVERS
WALKS WELL
WALKS BACKWARDS
IMITATES HOUSEWORK
USES SPOON, SPILLING LITTLE
PLAYS BALL WITH EXAMINER
HELPS IN HOUSE SIMPLE TASKS
REMOVES GARMENT
SCRIBBLES SPONTANEOUSLY
TOWER OF 2 CUBES
TOWER OF 4 CUBES
DUMPS RAISIN FROM BOTTLE-DEMONSTR.
DUMPS RAISIN FROM BOTTLE SPONT.
3 WORDS OTHER THAN MAMA, DADA
COMBINES 2 DIFFERENT WORDS
POINTS TO 1 NAMED BODY PART
NAMES 1 PICTURE
FOLLOWS DIRECTIONS/2 of 3
USES PLURALS
KICKS BALL FORWARD
THROWS BALL OVERHAND
WALKS UP STEPS
PUTS ON CLOTHING
VASHES & DRIES HANDS
PLAYS INTERACTIVE GAMES e.g., TAG
BUTTONS UP
DRESSES WITH SUPERVISION
SEPARATES FROM MOTHER EASILY
DRESSES WITHOUT SUPERVISION
COPIES +
COPIES O
IMITATES BRIDGE
TOWER OF 8 CUBES
IMITATES VERTICAL LINE WITHIN 30°
PICKS LONGER LINE 3 OF 3
COPIES 11
IMITATES I DEMONSTR.
DRAWS MAN 3 PARTS
DRAWS MAN 6 PARTS
COMPREHENDS COLD, TIRED, HUNGRY/2 of 3
COMPREHENDS PREPOSITIONS/3 of 4
RECOGNIZES COLORS/3 of 4
OPPOSITE ANALOGIES - 2 of 3
GIVES 1ST & LAST NAME
DEFINES WORDS/6 of 9
87%
COMPOSITION OF/3 of 3
87%
BALANCE ON 1 FOOT 1 SECOND
BALANCE ON 1 FOOT 10 SECONDS/2 of 3
HOPS ON 1 FOOT
CATCHES BOUNCED BALL/2 of 3
HEEL TO TOE WALK/2 of 3
BACKWARD HEEL-TOE/2 of 3
PEDALS TRICYCLE
JUMPS IN PLACE
BROAD JUMP
BALANCE ON 1 FOOT 5 SECONDS/2 of 3

SUFFICIENTLY COMPELLING REGULATIONS OR REQUIREMENTS EXIST FOR INSTITUTIONS TO MODIFY THEIR PROGRAMS AND PROCEDURES IN ORDER TO PROVIDE BILINGUAL AND CULTURALLY SENSITIVE PROCEDURES TO SPECIAL POPULATIONS, ESPECIALLY THE LOW-INCOME SPANISH-SPEAKING. THE PROVISIONS SET FORTH UNDER REVISED DHEW POLICIES AND REGULATION ON PROTECTION OF HUMAN SUBJECTS HOLD THE POTENTIAL OF HAVING A SIGNIFICANT IMPACT ON THE ISSUE OF RELEVANT SAFEGUARDS, AND IN ISOLATED EXPERIENCES SUCH A POTENTIAL IS BEING REALIZED. HOWEVER, THE FEDERAL GOVERNMENT HAS NOT MUSTERED THE WHEREWITHAL TO MONITOR COMPLIANCE ISSUES ON A COMPREHENSIVE BASIS.

IT IS APPARENT THAT THE NEED EXISTS FOR REFORM THAT ADDRESSES THE SPECIAL PROBLEMS OF BILINGUAL-BICULTURAL CITIZENS. THUS IT IS PROPOSED THAT POLICIES, GUIDELINES AND REGULATIONS BE AMENDED MANDATING THAT INSTITUTIONS CONDUCTING RESEARCH INVOLVING HUMAN SUBJECTS MUST PROVIDE FOR THE CONDUCT OF SUCH RESEARCH IN THE WAY MOST APPROPRIATE TO THE LANGUAGE AND CULTURAL PATTERNS OF BILINGUAL-BICULTURAL COMMUNITIES. IN THE CASE OF THE SPANISH-SPEAKING, SPANISH-SURNAMED, THE RESEARCH MUST PROVIDE FOR THE PROTECTION OF CULTURAL, SOCIAL, RELIGIOUS AND PERSONAL VALUES AND SHOULD BE CONDUCTED BY SPANISH-SPEAKING, SPANISH-SURNAMED PHYSICIAN-RESEARCHERS WHEREVER A SIGNIFICANT NUMBER OF SUCH INDIVIDUALS RESIDE IN THE COMMUNITY.

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9

RESOLUTION AND RECOMMENDATIONS

OF THE

WORKSHOP ON HEALTH CARE DELIVERY

National Minority Conference

on

Human Experimentation

January 8, 1976

Resolution and Recommendations of the Workshop on Health Care Delivery

National Minority Conference
on
Human Experimentation
January 8, 1976

Human experimentation must be justified by the biomedical necessity and scientific validity of the experiment. Priorities of human need must govern decisions as to the necessity of the experiments undertaken and their nature.

These experiments must adhere to ethical, moral and nondiscriminatory values. Protection of human subjects must be paramount.

To this end we recommend that:

1. The policies, priorities and practices of health care institutions should be monitored by (1) independent community organizations composed of nonscientists and (2) independent patient omsbudsmen with subpoena and other legal powers in order to insure the faithful observance of the ethical, moral values and guidelines presently existing or to be promulgated.

   Augmenting these outside monitoring devices should be the following:

   (a) Joint monitoring by federal and other funding agencies and recipient institutions of biomedical research projects to insure compliance with original research designs prior to and after the grant has been made.

   (b) Laws and/or regulations requiring public disclosure by all researchers and health care institutions of proposed and ongoing biomedical research.

   (c) Federally funded local groups who actively educate patients in their own language as to their rights with regard to a variety of health care practices, e.g., admittance, services due, experimentation.

2. It must be recognized that a significant amount of family planning (birth control) is an experimental procedure which has implications for future generations; and unknown risks to those currently involved, and is also discriminatory in that recruitment is primarily among the poor and that most programs are targeted almost exclusively towards women.

It is therefore recommended that (1) there be equitable representation of both sexes and all socioeconomic background in all family planning (birth control) research. (2) And that ongoing evaluation of the risks of such programs and the implications for future generations should be undertaken.

3. It is a fact that more information, care and concern is typically bestowed upon those patients and subjects of the same race and social status as the majority of medical professionals. This represents the highest standard of medical care available. In order to insure that this standard of medical care is available to all, it is therefore recommended that there be an equitable representation of non-minorities and persons of upper-level socioeconomic backgrounds as subjects in all experiments, especially those biomedical research projects involving great risk to health.

4. If human experimentation should be addressed to priorities of human need, it follows that the positive and beneficial results of such experiments should be immediately available to those who are the subjects of the research, frequently the poor and minority groups, as well as others.

   It should be a necessary prerequisite of human experimentation that it will offer support to the improvement of health care delivery.

   In order for this actually to occur, funding for human experimentation should be closely tied to adequate support of the health care delivery system.

   The current cuts in Medicaid and Medicare and other health programs present a serious problem to health care delivery and tend to negate any beneficial effects to the poor and minority groups from the progress of human experimentations.

   It should therefore be a priority to restore our ability to deliver the medical care that medical progress has already achieved before additional funding for human experimentations is granted.

5. The definition of human experimentation should be expanded to include protection of patients receiving their general medical care on "teaching services," e.g., those services students and post graduate students are involved in the delivery of medical care.

   The well publicized abuses of health care professionals and researchers in violation of ethical and moral standards, with their attendant tragic consequences for poor and minority persons (e.g., the large number of hysterectomies performed on minority women) reveals a serious lack of ethical consciousness on the part of their medical personnel. It is therefore recommended that all medical personnel be required to receive training in ethics with special emphasis on the requirements of informed consent and case studies of abuses to minorities and women and how to prevent them.

Where patients are treated in teaching hospitals every effort should be made to assure that said patients are fully informed of the training status of the medical students, that the patients have some choice regarding acceptance of treatment from students, that consistent and persistent supervision be available, that all appropriate alternatives regarding prescribed treatment be reviewed with the patient, and that no adverse actions be taken, or treatment denied to patients requesting consultation or the services of a fully trained physician or health professional.

6. The informed consent statement signed by subjects willing to participate in human experimentation must include a proviso that, in the event the subjects experience physical or psychological harm as a result of participation in the experiment, appropriate compensation, including monetary compensation, will be received. The determination of physical and psychological harm will be made by parties independent of the given institution or research site, with such a group containing professionals and laymen, at least one third of whom must be socioeconomic peers of the subject claiming injury or harm.

7. The science of medicine, whether as practiced in highly sophisticated Bicentennial America or by curanderos in the remotest villages of Mexico, embodies an intricate system of knowledge which the healer possesses and the patient does not. A knowledgeable patient is able to take more responsibility for his own health and to make intelligent decisions regarding the care he receives. The poor minorities in this country have the greatest health problems and are least equipped to cope with them or to make informed decisions whether those decisions involve seemingly simple medical choices or family planning, or participation in a research project.

We therefore recommend that the Commission assume leadership in the establishment of public health education geared toward the enlightenment of minorities regarding human experimentation and its specific implications for them, including their specific rights.

III

MATERIALS REVIEWED BY THE COMMISSION

10

AMERICAN HOSPITAL ASSOCIATION

STATEMENT ON A PATIENT'S BILL OF RIGHTS

AMERICAN HOSPITAL ASSOCIATION
Statement on a Patient's
Bill of Rights *

The American Hospital Association presents a Patient's Bill of Rights with the expectation that observance of these rights will contribute to more effective patient care and greater satisfaction for the patient, his physician, and the hospital organization. Further, the Association presents these rights in the expectation that they will be supported by the hospital on behalf of its patients, as an integral part of the healing process. It is recognized that a personal relationship between the physician and the patient is essential for the provision of proper medical care. The traditional physician-patient relationship takes on a new dimension when care is rendered within an organizational structure. Legal precedent has established that the institution itself also has a responsibility to the patient. It is in recognition of these factors that these rights are affirmed.

(1) The patient has the right to considerate and respectful care.

(2) The patient has the right to obtain from his physician complete current information concerning his diagnosis, treatment, and prognosis in terms the patient can be reasonably expected to understand. When it is not medically advisable to give such information to the patient, the information should be made available to an appropriate person in his behalf. He has the right to know, by name, the physician responsible for coordinating his care.

(3) The patient has the right to receive from his physician information necessary to give informed consent prior to the start of any procedure and/or treatment. Except in emergencies, such information for informed consent should include but not necessarily be limited to the specific procedure and/or treatment, the medically significant risks involved, and the probable duration of incapacitation. Where medically significant alternatives for care or treatment exist, or when the patient requests information concerning medical alternatives, the patient has the right to such information. The patient also has the right to know the name of the person responsible for the procedures and/or treatment.

(4) The patient has the right to refuse treatment to the extent permitted by law and to be informed of the medical consequences of his action.

(5) The patient has the right to every consideration of his privacy concerning his own medical care program. Case discussion, consultation, examination, and treatment are confidential and should be conducted discreetly. Those not directly involved in his care must have the permission of the patient to be present.

(6) The patient has the right to expect that all communications and records pertaining to his care should be treated as confidential.

(7) The patient has the right to expect that within its capacity a hospital must make reasonable response to the request of a patient for services. The hospital must provide evaluation, service, and/or referral as indicated by the urgency of the case. When medically permissible, a patient may be transferred to another facility only after he has received complete information and explanation concerning the needs for and alternatives to such a transfer. The institution to which the patient is to be transferred must first have accepted the patient for transfer.

(8) The patient has the right to obtain information as to any relationship of his hospital to other health care and educational institutions insofar as his care is concerned. The patient has the right to obtain information as to the existence of any professional relationships among individuals, by name, who are treating him.

(9) The patient has the right to be advised if the hospital proposes to engage in or perform human experimentation affecting his care or treatment. The patient has the right to refuse to participate in such research projects.

(10) The patient has the right to expect reasonable continuity of care. He has the right to know in advance what appointment times and physicians are available and where. The patient has the right to expect that the hospital will provide a mechanism whereby he is informed by his physician or a delegate of the physician of the patient's continuing health care requirements following discharge.

(11) The patient has the right to examine and receive an explanation of his bill regardless of source of payment.

(12) The patient has the right to know what hospital rules and regulations apply to his conduct as a patient.

No catalog of rights can guarantee for the patient the kind of treatment he has a right to expect. A hospital has many functions to perform, including the prevention and treatment of disease, the education of both health professionals and patients, and the conduct of clinical research. All these activities must be conducted with an overriding concern for the patient, and, above all, the recognition of his dignity as a human being. Success in achieving this recognition assures success in the defense of the rights of the patient.

* from: Background Papers: National Symposium on Patients' Rights in Health Care, May 17 and 18, 1976, DHEW Public Health Services Administration, Washington, D.C.

11

HEALTH SERVICES ADMINISTRATION

ADMINISTRATIVE GUIDELINES FOR FEDERALLY FUNDED AMBULATORY CARE CENTERS

PATIENT'S BILL OF RIGHTS

HEALTH SERVICES ADMINISTRATION

Administrative Guidelines
for Federally Funded
Ambulatory Care Centers

Patient's Bill of Rights*

The center has in effect a written patient bill of rights and responsibilities which is available to patients and which includes the following points:

- Is fully informed of all patient rights, rules and regulations governing patient conduct and responsibilities
- Is fully informed of the services available at the center
- Is fully informed of related charges, including any charges not covered by third-party payors
- Is fully informed of his or her medical condition unless medically contra-indicated and is afforded the opportunity to participate in the planning of medical treatment and to refuse to participate in experimental research
- May voice grievances and recommend changes in policies and services to center staff and the governing board
- Is assured confidential treatment of records and disclosures, and is afforded the opportunity to approve or refuse their release to any individual except as required by law or third-party payment contract
- Is treated with consideration, respect, and full recognition of dignity and individuality, including privacy in treatment and in care for personal needs
- Is responsible for keeping appointments and notifying the center in advance when unable to keep appointments

- Is responsible for giving truthful information
- Is to abide by the rules and regulations governing patient conduct and responsibilities

* from Background Papers: National Symposium on Patients' Rights in Health Care, May 17 and 18, 1976, DHEW, Public Health Services Administration, Washington, D.C.

12

PATIENT'S BILL OF RIGHTS

PHOENIX AREA

INDIAN HEALTH SERVICE

January 1974

PHOENIX AREA INDIAN HEALTH SERVICE
CHAPTER 1
INDIANS December 14, 1973

MANUAL INSTRUCTION 2-1.2

Distribution: All Service Units, Area Office and Branch Chiefs, Area Board

Subject: Patient's Bill of Rights for Phoenix Area IHS

Purpose: To establish the following as the official policy of the Phoenix Area.

1. The Indian patient has the right to considerate and respectful care including a sensitivity, on the part of the provider, to Indian culture and heritage. (Religious beliefs, folkways, mores, etc.)

2. The patient, or an appropriate member of his family in the case of minors, non-English speaking patients, or patients whose condition is such that they could not understand, has the right, when it is in his best interest medically, to get all information concerning his health care from his physician. When it is considered not to be in his best interest to have the information, the patient has the right for the information to be given to another appropriate person (family member, guardian, other physician, etc.) acting in his behalf. He also has the right to know who the physician is that is responsible for his care.

3. The patient has the following rights concerning informed consent. (Approval to do certain special procedures or treatments.)

a. His physician must give him all the information needed for him to make a decision whether or not to agree to the procedure or treatment.

b. The information provided should include at least an explanation and understanding of the procedures and/or treatments involved, the risks the patient may be taking and how long the patient may have to be incapacitated (out of work or restricted from normal activities) due to the procedures or treatments.

c. The patient has the right to know what other choices, if any, he may have other than the procedures or treatments indicated.

d. The patient has the right to know the name and qualifications of the person(s) who will be responsible for his procedures or treatment.

e. In emergency situations (life threatening or possibility of permanent loss of limbs, eyesight, or other critical functions) the physician

may not be able to provide extensive information to the patient because of lack of time. In such instances the physician would not be responsible for providing extensive information because giving such information may be taking precious time and, therefore, could be more dangerous for the patient.

4. The patient has the right to refuse treatment to the extent permitted by law -- but if he does, he must be informed of the risks he is taking by doing so. Example of this might be patient requesting early (premature) discharge from the hospital, or an early transfer to another hospital or Nursing Home, etc.

5. The patient has the right to privacy and dignity concerning his own illness and medical management of that illness. Case discussion, examination, and treatment shall be conducted in confidence. Medical students and para-professional trainees will always be introduced to the patient. The patient has the right to refuse permission for their presence if they are not directly involved in his care.

6. The patient has the right to expect that all the records and other information about his care be kept confidential.

7. The patient has the right for the following services when he requests care:

a. Services will be provided to the patient to the extent the facility and its resources can provide the services.

b. If the facility has such resources, it will provide:

(1) Evaluation (diagnosis and general health condition of the patient).

(2) Service - treatment or procedures to prevent, control, or cure illness.

(3) Referral - providing additional physicians or other appropriate individuals to provide care which may be required and is not available from the physician seeing the patient at the time.

c. The patient has the right to expect that his referring physician, or other appropriate person(s) designated, will secure up-to-date reports of his care and progress while he is receiving care in a referral or contract hospital.

d. When transferring a patient to another facility where he can receive care not available at the local facility:

(1) The transfer must be medically indicated.

(2) The patient must give his permission to be transferred.

(3) The patient has the right to know the alternatives to such a transfer before he gives his permission.

(4) The facility to which the patient is to be transferred must accept the patient before he is transferred.

8. The patient has the right to know how and to what extent his local health facility is related to other non-local health facilities (private, state, county, other Federal or University hospitals).

9. There are many conditions and illnesses that have no known generally accepted cures or treatments or which occur more frequently among certain population groups or in certain areas of the country. There is, however, a continual effort to find such cures or to discover why these conditions occur as they do. The way cures are discovered is through research. Some patients develop these difficult or generally uncureable diseases. When it is generally considered by the best medical authorities to be untreatable by normal accepted methods, then the following choices are available to the patient and his physician:

a. Make the patient as comfortable as possible and let the disease run its course.

b. Suggest to the patient that he might consider treatments by new and experimental (unproven) methods.
The patient has the right to know if the hospital or any institution plans to use unproven methods of treatment that will affect his care or treatment. The patient has the right to refuse to take part in any of these research projects.

10. The patient has the right to expect reasonable continuity of care such as:

a. To know ahead of time what appointment times are available to him.

b. To know what physicians are available to him.

c. To know where the services can be obtained.

d. That an appropriate person from his health facility will keep him informed as to other things he needs to have done after he is discharged from the hospital.

11. The patient has the right to know what hospital rules and regulations apply to his conduct.

12. The patient has the right to take complaints on health services to either the Service Unit Director or Chairman of local Indian Health Board or their designated patient advocate. The Service Unit Director shall be held accountable to hear and begin investigation on patient complaints within 48 hours. The patient should receive a reply in writing on the status of his complaint within five (5) working days following his complaint. A patient, Chairman of local Board and/or Service Unit Director may report unresolved problems to Chairman of Area Health Board and/or Area Director who must take immediate action to investigate and resolve patient's problems.

In the event the Service Unit Director and/or Chairman of local health Board feels that a patient's allegations relate to severely substandard medical practice, he will request the Area Director to arrange for an investigation by an independent authority who will report his findings to Area Director and Chairman Area Health Board.

Review – Annually the Area Office and Area Indian Health Board shall review this issuance for purpose of updating and/or amending.

Charles S. McCammon, M. D.
Director, Phoenix Area Indian
Health Service

13

CONDITIONS OF PARTICIPATION

MEDICARE/MEDICAID

SKILLED NURSING FACILITY

PATIENT'S BILL OF RIGHTS

CONDITIONS OF PARTICIPATION
MEDICARE/MEDICAID
Skilled Nursing Facility
Patient's Bill of Rights *

The governing body of the facility establishes written policies regarding the rights and responsibilities of patients and, through the administrator, is reasonsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients, to any guardians, next of kin, sponsoring agency(ies), or representative payees selected pursuant to section 205(j) of the Social Security Act, and Subpart Q of Part 404 of this chapter, and to the public. The staff of the facility is trained and involved in the implementation of these policies and procedures.

These patients' rights policies and procedures ensure that, at least each patient admitted to the facility:

(1) Is fully informed, as evidenced by the patient's written acknowledgment, prior to or at the time of admission and during stay, of these rights and of all rules and regulations governing patient conduct and responsibilities;

(2) Is fully informed, prior to or at the time of admission and during stay, of services available in the facility, and of related charges including any charges for services not covered under titles XVIII or XIX of the Social Security Act, or not covered by the facility's basic per diem rate;

(3) Is fully informed, by a physician, of his medical condition unless medically contraindicated (as documented, by a physician, in his medical record), and is afforded the opportunity to participate in the planning of his medical treatment and to refuse to participate in experimental research;

(4) Is transferred or discharged only for medical reasons, or for his welfare or that of other patients, or for non-payment for his stay (except as prohibited by

titles XVIII or XIX of the Social Security Act), and is given reasonable advance notice to ensure orderly transfer or discharge, and such actions are documented in his medical record;

(5) Is encouraged and assisted, throughout his period of stay, to exercise his rights as a patient and as a citizen, and to this end may voice grievances and recommend changes in policies and services to facility staff and/or to outside representatives of his choice, free from restraint, interference, coercion, discrimination, or reprisal;

(6) May manage his personal financial affairs or be given, at least quarterly, an accounting of financial transactions made on his behalf should the facility accept his written delegation of this responsibility for any period of time, in conformance with State law;

(7) Is free from mental and physical abuse, and free from chemical and (except in emergencies) physical restraints except as authorized in writing by a physician for a specified and limited period of time, or when necessary to protect the patient from injury to himself or to others;

(8) Is assured confidential treatment of his personal and medical records, and may approve or refuse their release to any individual outside the facility, except, in case of his transfer to another health care institution, or as required by law or third-party payment contract;

(9) Is treated with consideration, respect, and full recognition of his dignity and individuality, including privacy in treatment and in care for his personal needs;

(10) Is not required to perform services for the facility that are not included for therapeutic purposes in his plan of care;

(11) May associate and communicate privately with persons of his choice, and send and receive his personal mail unopened, unless medically contraindicated (as documented by his physiican in his medical record);

(12) May meet with, and participate in activities of, social, religious, and community groups at his discretion, unless medically contraindicated (as documented by his physician in his medical record);

(13) May retain and use his personal clothing and possessions as space permits, unless to do so would infringe upon rights of other patients, and unless medically contraindicated (as documented by his physician in his medical record); and

(14) If married, is assured privacy for visits by his/her spouse; if both are in-patients in the facility, they are permitted to share a room, unless medically contraindicated (as documented by the attending physician in the medical record).

All rights and responsibilities specified in paragraphs (k)(1) through (4) of this section as they pertain to (a) a patient adjudicated incompetent in accordance with State law, (b) a patient who is found, by his physician, to be medically incapable of understanding these rights, or (c) a patient who exhibits a communication barrier--devolve to such patient's guardian, next of kin, sponsoring agency(ies), or representative payee (except when the facility itself is representative payee) selected pursuant to section 205(j) of the Social Security Act and Subpart Q of Part 404 of this chapter.

* from: Background Papers: National Symposium on Patients' Rights in Health Care, May 17 and 18, 1976, DHEW, Public Health Services Administration, Washington, D.C.

14

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE REGULATIONS FOR PROJECT GRANTS FOR OPERATING COMMUNITY HEALTH CENTERS

June 11, 1976

Federal Register

June 11, 1978

Subpart C—Grants for Operating Community Health Centers

§ 51c.301 Applicability.

The regulations of this subpart, in addition to the regulations of Subpart A, are applicable to grants awarded pursuant to section 330(d)(1)(A) of the Act for the costs of operation of community health centers which serve medically underserved populations.

§ 51c.302 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 51c.104 of Subpart A,

(a) Be submitted by an entity which the Secretary determines is a community health center, and

(b) Contain information sufficient to enable the Secretary to determine that the center will meet the requirements of § 51c.103.

§ 51c.303 Project elements.

A community health center supported under this subpart must:

(a) Provide the health services of the center so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to the residents of the center's catchment area.

(b) Implement a system for maintaining the confidentiality of patient records in accordance with the requirements of § 51c.110 of Subpart A.

(c) Have an ongoing quality assurance program which provides for the following:

(1) Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care;

(2) Periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided to individuals served by the center. Such assessments shall:

(i) Be conducted by physicians or by other licensed health professionals under the supervision of physicians;

(ii) Be based on the systematic collection and evaluation of patient records; and

(iii) Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated.

(d) Develop management and control systems which are in accordance with sound financial management procedures, including the provision for an audit on an annual basis (unless waived for cause by the Secretary) by an independent certified public accountant to determine, at a minimum, the fiscal integrity of grant financial transactions and reports, and compliance with the regulations of this part and the terms and conditions of the grant.

(e) Where the cost of care and services furnished by or through the project is to be reimbursed under Title XIX or Title XX of the Social Security Act, obtain or make every reasonable effort to obtain a written agreement with the Title XIX or Title XX State agency for such reimbursement.

(f) Have prepared a schedule of fees or payments for the provision of its services designed to cover its reasonable costs of operation and a corresponding schedule of discounts adjusted on the basis of the patient's ability to pay. *Provided*, That such schedule of discounts shall provide for a full discount to individuals and families with annual incomes at or below those set forth in the most recent CSA Poverty Income Guidelines (45 CFR 1060.2) and for no discount to individuals and families with annual incomes greater than twice those set forth in such Guidelines.

(g) Make every reasonable effort, including the establishment of systems for eligibility determination, billing, and collection, to:

(1) Collect reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under Title XVIII of the Social Security Act, to medical assistance under a State plan approved under Title XIX of such Act, to social services and family planning under Title XX of such Act, or to assistance for medical expenses under any other public assistance program, grant program, or private health insurance or benefit program on the basis of the schedule of fees prepared pursuant to paragraph (f) of this section without application of any discounts, and

(2) Secure from patients payments for services in accordance with the schedule of fees and discounts required by paragraph (f) of this section.

(h) Have a governing board which meets the requirements of § 51c.304.

(i) Have developed an overall plan and budget for the center that:

(1) Provides for an annual operating budget and a three-year financial management plan which include all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items;

(2) Provides for a capital expenditures plan for at least a three-year period (including the year to which the operating budget described in paragraph (i)(1) of this section is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objective of, each anticipated expenditure in excess of $100,000 related to the acquisition of land, the improvement of land, buildings, and equipment and the replacement, modernization and expansion of buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(3) Provides for plan review and updating at least annually; and

(4) Is prepared under the direction of the governing board, by a committee consisting of representatives of the governing board, and administrative staff, and the medical staff, if any, of the center.

(j) Establish basic statistical data, cost accounting, management information, and reporting or monitoring systems which shall enable the center to provide such statistics and other information as the Secretary may reasonably require relating to the center's costs of operation, patterns of utilization of services, and the availability, accessibility, and acceptability of its services and to make such reports to the Secretary in a timely manner with such frequency as the Secretary may reasonably require.

(k) Review its catchment area annually to insure that the criteria set out in § 51c.104(b)(2) of Subpart A are met and, where such criteria are not met, revise its catchment area, with the approval of the Secretary, to conform to such criteria to the extent feasible.

(l) In the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, have developed a plan and made arrangements responsive to the needs of such populations for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and have identified an individual on its staff who is fluent in both that language and in English and whose responsibilities include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences. If more than one non-English language is spoken by such group or groups, an individual or individuals fluent in those languages and English shall be so identified.

(m) Be operated in a manner calculated to preserve human dignity and to maximize acceptability and effective utilization of services.

(n) To the extent possible, coordinate and integrate project activities with the activities of other Federally funded, as well as State and local, health services delivery projects and programs serving the same population.

(o) Establish means for evaluating progress toward the achievement of the specific objectives of the project.

(p) Provide sufficient staff, qualified by training and experience, to carry out the activities of the center.

(q) Assure that facilities utilized in the performance of the project meet applicable fire and life safety codes.

(r) Utilize, to the maximum extent feasible, other Federal, State, and local,

and private resources available for support of the project, prior to use of project funds under this part.

(s) Provide for community participation through, for example, contributions of cash or services, loans of full- or part-time staff, equipment, space, materials, or facilities.

(t) Where the center will provide services through contract or other cooperative arrangements with other providers of services, establish rates and methods of payment for health care. Such payments must be made pursuant to agreements, with a schedule of rates and payment procedures maintained by the project. The project must be prepared to substantiate that such rates are reasonable and necessary.

(u) Operate in a manner such that no person shall be denied service by reason of his inability to pay therefor. *Provided, however,* That a charge for the provision of services will be made to the extent that a third party (including a Government agency) is authorized or is under legal obligation to pay such charges.

(v) In addition to the above, projects which are supported with grant funds for the operation of a prepaid health care plan also must provide:

(1) A marketing and enrollment plan, including market analysis, marketing strategy, and enrollment growth projections.

(2) A plan that provides for funding on a capitation basis of such portion of the residents of the catchment area of the center, as the Secretary shall determine.

(3) An assurance that services shall be available to all residents of the catchment area without regard to method of payment or health status.

§ 51c.304 Governing board.

A governing board for the center shall be established by an applicant as follows:

(a) *Size.* The board shall consist of at least 9 but not more than 25 members.

(b) *Composition.* (1) A majority of the board members shall be individuals who are or will be served by the center and who, as a group, represent the individuals being or to be served in terms of demographic factors, such as race, ethnicity, sex.

(2) No more than one-half of the remaining members of the board may be individuals who derive more than 10 percent of their annual income from the health care industry.

(3) The remaining members of the board shall be representative of the community in which the center's catchment area is located and shall be selected for their expertise in community affairs, local government, finance and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social service agencies within the community.

(4) No member of the board shall be an employee of the center, or spouse or child, parent, brother or sister by blood or marriage of such an employee. The project director may be a non-voting, ex-officio member of the board.

(c) *Selection of members.* The method of selection of all governing board members shall be prescribed in the by-laws or other internal governing rules of the center. Such by-laws or other rules must specify a process of selection of individuals on the governing board who represent the population served or to be served by the center so that such individuals, as a group, are representative of such population. Such process of selection in the by-laws or other rules is subject to approval by the Secretary.

(d) *Functions and responsibilities.* (1) The governing board for the center shall have authority for the establishment of policy in the conduct of the center.

(2) The governing board shall hold regularly scheduled meetings, at least once each month, for which minutes shall be kept.

(3) The governing board shall have specific responsibility for:

(i) Approval for the selection and dismissal of a project director or chief executive officer of the center;

(ii) Establishing personnel policies and procedures, including selection and dismissal procedures, salary and benefit scales, employee grievance procedures, and equal opportunity practices;

(iii) Adopting policy for financial management practices, including a system to assure accountability for center resources, approval of the annual project budget, center priorities, eligibility for services including criteria for partial payment schedules, and long-range financial planning;

(iv) Evaluating center activities including services utilization patterns, productivity of the center, patient satisfaction, achievement of project objectives, and development of a process for hearing and resolving patient grievances;

(v) Assuring that the center is operated in compliance with applicable Federal, State, and local laws and regulations; and

(vi) Adopting health care policies including scope and availability of services, location and hours of services, and quality-of-care audit procedures.

§ 51c.305 Grant evaluation and award.

Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(d)(1)(A) of the Act and the applicable regulations of this part, taking into consideration:

(a) The extent to which the project would provide for the elements set forth in § 51c.303;

(b) The relative need of the population to be served for the services to be provided;

(c) The potential of the center for the development of new and effective methods for health services delivery and management;

(d) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(e) The administrative and management capability of the applicant;

(f) The extent to which grants approved under this part will provide for an appropriate distribution of resources throughout the country, taking into consideration the following factors:

(1) The urban-rural area to be served;

(2) The nature of the organization applying;

(3) The organizational structure for delivery of services;

(g) The number of users of the center and the level of utilization of services in previous operational periods, if any;

(h) Whether the center's catchment area is exclusive of the area served by another center;

(i) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health services or reimbursement programs or projects;

(j) The extent to which community resources will be utilized by the project;

(k) The extent to which the center will provide preventive health services so as to maintain and improve the health status of the population served; and

(l) The extent to which center operations will emphasize direct health services, efficiency of operations and sound financial management.

"PERSONAL PRIVACY IN AN INFORMATION SOCIETY,": EXCERPTS FROM REPORT OF THE PRIVACY PROTECTION STUDY COMMISSION, JULY 1977

A. THE CITIZEN AS A BENEFICIARY OF GOVERNMENT ASSISTANCE

B. PATIENT ACCESS TO MEDICAL RECORDS

Excerpt from:

Personal Privacy in an Information Society

Chapter 11: The Citizen as Beneficiary of Government Assistance

The Report of
The Privacy Protection Study Commission

July 1977

Chapter 11

The Citizen as Beneficiary of Government Assistance

Two factors led the Privacy Protection Study Commission to study the record-keeping practices of public assistance and social services[1] agencies.[2] First, the number of Americans who receive government assistance or service in some form is enormous. Second, the process of administering the welfare system[3] depends on the collection and use of personal information. The collaboration between the Federal government and the various States in developing the present welfare system has provided a complex set of eligibility criteria and formulae for determining the level of benefits to which an individual is entitled. Applying them demands a great deal of personal information. No one could deny that the welfare system is "intrusive," if one test of intrusiveness is the volume, detail, and sensitivity of the information collected about clients[4] of the system.

Perhaps because the intrusive nature of the system is so widely acknowledged, Congress has, since the 1930's, recognized the need to provide some protection from unfairness in the use of records about clients of federally assisted welfare programs. Federal law regarding record keeping does not, however, encompass all the basic issues of fairness identified by the Commission. In addition, although the largest federally assisted welfare

[1] "Public assistance and social services" include, for the Commission's purposes, cash or in-kind benefits (including, for example, food coupons, medical services, day care, counseling, alcohol and drug abuse treatment, employment training and housing) subsidized by government funding and provided to individuals or families on the basis of financial need. The term does not include benefits provided under an insurance scheme, such as Old-Age, Survivors and Disability Benefits, Medicare, or Unemployment Insurance. This chapter, and the recommendations contained herein, do not apply to any public assistance and social services program that is federally administered (such as Supplemental Security Income) and thus subject to the Privacy Act of 1974.

[2] "Agencies" include, for the Commission's purposes, any public or private organization administering, supervising the administration of, or delivering services to individuals or families pursuant to, a public assistance or social services program. This definition would include, for example, private service organizations providing services to clients under Title XX of the Social Security Act. It does not include medical-care providers rendering medical assistance to Medicaid and Title XX recipients, except insofar as these institutions determine eligibility for the Medicaid and Title XX programs. Recommendations affecting the record-keeping practices of medical-care providers are found in Chapter 7.

[3] "Welfare system" and "welfare," as used in this chapter, refer to the entire complex of public assistance and social services programs.

[4] The term "client" will be used throughout this chapter to refer to both applicants and recipients of the programs under discussion.

programs are required by Federal law to maintain some standards of fairness, many are not required to take into account even minimal considerations of fairness in their record keeping. Moreover, programs funded only by a State or local government are often constrained by no laws or standards for protecting the personal privacy interests of clients.

Two main considerations guided the Commission in its task of analyzing current Federal policy with respect to the practices of agencies providing public assistance and social services. The first consideration was the principle that individuals compelled by necessity to seek assistance and services from programs funded by government agencies should not have to renounce all claim to personal privacy in exchange for the benefits they seek. In the Commission's view, 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.

Second was the need to maximize the strengths and minimize the weaknesses of a welfare system which divides responsibilities—for funding and for administration—among Federal, State, and local government agencies. Although its great spending power gives the Federal government a powerful regulatory tool, when the Federal government lacks sufficient knowledge of, or sensitivity to, local circumstances, some discretion should appropriately be left to the States and localities.

While this report was in preparation, the Department of Health, Education, and Welfare and other government agencies and private organizations were exploring various welfare reform alternatives. Although the shape reform will take is not yet clear, safeguards against unfairness to individuals will always be needed, and thus review of record-keeping policies and practices is timely. The Commission hopes this report will help policy makers both in modifying record-keeping practices under the present welfare system and in formulating policies to protect the privacy rights of clients under whatever system may emerge. In particular, in the event that the administration of certain welfare programs is assumed by the Federal government, this chapter may help concerned parties to determine whether special protections should be provided for records about welfare clients that supplement those provided in the Privacy Act of 1974.

Method of Study and Analysis

There are dozens of federally assisted programs for providing help to the needy, and unnumbered assistance and services programs funded by State and local governments. Since in-depth study of all these programs was impossible, the Commission confined its detailed examination to the record-keeping policies applicable to agencies administering the four largest federally assisted programs in terms of dollars and clients. These programs are Aid to Families with Dependent Children, Medicaid, Title XX Social Services, and Food Stamps. In addition, the Commission examined the Child Support Enforcement Program. This program seemed to merit the

Commission's attention because it has been particularly controversial, some groups seeing it as entailing abrogation of absent parents' privacy interests.

The Commission did not study in detail the public assistance and social services programs administered directly by the Federal government rather than by States and localities, and therefore makes no recommendations regarding them. The Privacy Act of 1974 already covers such programs, including Supplemental Security Income (SSI) for the aged, blind, and disabled and cash benefits for veterans with disabilities not related to military service.

The Commission's study of the four specified programs included a review of pertinent Federal statutes and regulations, meetings with Federal, State, and local officials and representatives of private organizations and public interest groups, and the services of an expert consultant with many years of experience in the welfare field. After completing the initial study, the Commission formulated a set of draft recommendations which were published in the *Federal Register*[5] and otherwise made available for public comment. Three days of public hearings on the recommendations were held in January, 1977, and, in addition, the Commission has received more than 90 written comments regarding them. Although the Commission could not make detailed studies of record keeping by the welfare agencies of all fifty States, the written comments and oral and written testimony offered at the hearings yielded rich and valuable information regarding current practice in these agencies.

The Commission's inability to make a detailed study of the record-keeping policies applicable to all of the various federally funded assistance and services programs reflects a central problem: present law provides no clear, consistent set of policies applicable to record keeping in all federally assisted welfare programs. Each of the various statutes establishing a program either prescribes its own policy or is silent on the subject. Anyone who tries to administer public assistance and social services programs established by different Federal statutes may well encounter inconsistent, and perhaps incompatible, statutes and regulations governing record keeping. It is doubtful that anyone has, or, without very substantial resources, could have, a clear picture of how the laws governing this multitude of programs interrelate. In short, the Commission found that the descriptive word for record-keeping policy in this area is "complex." Thus, a primary Commission goal was to find ways of simplifying the complexity.

PROGRAM OVERVIEWS

The public assistance and social services programs studied by the Commission serve specific client populations. Each program operates within organizational and funding structures defined by Federal statute and regulations and, in some cases, by State and local statutes and regulations. Administrative responsibilities are delegated to Federal, State, and local government units as the laws require. The following sections briefly identify

[5] 41 *Federal Register* pp.43724-27, (December 8, 1976).

the clients served and the basic administrative characteristics of the programs studied.

Aid to Families with Dependent Children

Title IV-A of the Social Security Act authorizes payments to States for the provision of financial assistance to needy families with dependent children. The Act defines dependent children as those children under 18 (or in the case of children attending school, under 21) who have been deprived of parental support or care by reason of the death, continued absence from home, physical or mental incapacity, or, under certain conditions, the unemployment of a parent. Within the broad requirements of the Social Security Act, a State has considerable latitude in defining the categories of the needy who will be served by the program in that State (e.g., whether or not to include families with an unemployed parent), in applying the eligibility criteria, and in determining what level of assistance will be provided to those eligible.

Aid to Families with Dependent Children (AFDC) provides financial assistance to help cover the costs of food, shelter, clothing, and other basic living costs. Emergency assistance and funds to support certain children in foster homes and institutions may also be provided. To supplement this assistance, an AFDC recipient is also eligible for assistance under the Medicaid, Food Stamp, and Title XX Social Services programs, and may also qualify for other forms of public assistance and social services.

Administrative and funding responsibilities for AFDC are shared by the Federal government and State and local governments. Program administration is overseen by the Social Security Administration of the Department of Health, Education, and Welfare (DHEW).[6] A State may either administer the program or supervise its administration by local governments. Federal funds (ranging from 50 percent to 65 percent of the total cost) help to finance assistance payments to recipients and may also be used to help cover administrative costs at the State and local level. States must share in the cost of the program and, in some but not all cases, local governments also contribute.

Medicaid

The Medicaid program authorized by Title XIX of the Social Security Act provides Federal funds to States for use in paying for medical services rendered to both the categorically needy and the medically needy. The categorically needy are those receiving assistance under the AFDC or Supplemental Security Income programs. The medically needy are those who meet all criteria for federally funded cash assistance, except the income criterion, and who lack the income and resources to meet the costs of

[6] Prior to the March 1977 reorganization of the Department of Health, Education, and Welfare, administration of the AFDC program was supervised by the Assistance Payments Administration of the Social and Rehabilitation Service.

necessary medical care and services. Their income may not exceed 133-1/3 percent of the State's cash assistance standard.

At minimum, a State must provide categorically needy individuals with:

- inpatient hospital services;
- outpatient hospital services;
- other laboratory and x-ray services;
- skilled nursing facility services for individuals 21 years of age or older;
- early and periodic screening and diagnosis of individuals under 21 to discover and treat mental and physical defects;
- family planning services and supplies; and
- physician's services.

The State may use the Federal funds in providing the medically needy with the above services or with other services which qualify for Federal funding under the Act. The services are rendered to recipients by qualified medical-care providers who are then reimbursed by the State.

The Health Care Financing Administration of the Department of Health, Education, and Welfare[7] oversees the administration of the Medicaid program. A State agency is responsible for either the administration of the program or the supervision of its administration by local government units. The designated State agency may, however, contract with other State agencies for performance of specified functions such as utilization review. States may also contract with private organizations to process claims, to act as the State's fiscal agent, or to develop and operate its Medicaid Management Information System, a mechanized claims-processing system for which special Federal funding is available.

The Federal share of Medicaid program costs is calculated according to a formula based on the State's per capita income in relation to national per capita income. The Federal share ranges from a low of 50 percent in many States to a high of 78 percent in one. States or localities, or both, provide the remaining funds.

Social Services

Title XX of the Social Security Act authorizes Federal grants to States for the provision of social services to recipients of public assistance under the AFDC or Supplemental Security Income programs and to other low-income persons who do not qualify for public assistance but whose income does not exceed 115 percent of the median income of a family of four in the State. The grants provided under Title XX are to be used for five specified purposes:

1. achieving or maintaining economic self-support to prevent, reduce, or eliminate dependency [of eligible clients];

[7] The Medical Services Administration of the Social and Rehabilitation Service, DHEW, supervised Medicaid administration prior to the March 1977 DHEW reorganization.

2. achieving or maintaining self-sufficiency, including reduction or prevention of dependency;
3. preventing or remedying neglect, abuse, or exploitation of children and adults unable to protect their own interests, or preserving, rehabilitating, or reuniting families;
4. preventing or reducing inappropriate institutional care by providing for community-based care, home-based care, or other less intensive forms of care; and
5. securing referral or admission for institutional care when other forms of care are not appropriate, or providing services to individuals in institutions.

Among the many services Title XX cites as appropriate to these five purposes are: child care services; services related to the management and maintenance of the home; day care services for adults; employment services; information, referral, and counseling services; health support services; appropriate combinations of services designed to meet the special needs of: (1) children; (2) aged, mentally retarded, blind, emotionally disturbed and physically handicapped individuals; and (3) alcoholics and drug addicts.

A single agency of each State administers or supervises the administration of the services programs of Title XX under the oversight of the Office of Human Development, DHEW.[8] In providing services to those eligible, a State may elect to use State facilities and personnel, to purchase services from private providers, or to use a combination of these alternatives. The State may also delegate certain administrative responsibilities to providers. For example, responsibility for determining an applicant's eligibility for a Title XX service may be delegated to the provider.

Federal funds totaling approximately $2.7 billion a year are available under Title XX. They can be used to reimburse States for 75 percent of the cost of social services, and in the case of family planning services, for 90 percent of the cost.

Food Stamps

The Food Stamp Program permits low-income households to buy coupons for less than the coupons are worth in exchange for food at federally certified food stores. Families receiving cash assistance under the AFDC or SSI programs are eligible for food stamps, as are those whose income falls below levels established by the Federal government.

State or local welfare offices administer the program under the supervision of the Food and Nutrition Service of the Department of Agriculture. The Department of Agriculture pays 100 percent of the cost of the food stamp coupons and 50 percent of the administrative costs incurred by States and localities.

[8] Before the March 1977 reorganization of the Department of Health, Education, and Welfare, the administration of Title XX programs was overseen by the Public Services Administration in the Social and Rehabilitation Service.

Programs Not Studied by the Commission

As noted above, the Commission could not make a detailed study of all the public assistance and social services programs funded by Federal, State, and local governments, and it made no attempt to study social services programs administered by private organizations that do not receive any government funding. Examples of the different types of government programs the Commission did not study are cited here to lend perspective on the universe of public assistance and social services programs.

Besides the four major programs studied by the Commission, the Federal government funds a great many categorical grant programs that provide assistance and services to the needy. Illustrative of these are:

- nutrition programs administered under Department of Agriculture supervision, such as the School Breakfast and School Lunch Programs, the Special Supplemental Food Program for Women, Infants and Children, and the Summer Food Service Program;
- health programs administered under the supervision of the Department of Health, Education, and Welfare, such as Family Planning Projects, Maternal and Child Health Services, Drug and Alcohol Abuse Community Services Programs, and Community Mental Health Programs;
- education programs under the auspices of DHEW, including Follow Through and Vocational Education;
- human development programs administered under the supervision of DHEW, including Head Start, Runaway Youth, Vocational Rehabilitation, and Special Programs for the Aging;
- housing programs funded by the Department of Housing and Urban Development, such as public housing and rent supplement programs; and
- employment programs of the Department of Labor, such as the Work Incentive Program, Job Corps, and Comprehensive Employment and Training Programs.

States also fund cash assistance and social services programs, especially to meet needs in areas where Federal financial assistance has not been made available. The most common of these State programs, usually called "general assistance," makes cash available to the needy who are not eligible for Federal cash assistance under AFDC or SSI, such as young, single individuals and young couples with no children. States may also fund special purpose programs to supplement Federal programs. Examples of these in California are the State's Emergency Loan Programs and Special Circumstances Program.

Obviously, the record-keeping issues inherent in administering the AFDC, Medicaid, Social Services, and Food Stamp programs also arise in these other programs. Eligibility for these programs is generally based on financial need. Those seeking assistance under any of the programs must

apply for it and submit to the prescribed methods of verifying the information they supply. Inevitably, a record is created to document the relationship between the client and the agency administering the program. Therefore, as explained in more detail below, the Commission believes that the information safeguards recommended for the four major programs which the Commission studied in detail should be required of the other programs as well.

PRINCIPAL FINDINGS AND CONCLUSIONS

The basic philosophy of any system of government is reflected in its welfare system and in the way policy regarding the welfare system evolves. In a federal system, responsibilities for governing are divided between national and state governments. The welfare system of the United States is a product of our federal system of government, and methods of determining welfare policy and the policy itself must reflect this reality.

Historically, "poor relief" was a local responsibility. During the Great Depression of the 1930's, the tidal wave of unemployed quickly overwhelmed community resources, throwing the burden of supporting them on the States. When the States, in turn, found themselves helpless against the floodtide, the Federal government stepped in. Since the 1930's, the funding of welfare has been a shared responsibility of Federal, State, and in some cases local, governments; administrative responsibility for alleviating the plight of the needy, however, has remained with the States, even though the Federal government has assumed an ever larger share of responsibility for financing the benefits and the cost of administering them.

The States are not, however, free to administer welfare programs as they see fit. Acceptance of Federal funds carries with it the obligation to adhere to Federal standards and requirements. The extent of Federal constraint on the States has fluctuated over the years and varies from program to program, in record keeping as in other aspects of administration.

When Federal law is silent on a record-keeping activity, States retain the discretion to establish their own policies and practices within the limits established by the Constitution. To the extent that the Federal government has chosen to regulate the record keeping of agencies administering federally assisted programs, the minimum requirements for acceptable practices are set forth in Federal statute and regulation. These, or more stringent, requirements must be included in State statutes, regulations, or plans. The result is that welfare record keeping reflects a medley of practices prescribed by Federal statutes and regulations in some areas, by State laws in others, by a combination of the two, or, in some cases, by no formal policy at all.

A comprehensive policy to guide all the record-keeping activities of welfare agencies has never been formulated by the Federal government. A few States have recently enacted laws that deal comprehensively with fair information practice, but the laws are general in scope, applicable to all State records. Some federally assisted programs must conform to Federal requirements, such as those regarding client access to records, contents of a

case file, and permissible disclosures of records, while others—either through oversight or deliberate omission—need not. For the great bulk of federally assisted programs, Federal law has not yet prescribed fair practice regarding such factors as the accuracy, timeliness, completeness, and relevance of information used, and the ability of a client to contest erroneous information. In the case of programs funded solely by State or local governments, the administrators, however attentive they may be to professional ethics, often receive little direction from State legislatures in setting record-keeping policy.

It is against this background that the Commission's general findings must be understood. The Commission has evaluated the extent to which existing law on record keeping is faithful to the principles of fair information practice described earlier in this report. Specific recommendations (see below) focus on the deficiencies of existing policy; the following general findings help put them into perspective.

First, the Commission could find no general, overall policy on public assistance and social services record keeping. In the few programs that address and attempt to control practices from which unfairness to clients can flow, attention has concentrated on some controls—most notably constraints on disclosures of records—while other sources of unfairness have been largely ignored. Failure to define general policy leaves the way open for unfair record-keeping practices.

Second, the Commision finds that the lack of a general policy creates problems within an agency. Even where law has been developed to regulate the record-keeping practices of the federally assisted programs, the resolutions arrived at are not necessarily consistent from one program to another. For example, the AFDC, Medicaid, Social Services, and Food Stamp programs are each subject to somewhat different restrictions on disclosure of client records to third parties. Nor are the rules regarding client access to a case file the same in the Food Stamp program as in the AFDC program. Such policy inconsistencies often confuse those administering a program, as well as the program's clients, and may create unnecessary administrative costs. The confusion is compounded when a private services agency receives funds under several federally assisted programs. Such a private agency may find it all but impossible to keep its records so that they meet the requirements of the different funding sources.

Third, the Commission finds that lack of a general policy creates great problems in the exchange of information among and within agencies. Federal record-keeping policy fails to take full account of the interrelationship in administration of all of the federally assisted programs. Again, this problem is especially acute in the area of policy that defines and limits the range of permissible disclosures of a program's records. Information about Medicaid and Food Stamp clients, for instance, may not be disclosed for purposes other than the administration of the program for which it was collected. Yet one worker in a State or local welfare agency may have responsibilities for administering not only these two programs, but others, such as AFDC and Social Services, as well. It may be impractical for the agency to segregate records about the client as a Medicaid or Food Stamp

recipient from those about the same client as an AFDC or Social Services client.

Fourth, the Commission finds uncertainty about the extent to which the Federal government should dictate the record-keeping practices of State and local welfare agencies. Federal law in some areas clearly directs the practices to be followed, while in other equally crucial areas, Federal law is silent, leaving the States with wide discretion in formulating their own policies. Disclosure policy, for example, is clearly specified in Federal law, whereas the States are left to decide what practices are permissible in verifying information.

Fifth, the Commission finds weak oversight of record-keeping practices, even where requirements are quite clear. Federal agencies like the Departments of Agriculture and Health, Education, and Welfare apparently lack the resources to monitor State practices adequately, so that a State which ignores or circumvents their regulations can probably do so with impunity. For example, despite a clear DHEW regulation permitting an AFDC client access to his case file prior to a hearing, the Commission found substantial evidence that some States deny this right.

Sixth, the Commission finds that even when State policy incorporates Federal requirements, the workers at the State and local level sometimes fail to translate policy into practice. Factors which contribute to these failures include the complexity of the laws and frequent changes in requirements, which increase the work load to no purpose and make it difficult for workers to know what is required of them. Complexity and frequent change in requirements are not the exclusive prerogative of Federal legislators; State legislators also contribute.

Finally, the manner in which Federal spending power has been exercised and the inaction of the States have meant that cash assistance and social services programs funded by State and local governments may be subject to record-keeping requirements that are different from those applicable to federally assisted programs or, in some cases, to no requirements at all. This is true even when such programs are administered by the same State agency responsible for administering federally assisted programs. This means that the privacy interests of clients of these programs may be wholly unprotected and that flows of information between federally assisted programs and those financed through other means are subject to no coherent policy.

GENERAL RECOMMENDATIONS

The above findings should make clear the advantages of establishing a comprehensible and generally applicable record-keeping policy to guide public assistance and social services programs at all levels. Such a policy would have to be enacted by the Congress, spelled out in Federal regulations, and overseen by Federal agencies. To the large and growing number of citizens who perceive welfare as a national problem, this is the obvious approach. Since most of the money for welfare comes from the Federal government, it has a strong responsibility for directing how the

programs will be carried out. Furthermore, the Federal government, having created a patchwork of uncoordinated public assistance and social services programs and equipping them with inconsistent regulations, can fairly be charged with responsibility for bringing the record keeping of at least the federally assisted programs into alignment, and for assuring the fair use of records about their clients.

On the other hand, standardization always carries a price tag. It is difficult for any national policy to take full account of the particular needs of each of the States and the variety of arrangements the States have devised for providing public assistance and social services. Furthermore, a balance must always be struck between privacy and other goals and values, and the trade-off satisfactory to the citizens of one area may or may not be acceptable to the citizens of another area. The controversy over how private providers report individually identifiable data about Title XX clients to State agencies illustrates this problem.[9] An added cost is that standardization inevitably stifles innovation.

After considering all of these arguments, the Commission concluded that the need for a Federal policy on record keeping by public assistance and social services agencies overwhelmingly outweighs the potential drawbacks. These drawbacks can be minimized by leaving the States significant latitude in formulating the specifics of a record-keeping policy within the guidelines imposed by Federal law.

Accordingly, the Commission recommends:

Recommendation (1):

(a) That the Congress enact a statute that requires each State, as a condition of the receipt of Federal financial assistance for public assistance and social services programs, to enact a fair information practice statute applicable to records about public assistance and social services clients of any agency administering or supervising the administration of any federally assisted public assistance or social services program (the requirements of the State statute are described below);

(b) That Congress give a State two full State legislative sessions to enact the required statute before it is considered not to be in compliance with Federal law;

[9] A controversy arose when private providers under contract with State agencies to provide Title XX services objected to a requirement that they report individually identifiable client data to State agencies. The information was needed by State agencies to report to DHEW an "unduplicated count" of Title XX recipients. Some provider agencies, especially those providing legal assistance and mental health services, protested that compliance with such a reporting requirement would breach the confidentiality of their relationship with their clients, deter individuals from seeking needed services, and give the State agency the capability to construct a Title XX client "data bank" which could be used to the detriment of clients. Although this controversy reached crisis proportions in some States, it simply never became a significant issue in others. Although DHEW responded by making it possible for States to report an estimated, rather than actual, unduplicated count, some State agencies would like to continue to collect individually identifiable data for their own planning and evaluation purposes.

(c) That the Congress specify in the statute the general principles of the fair information practice policy, leaving to the States some discretion to tailor specific means of implementing the principles to their own needs, where appropriate;

(d) That the Congress make the Secretary of Health, Education, and Welfare responsible for determining that each State has enacted the required State statute and that it has the characteristics required by Federal law. The Secretary should consult with the heads of other Federal agencies funding public assistance and social services programs in carrying out this responsibility;

(e) That every Federal agency responsible for overseeing the administration of a public assistance or social services program be required by Federal statute to review State compliance with the record-keeping requirements set forth in Federal and State statute;

(f) That the process that States use for formulating and enacting specific fair information practice requirements provide ample opportunity for public participation, including public hearings; and

(g) That appropriate sanctions and remedies, at the Federal and State level, be available to deal with violations of the statutorily prescribed requirements.

Adoption of this recommendation would achieve several ends. It would:

- resolve most of the problems created by inconsistencies in Federal policy regarding the records of various programs while at the same time allowing the States a measure of flexibility in implementing the policy;
- provide the same protections for all client records maintained by agencies that receive Federal financial assistance, including their records about clients of programs that are not federally assisted;
- supersede with a single Federal and a single State statute the myriad laws that currently govern record-keeping practices, thereby substantially reducing the complexity which renders such laws ineffective;
- remove the temptation for agencies to diversify their record-keeping practices in incompatible directions by embodying a uniform general policy in statute;
- strengthen oversight by Federal agencies; and
- provide legal sanctions and remedies to deal with violations.[10]

Simplicity and comprehensiveness are the goals of these general recommendations. Comments submitted to the Commission by many public

[10] See Chapter 10 for a discussion of the need for Federal sanctions that are proportionate to the seriousness of State non-compliance.

agencies and private organizations attest that these goals are urgently desired. As the representative of one welfare agency noted in testimony before the Commission:

> We strongly urge the adoption of the same standards for all the programs under consideration. It is sufficiently difficult to administer complex and varied programs, without having to be constrained by different standards for different programs. Not only is it confusing to staff but to recipients who begin to view us as a "schizophrenic" agency.[11]

States will need a reasonable period of time—two legislative sessions—to formulate the recommended statute. Only after that time would a State not be in compliance with Federal law, if the Commission's recommendation were adopted.

Because of the central role of the Department of Health, Education, and Welfare in funding and overseeing the administration of public assistance and social services programs, the Commission considers the HEW Secretary the appropriate person to assume primary responsibility for evaluating State compliance in enacting the recommended statute with, of course, the benefit of consultation with heads of other Federal agencies to assure coordination and understanding.

The Commission further believes that record keeping by government agencies and private providers that do not receive any Federal funding should also be subject to the fairness standards set forth for agencies receiving some Federal assistance, but the Commission acknowledges the fact that the Federal government cannot impose such standards on them. Therefore, the Commission recommends:

Recommendation (2):

That every State enact a statute applying the fair information practices required of agencies receiving Federal public assistance and social services funds to records of cash assistance and social services agencies that do not receive any Federal funding.

SPECIFIC RECOMMENDATIONS

This section discusses the policies underlying the Commission's specific recommendations for a State fair information practice statute. Some of the recommended provisions simply embody present practice. They would serve the purpose of making such practice a statutory requirement. Others broaden the rights already accorded to clients. The remainder prescribe new record-keeping requirements. All of these recommendations are framed to apply to *all* client records maintained by agencies that receive

[11] Written statement of the Middlesex County, New Jersey, Welfare Board, *Public Assistance and Social Services Record Keeping,* Hearings before the Privacy Protection Study Commission, January 12, 1977, p. 12, (hereinafter cited as Public Assistance and Social Services Hearings).

any Federal funds, not just to those records of an agency about clients for whom Federal assistance has been secured.

For the Commission's specific recommendations to take effect, two legislative steps would be required: (1) enactment of a Federal statute requiring that a State, as a condition of receiving Federal financial assistance for any public assistance and social services program, adopt a statute mandating certain minimum record keeping requirements; and (2) enactment of such a statute by the State.

Intrusiveness

Only details about the circumstances of a particular applicant can show whether he or she qualifies for help under any public assistance or social services program, and additional data about an eligible applicant inevitably accumulate as long as he or she receives assistance or services. When the eligibility requirements are complex, and verification requirements stringent, as they are in many welfare programs, the information collected about applicants for, and recipients of, welfare becomes very detailed indeed. In some areas of the country, for example, a worker visits clients' homes to verify their statements. These home visits, although made by prior appointment, give the agency an opportunity to collect more detailed personal information than the client might be willing to disclose. Furthermore, a welfare agency striving conscientiously to provide as much help as it can to its clients has a strong incentive to delve deeply into a family's problems in order to make sure all members of the family are getting all the help to which they are entitled.

Such efforts produce detailed records about virtually all aspects of a welfare family's personal life—its finances, possessions, habits, sexual relationships, need for family planning services, physical and mental health problems, education, prior employment, dependence on alcohol and drugs, and utilization of medical services. Welfare agencies are more likely than the other agencies and organizations studied by the Commission to have the makings of a profile covering every aspect of client families' lives.

The ability of a welfare agency to collect such sensitive information imposes the obligation to control its records with exceptional care, as explained below. In addition, the Commission was prompted to consider the need for constraints on the power of a welfare agency to collect and record some kinds of information.

Criticism of welfare agencies often focuses on the kinds of questions asked regarding eligibility and resources. Eligibility criteria, and consequently the questions asked on application forms, differ from State to State. Even when information collected for eligibility determination is clearly relevant to that purpose, some critics nonetheless oppose its collection on the grounds that it is so sensitive that its collection constitutes an unwarranted invasion of personal privacy.

In the welfare area—unlike some of the other areas the Commission studied—a disgruntled client cannot choose among a number of different agencies with different eligibility criteria from which to seek assistance or

services. Only one State agency can serve him. Thus, one might conclude that there is no way in which an individual can limit the degree of intrusion to which he must submit in order to get public assistance and social services.

To a certain extent this is true. A client, acting independently, is not likely to be able to exercise much control over a welfare agency's probing into the details of his personal life. But clients who feel the intrusion goes too far are not totally without recourse.

There are now two ways of settling disputes between clients and a welfare agency over the appropriateness of using particular items of information in a determination or redetermination of eligibility. If a client claims that a denial of benefits was based on irrelevant information, he can demand a hearing to contest the basis of the decision. Because eligibility criteria are set out in State statutes, regulations, and plans, they provide some objective standards against which the relevance of the disputed information can be assessed that are independent of the whim of an agency or worker.

Because eligibility criteria are usually determined either by State legislatures or through some sort of rule-making process, there is a second recourse for clients, or alternatively, organizations of clients or others acting in their interests, and that is to seek amendment of the official eligibility criteria. The need to ask certain questions can be removed if the eligibility criteria are changed. Louisiana, for example, now specifies that the value of musical instruments and jewelry of a sentimental value will not be taken into account in its assets tests. Although the exception may not have been prompted by concern about intrusiveness, the example illustrates that this method of limiting the collection of information is feasible.

The question of intrusiveness may also arise when an agency believes that a client is entitled to services other than the ones for which he has applied. After a family is found eligible for AFDC, for example, the AFDC worker may try to help the members of the family determine what other services they need, and then refer them to appropriate service providers. In some instances, referral to another agency is mandatory. An eligible AFDC client must be referred to the Work Incentive Program (WIN), and thus has no choice but to acquiesce in the exploration of factors relevant to WIN status. But where the acceptance of services is voluntary, an agency is hardly justified in demanding more information than the individual client or family is willing to divulge.

The exploration by agencies of factors relating to possible needs of a family that are not being met is wholly laudable. Unless participation in another program is a condition of eligibility under the program for which the client has initially applied, however, the Commission believes that clients of a public assistance or social services program should not be *required*, or *coerced*, to divulge information about either need or potential eligibility for other assistance or services programs. The Commission has therefore concluded in its recommendation on "Notification of Rights" (see below) that a client be told, at the time information is requested of him, whether he must divulge the information as a condition of receiving benefits, or whether its disclosure is voluntary.

Fairness

Fairness in Collection

In making determinations about a client's initial or continuing entitlement to benefits, an agency may contact third-party sources (e.g., banks, schools, neighbors, State agencies) in order to verify information the client has supplied. The extent to which such collateral verification is sought, and the methods by which it is obtained, vary among States and programs, among agencies, and even among workers responsible for determining a client's eligibility in a single locality.

Federal statutes and regulations currently give agencies little guidance with respect to the collateral verification process. Food Stamp regulations, for example, require verification of income, and also of eligibility factors if the information the applicant has provided is unclear, inconsistent, incomplete, or otherwise raises doubts about eligibility. *[7 C.F.R. 271.4(a)(2)(iii)]* To supplement these directions, the Department of Agriculture prescribes the "prudent person rule" which advises eligibility workers to use reasonable judgment in deciding what information supplied by the applicant should be verified with other sources.

In 1969, the Social and Rehabilitation Service of DHEW promulgated regulations outlining acceptable verification procedures for the AFDC, Medicaid, and pre-Title XX social services programs.[12] The regulations provided that verification be limited to that which is reasonably necessary to ensure the legality of expenditures under a program and required the agency to rely on the client as the primary source of information in determining eligibility. The agency could, however, help the client obtain information or obtain information for a client who could not get it himself without help (e.g., because of mental or physical impairment). If collateral contacts were necessary, the regulations required the agency to explain to the client what information would be needed, why it was needed, and how it would be used. The agency then had to obtain the client's consent to the contact. If the information supplied by the applicant or recipient could not support an eligibility decision, the agency had to explain what else was needed, and try again to get it from the client. If the client could not supply the necessary information and refused permission for the agency to contact a source, assistance could be denied or terminated.

These regulations were repealed in 1973, apparently to give States greater flexibility in developing their own collateral verification processes. The large number of overpayments to clients and payments to ineligibles that had been uncovered made greater flexibility seem desirable.

The Commission recognizes that collateral verification can be necessary, especially when inconsistencies or vagueness in the information received from an applicant or recipient, or inadequate records, raise doubt about eligibility. It also believes that State and local agencies unquestionably need a degree of flexibility in determining when verification is

[12] Prior to the enactment of Title XX, Federal funding for State administered social services was available under Titles IV, VI, X, XIV, and XVI of the Social Security Act.

necessary and from what sources verification may be secured. Nevertheless, because stigma sometimes attaches to the receipt of public assistance and social services, the Commission believes that there should be some Federal prescription of procedures to be followed by agencies so as to assure that the collateral verification process does not result in more information than necessary about a client being disclosed to third parties. Therefore, the Commission recommends:

Recommendation (3):

That the Congress require the States to provide by statute that public assistance and social services agencies must, to the greatest extent practicable, collect information and documentation directly from the client, unless otherwise requested by the client.

The Commission believes that both agency and client will benefit if the agency's need to contact collateral sources is kept to a minimum. When the client supplies documentation supporting the eligibility decision, the agency saves the time that eligibility workers would otherwise spend contacting collateral sources. At the same time, the client retains some control over the collection, use, and disclosure of information about himself. The client can usually seek records about himself from third parties without explaining why he is asking, whereas the agency would need to disclose the fact that the client is applying for or receiving a benefit and, in some cases, the nature of the benefit.

Current agency practice, according to witnesses and those who submitted written comments to the Commission, is generally for agencies to rely on clients for verification of the information they supply. Clients are usually requested to bring with them documentation of the information on the application form when they come to the welfare agency for an interview. Agencies will usually accept as evidence documents such as rent receipts, wage statements, bank books, report cards, or insurance policies supplied by the client. Client representatives stressed to the Commission that most applicants and recipients are quite able to supply adequate documentation, and that all should therefore have a chance to do so before the agency starts contacting third-party sources. Clients who are not able to obtain the information may, of course, require the agency's help in getting it.

On the other hand, Federal, State, and local agency representatives affirmed the need of agencies to contact collateral sources. They see a positive relationship between an agency's ability to contact third-party sources and its ability to reduce error rates and thus assure the accuracy of eligibility determinations. Even among the client and professional association representatives, most conceded that agencies need to contact third parties, at least under certain circumstances (e.g., where there is uncertainty about the information supplied by the client or reasonable cause to believe that the client is misrepresenting his situation), although there was little consensus among them beyond that point.

The Commission recognizes that there are circumstances that justify an agency's contacting third parties for information on clients. At the same

time, the Commission contends that applicants and recipients should have a right, albeit qualified, to determine what sources are contacted. Clients have an undeniable interest in limiting not only the number but also the kinds of sources to be contacted by agencies. Clients have reason to fear unwarranted consequences, such as loss of residence or employment, if people in certain relationships to them (e.g., landlords or employers) learn that they have applied for or are receiving public assistance or social services. Even clients who do not fear such adverse consequences may simply not wish certain individuals to know of their application for or receipt of benefits.

The Social and Rehabilitation Service, DHEW, submitted to the Commission samples of forms and letters used by State and local agencies to secure, for AFDC purposes, client authorization for the release of information from third-party sources. Several of these forms contained authorization statements which the Commission found unduly broad. For example, a South Carolina form provides that the client authorize

> . . . any person, agency, or organization to furnish such information as may be requested by an authorized representative of the County Department of Social Services or the State Department of Social Services, with or without additional consent from me.

As in other areas it has examined, the Commission believes that collateral verification authorizations of that type effectively deprive the individual of any control over inquiries made about him to third parties, and are both unacceptable and unnecessary. Moreover, because of the special problems associated with being identified as a welfare applicant or recipient, the Commission also believes that no collateral contacts should be made by a welfare agency until the client has been informed that his documentation is unacceptable and why, and has had a chance to produce alternative evidence to the agency. Therefore, the Commission recommends:

Recommendation (4):

That the Congress require the States to provide by statute that a public assistance or social services agency must:

(a) notify a client as to:
- **(i) all types of information which may be collected about him;**
- **(ii) the techniques that may be used to collect or verify such types of information;**
- **(iii) the types of sources that may be asked to provide each type of information.**

(b) limit its collection practices to those specified in any such notice;

(c) provide the client an opportunity to indicate particular sources of information which he does not want the agency to contact and to provide alternatives to those sources so indicated;

(d) provide the client an opportunity to withdraw his application should the agency require that a source be contacted notwithstanding his objections;

provided, however, that such procedures shall not be required when there is a reasonable belief that the client has violated a law relating to the administration of the assistance or services program.

This recommendation, in the Commission's view, outlines an effective mechanism for balancing an agency's need to contact collateral sources against the interest of the client in limiting the collection of information about himself from others. Moreover, it also conforms to present practice in some agencies. The authorization form used by the Oregon Division of Public Welfare, for example, lists the commonly contacted sources, some by category (e.g., employers, financial institutions, schools) and others by name (e.g., agencies or organizations), and invites applicants to check the ones they authorize. The authorization form used by the Tennessee Department of Human Services lists a broader spectrum of sources to be contacted, and adds "any other individual or organization" having knowledge of the client's circumstances. There is, however, a space on the form where clients can list specific sources the Department may not contact.

It has been argued that the protections for client rights recommended by the Commission are meaningless because "everybody knows who's on welfare," and because clients must ultimately choose between bowing to the agency's insistence on contacting a "necessary" source or foregoing benefits. Since a client who needs the assistance can ill afford to forego the benefits, the argument continues, his choice is hollow. The Commission believes, however, that clients should have the opportunity to decide for themselves whether or not such rights are meaningless. Moreover, it believes that the procedural modifications outlined in the Commission's recommendations and compliance in good faith on the part of agencies and clients will offer clients intermediate alternatives to a stark choice between yielding to an agency's demands for information and foregoing assistance.

The Commission recognizes that an exception to the collateral verification practices outlined in the above recommendations may be necessary when a client is suspected of violating laws relating to the administration of the welfare programs. Under those circumstances, the agency could not logically be expected to notify the client of the verification sources it intended to contact or to ask the client to suggest alternative sources, since doing so might well compromise fulfillment of the agency's duty to gather evidence.[13]

The Commission also realizes that some States operate automated verification systems in which lists of clients are matched with records maintained by other State agencies, such as State employment agencies. Although the Commission recognizes the utility of such systems in reducing both overpayments and payments to ineligibles, it believes that each client should be informed that such methods will be used and offered an opportunity to withdraw his application should he object to this means of collateral verification. Withdrawal of an application by an individual who is

[13] The agency would, of course, have to comply with the restrictions on disclosure of records imposed by agencies and organizations from which it seeks information for a law enforcement purpose including, in some cases, the production of a subpoena.

not in fact eligible would in effect achieve the desired end—reduction of payments to ineligibles.

The Commission further contends that, just as a client has an interest in limiting the number or kinds of sources contacted, he also has an interest in limiting the amount and kind of information disclosed to third-party contacts in the course of collateral verification. More specifically, while a client may not object to collateral contacts which disclose that he is seeking benefits, he may well object to a contact's learning of the particular kind of benefit sought, and the same applies to any information which does not directly relate to verification. The client's interest may be especially acute when he or she is seeking a service that is widely perceived to be sensitive, such as alcohol and drug abuse treatment or mental health counseling.

Regulations applicable to the Title XX Social Services program already require that a provider agency under a State agency contract to determine eligibility must notify a client if collateral contacts are to be made, so that a client who wishes to keep the nature of the service he is seeking confidential may ask that the State agency make the contact. When notified of the client's request, the State agency must make the necessary contact and relay the information to the provider. *[45 C.F.R. 228.61(f)(1) and (2)]* This regulation implies acknowledgement of the State agency's responsibility to make the contact discreetly without revealing the nature of the service being sought.

The Commission supports this regulation and recommends that it be adopted by all agencies that provide social services to clients. While the Commission understands than an agency may not be able to disguise the fact that an individual has applied for cash assistance, or some type of social service, it does believe that the specific nature of the service sought need not be revealed to a third-party source in order to obtain necessary collateral verification. Accordingly, the Commission recommends:

Recommendation (5):

That Congress require States to provide by statute that public assistance and social services agencies must give clients of social services programs the opportunity to require that collateral contacts, made to secure information about their eligibility in a services program, are made in a manner that, to the maximum extent possible, does not reveal the specific nature of the service sought by the client.

More broadly, the Commission recommends that all public assistance and social services agencies adopt a policy of revealing only the very minimum amount of any kind of information about the client consistent with obtaining verification even in cases in which it is necessary to reveal that the client has applied for cash assistance, as opposed to social services. This issue is further dealt with in the Commission's recommendation on disclosure of records, below.

Fairness in Use

Access to Records

DHEW regulations governing the AFDC, Medicaid, and Title XX Social Services programs *[45 C.F.R. 205.10(a)(13)(i)]* specify that an applicant or recipient who has requested a hearing may examine at reasonable times before the date of the hearing, as well as during the hearing, the contents of his case file and all documents and records to be used by the agency at the hearing. A hearing may be requested by a client whose claim for benefits has been denied or not acted upon with reasonable promptness, or who has been aggrieved by any agency action resulting in suspension, reduction, discontinuance, or termination of assistance.

Regulations applicable to the Food Stamp program afford clients who have requested a hearing a more limited right of access: these clients may examine at reasonable times before and during the hearing only those documents and records to be used by the agency at the hearing. *[7 C.F.R. 271.1(o)(5)(i)]* A hearing may be requested by a client whose household has been aggrieved by any action of the State agency, or of a coupon-issuing agency, in the course of its administration of a Food Stamp program, provided the action affects the participation of the household in the program.

Although the DHEW regulations governing hearings in the Medicaid, AFDC, and Social Services programs specify that a client may inspect the contents of his *entire* case file, the Commission has found substantial evidence to suggest that agencies often do not, in fact, make the entire case file available on request. To the extent that this is true, a client is denied the opportunity to decide what information in the case file he feels should be introduced at the hearing. For example, a representative of Community Legal Services, Philadelphia, Pennsylvania, attested that a client's right to full access to his case file before and during the hearing process is not always respected, noting:

> . . . 45 C.F.R. 205.10(a)(13)(i) allows for inspection of case files and documents when there is a hearing, but is written in such a way that most States feel that it only gives the recipient the right to inspect such documents as are actually produced in evidence for the hearing. This leads to significant problems, since a lot more information may prove useful to the person, including any exculpatory evidence that he may want to raise or that the administration may know of . . . .[14]

For another example, a manual for welfare advocates in New York City prepared by Community Action for Legal Services, Inc. noted that New York State and New York City policies regarding access to the case record are more restrictive than Federal policy. For example, New York City regulations provide that, upon request, the client or his authorized representative is entitled to receive copies of only those portions of the

[14] Testimony, Public Assistance and Social Services Hearings, January 11, 1977, p. 587.

client's record which would be "beneficial" to the client *[18 New York Code of Rules and Regulations (N.Y.C.R.R.) 357.3(c)]* or which will be introduced at a hearing. *[18 N.Y.C.R.R 358.9(d) and 358.12 (a)]* The manual advises advocates that when access is denied, the denial should be raised as an issue at the hearing.[15]

The Commission also received a written comment from the Land of Lincoln Legal Assistance Foundation, Inc. (Danville, Illinois) citing its attorneys' inability to obtain full access to a client's case record. The Foundation states that even when the client's written authorization has been obtained, the local department of welfare will not permit a client's attorney to examine any portion of the client record unless a notice of appeal to initiate a hearing has been filed with the department. After the notice has been filed, according to this comment, the local department will allow examination only of material relating specifically to the issues raised in that notice.

Even if full access to the case file prior to a hearing were in all cases permitted, the applicant or recipient with no legally acceptable reason to seek a hearing cannot currently be assured an opportunity to inspect his record, and so can neither discover nor request correction of inaccuracies. Moreover, except for these rights of access in connection with the hearing procedure, the four major welfare programs are not required by Federal law to permit a client to inspect records about himself, nor are other public assistance and social services programs. Although in some instances eligibility workers may, upon client request, give a client access to records about himself, this is usually at the sole discretion of the eligibility worker involved with the case.

The Commission believes that without a general right of access a client cannot make informed decisions about the use of information in a record by others than the welfare agency, nor can he discover and request correction of inaccuracies in the record before the information is used to his detriment. The Commission believes that the right of access is an essential component of fairness in record keeping and therefore recommends:

Recommendation (6):

That the Congress require States to provide by statute that a client who is the subject of a record maintained by a public assistance and social services agency shall have a right to see and copy that record upon request.

The Commission recognizes that implementing the general right of access may put additional administrative burdens and cost on the agencies and individuals charged with welfare administration.[16] Data gathered by the Commission indicates, however, that the advantages and protections

[15] Community Action for Legal Services, Inc., *Manual for Welfare Advocates in New York*, New York, 1976, p. 125.

[16] The Commission believes that if any fees for copying records are charged clients, they should not exceed the actual cost of copying, and further, that fees should be closely related to the ability of clients to pay them.

afforded the client would far outweigh the additional burden, especially if agencies are allowed to set reasonable limits on the hours during which clients may view their records. The Minnesota Data Privacy Act, for example, gives individuals a right of access, with certain qualifications, to information maintained about them by the State. Representatives of the Minnesota Department of Public Welfare attested to the Commission that:

> We anticipated that far more clients would ask to see their record than we could possibly process. To our surprise, this multitude did not materialize. As we look back on it now, we attribute the lack of interest to the openness by which most of the counseling, therapy, and casework operations are carried out by our local agencies. Our agencies have kept clients reasonably well informed during our involvement with them—how they will use the information, with whom they will share it, et cetera—to the extent that most clients probably don't feel the record would tell them anything they don't already know . . . .[17]

The Commission expects that the openness which its other recommendations should foster will minimize clients' demands for access to their records.

The arguments presented to the Commission in oral testimony and written comments brought out the need to qualify or deny the right of access in certain situations. The Commission identified six kinds of situations meriting special consideration:

1) *Clients' access to medical information.*[18] Agency records on clients may include sensitive information regarding a client's physical or mental health or status (e.g., information regarding the physical or mental incapacity of an AFDC client). Allowing clients access to such information might, in some instances, jeopardize their health or impede their recovery. The Commission heard a number of recommendations that the right of access be qualified when, in the opinion of a qualified medical professional, full access might adversely affect the client. In such cases, an alternative might be to assign the client's right to full access to someone qualified to represent him. When a medical record is the basis of an adverse determination about a client, however, the Commission believes that it should be available to him.[19]

2) *Parents' access to records of minors.* Should a parent or guardian be granted access to the child's record? Should the minor be granted access? Most of the opinions submitted to the Commission held that a minor who seeks treatment on his own initiative (e.g., for family planning services, drug rehabilitation) should have access to that record, especially if State law permits the minor to obtain treatment without the knowledge or consent of

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[17] Testimony, Public Assistance and Social Services Hearings, January 11, 1977, p. 764.

[18] As noted earlier, the recommendations in this chapter are not intended to apply to records maintained by medical-care providers rendering services to Medicaid and Title XX clients, except insofar as they are used to determine eligibility. Recommendations regarding client access to, and correction of, records maintained by medical-care providers are found in Chapter 7.

[19] See Chapter 7 for additional discussion of this problem.

his parents. Furthermore, it was argued that parents or guardians of such minors be given access in such situations only upon the minor's authorization. These arguments are based on the belief that a minor is likely to be discouraged from seeking necessary treatment by the knowledge that his parents will be notified that he is seeking the treatment and, especially, if he knows that his parents will have access to his records.

3) *Access to adoption records.* The Commission, which unfortunately could not make a study of the special problems involved in access to adoption records, suggests that this matter be addressed in a special inquiry.

4) *Clients' access to information submitted under assurance of confidentiality.* Agency administrators stressed to the Commission their belief that it would be impossible for them to get the information necessary for the detection of fraud if they could not promise the sources of such information confidentiality. This is true primarily in cases in which the source is an individual, rather than a record maintained by another agency or organization. Opinions differed as to whether or not both the source and the information provided should be kept confidential. It was generally agreed, however, that information provided by confidential sources should not be used as the basis of an adverse decision about the client unless it could be revealed to the client prior to, or during, a hearing. Implicit in this argument is the Commission's belief that an agency should adequately inform its sources of information about the agency's policies regarding the release of information to the client. Furthermore, upon soliciting or accepting information about a client from a source seeking an assurance of confidentiality, the agency should determine whether the source would be willing to have the information he supplied revealed to the client during a hearing—that is, whether he is seeking an absolute guarantee of confidentiality that extends not only to his name but to the information he supplies. His decision will influence the uses to which the agency will be able to put such information.

Arguments in favor of protecting the confidentiality of informants indicate that confidential sources may be essential in detecting and investigating cases of child abuse and neglect. Agency representatives are convinced that the very people who are in a position to know of abused or neglected children would be unwilling and often afraid to report the situation if they could not report in confidence. Those who report such cases may have good reason to fear reprisal, especially if the informant is a member or close friend of the child's family.

5) *Access during an investigation of a violation of laws relating to the administration of a program.* The argument for this exception is that allowing clients suspected of fraud access to their records would give guilty clients a chance to evade justice by concealing or destroying evidence or by absconding.

6) *Access to records covering more than one client.* Public assistance and social services records often contain information about more than one individual. AFDC records, for example, deal with individuals as members of an assistance unit; Food Stamp records treat individuals as members of their household; and a services agency may keep a single record on several

individuals who apply as a group. These records raise special access problems. For example, which members of an assistance unit, household, or treatment group have a right of access to the entire record? Does a member have the right to the record's information concerning the other members, or only the information on himself or herself? Has a minor a right of access to information maintained on his parents?

The Commission found merit in the arguments for qualifying or denying access in the situations described above. On the theory that the States rather than the Federal government are best able to find reasonable solutions to the problems they raise, the Commission recommends:

Recommendation (7):

That the Congress permit the States to enact provisions of law that:

(a) provide that a medical record may be disclosed either directly to the client or through a medical-care professional designated by the client, provided, however, that a client must be given direct access to any medical-record information that is used to make a determination about his eligibility;

(b) restrict a parent or guardian's access to a minor's record, or a minor's access to a record that contains information about him;

(c) provide that the source of information in a record, or the information itself to the extent that it would reveal the identity of the source, need not be disclosed to the client if the source is an individual who has requested an assurance of confidentiality or, absent such a request, if disclosure can reasonably be expected to result in harm to the source, provided, however, that an adverse determination may not be based on information that is not disclosed to the client;

(d) deny a client access to a record that is being used for an ongoing investigation of a suspected violation by the client of a law relating to the administration of the welfare program; and

(e) provide for segregation of information in records maintained about multiple subjects so that a client may see only that information in a record that pertains directly to him.

Correction of Records

As in the other areas it has studied, the Commission believes that an individual's right to review records about himself is of little value unless a procedure for correcting any erroneous information he may find is available to him as a matter of right. If the client could inspect but not request correction of information in records, inaccurate, outdated, irrelevant, or incomplete information could be used by the welfare agency or others to unfairly deny him a right, benefit, or opportunity. Accordingly, the Commission recommends:

Recommendation (8):

That the Congress require States to provide by statute that public assistance and social services agencies will permit a client to request correction or amendment of a record pertaining to him, and that the agency must:

(a) promptly correct, amend (including supplement), or delete any portion thereof which the individual can show is not accurate, timely, relevant, complete, or within the scope of information which he was originally told would be collected about him, except that in the case of a medical record, the agency shall disclose to the client the identity of the medical-care provider who was the source of the record, and, if the latter agrees to the requested correction, the agency must make the correction;

(b) assure that any corrections, amendments, or deletions are reflected wherever information about the client is maintained that is similar to that which has been corrected, amended, or deleted; or

(c) inform the client of its refusal to correct, amend, or delete part of the record in accordance with his request and the reason(s) for the refusal, permit the client to have the refusal reviewed at a hearing, and permit a client who disagrees with the refusal to correct, amend, or delete the record to have placed with the record a concise statement setting forth his disagreement; and further

(d) provide reasonable procedures to assure that corrections, amendments, and deletions made pursuant to (a), or statements of disagreement filed pursuant to (c), are made available to prior and subsequent recipients of the record.

It should be noted that adoption of this recommendation would broaden the conditions under which a client may request a hearing. Currently, a client cannot obtain a hearing to challenge information unless that information has been used as the basis of an adverse decision against him. The Commission wishes to emphasize, however, that this proposal to expand the use of the hearing process should not be interpreted as a license for clients to contest earlier hearing decisions about the merits of cases, although the correction of information may, of course, be relevant to a future decision.

The injustices that may be perpetrated because clients lack a means of forcing a welfare agency to correct information in their files which they believe to be inaccurate, or to place in the file a statement of dispute, are illustrated by the experience of Catherine Tarver. Tarver, an AFDC recipient, learned that a caseworker's report in the file on her maintained by the Department of Health and Social Services in the State of Washington contained detailed allegations accusing her of child neglect. Shortly after the report was written, Tarver had been exonerated of these charges by a juvenile court. With this exoneration to back her, she asked the county

Department of Public Assistance for a hearing to request it to correct its file, but the Department refused. The Washington State Supreme Court supported the Department, holding that the hearing provision was not intended as a forum in which to litigate general grievances against the Department's administration of the welfare laws. *[State ex rel. Tarver v. Smith,* 78 Wash. 2d 152, 470 P.2d 192 (1970); *cert. denied,* 402 U.S. 1000 (1971)]

Although adoption of *Recommendation (8)* would not mitigate such past injustices, it would go far toward preventing future ones.

Accuracy, Timeliness, Completeness, and Relevance

The Commission recommends:

Recommendation (9):

That the Congress require States to provide by statute that public assistance and social services agencies must have reasonable procedures to assure that all records they use in making any determination about a client are maintained with such accuracy, timeliness, completeness, and relevance as is reasonably necessary to assure that the records themselves are not the cause of an unfair determination.

Those who suffer when benefits are unfairly denied are not the agencies, but people who are already experiencing hardship. Thus, it is clear to the Commission that both the agency and its clients should share the responsibility for assuring the accuracy, relevance, timeliness, and completeness of the agency's files. Clients have an obvious interest in seeing that the responsibility is fulfilled, but the agencies' obligation is nowhere spelled out in Federal law. When benefits are unfairly denied because of carelessly kept records, the affected person has only one formal, assured recourse: to ask for a hearing where he can at least challenge the accuracy of the information used as a basis for the adverse decision.

The Commission's recommendations regarding the general right of access and procedures for requesting correction would provide a second and more comprehensive safeguard. *Recommendation (9),* above, provides a third. For example, it would encourage agencies to investigate third-party source information before entering it in a record or relying on it to make a judgment, and might prompt agencies to take the obvious step of asking the client to explain or document information that may be inaccurate before incorporating it in the file.

It should be noted that many agencies are consciously attempting to modify the traditional practice of routinely including in a case file not only the worker's professional assessment of the client's circumstances, behavior, and needs, but also notes on almost everything that transpires between worker and client. While that practice may sometimes work to the client's best interest, it often means that irrelevant and extremely subjective judgments become part of the file. Such judgments are useful only to the extent that social workers have been trained to recognize information

pertinent to the case, and not all personnel employed by public assistance and social services agencies have such training. This is increasingly true of eligibility workers, many of whom have had no professional training.

Comments received by the Commission indicate that many agencies currently consider fulfilling their responsibility for accuracy, timeliness, completeness, and relevance as fully consistent with sound public assistance and social services delivery practices. For example, the Iowa Department of Social Services noted that acceptance of such responsibility:

> . . . would appear to be the practice in any agency which follows personal and professional, accepted ethical standards, and which complies with an effective administrative procedures act, especially concerning contested cases.[20]

Expectation of Confidentiality

Disclosure of Client Records

Any comprehensive revision of Federal policy on disclosure must start with an assessment of the adequacy of present restrictions. In considering the matter of confidentiality, the Commission was guided by the principle that records about individuals should not be disclosed for purposes incompatible with those for which they were compiled without the consent of the individual, except as specifically authorized by law.

The Commission was not able to analyze the statutory constraints on the use or disclosure of information about clients in all of the federally assisted programs. A review of some of these laws, however, was enough to show that coverage is distinctly uneven. For example, there are no provisions on confidentiality in the laws regarding the National School Lunch Program, Maternal and Child Health Services, and Services for Crippled Children. By contrast, the regulations governing Juvenile Delinquency Prevention Programs require that records about youths served by these programs "shall be held to be confidential," and the ". . . use of such information and records shall be limited to purposes directly connected with the system . . . ." *[45 C.F.R. 1350.61(c)]*

There are also variations in the statutes governing the four programs studied in detail. While Federal statutes and regulations require State plans for carrying out AFDC, Medicaid, and Title XX Social Services programs to include certain provisions relating to the confidentiality of program records, the specific requirements are not the same for all three. Thus, a State plan for AFDC must prescribe restrictions on the use or disclosure of information concerning applicants or recipients to purposes directly connected with:

> the administration of the AFDC, Child Welfare, Work Incentive, Medicaid, Social Services, or Supplemental Security Income programs;

[20] Submission of Commissioner, Iowa Department of Social Services, Public Assistance and Social Services Hearings, January 11, 1977, p. 5.

- any investigation, prosecution, or criminal or civil proceeding conducted in connection with the administration of any such plans or programs; and
- the administration of any other Federal or federally assisted program which provides assistance in cash or in kind, or services, directly to individuals on the basis of need. *[42 U.S.C. 602(a)(9)]*

The AFDC statute also prohibits disclosure of individually identifiable information about clients to any committee or legislative body. Under another provision of Federal law, a State may, notwithstanding the confidentiality provisions cited above, enact a law making the names of AFDC recipients and the amount of assistance they receive available to the public. Finally, DHEW regulations governing the AFDC, Medicaid, and Title XX Social Services programs provide that:

> In the event of the issuance of a subpoena for the case record or for any agency representative to testify concerning an applicant or recipient, the court's attention is called, through proper channels, to the statutory provisions and the policies or rules and regulations against disclosure of information. *[45 C.F.R. 205.50(a)(2)(iv)]*

Agency officials are apparently successful in contesting such disclosure in most, but not all, cases.

The Federal statute governing the Medicaid program provides that a State Medicaid plan must:

> provide safeguards which restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan. *[42 U.S.C. 1396a(a)(7)]*

The Social Security Act also contains restrictions on the use of information concerning Title XX Social Services clients, namely:

> the use or disclosure of information obtained in connection with administration of the State's program for the provision of the services [funded under Title XX] concerning applicants for and recipients of those services will be restricted to purposes directly connected with the administration of that program, the plan of the State approved under part A of Title IV [AFDC], the plan of the State developed under part B of that title [Child Welfare Services], the Supplemental Security Income program established by Title XVI, or the plan of the State approved under Title XIX [Medicaid]. *[42 U.S.C. 1397b(d)(1)(B)]*

Finally, the Federal statute establishing the Food Stamp program provides that a State Food Stamp plan must include:

> safeguards which restrict the use or disclosure of information obtained from applicant households to persons directly connected with the administration and enforcement of the provision of [the

> Food Stamp Act] or the regulations issued pursuant to [the Act]. *[7 U.S.C. 2019(e)(3)]*

The Commission reached several conclusions about the adequacy of current disclosure policy.

1) *Federal disclosure policy for federally assisted programs is neither consistent nor comprehensive.* While the four programs the Commission studied in detail do contain restrictions on disclosure of program records, some of the other federally assisted programs do not, and the policies of still others are inconsistent with those of the major programs.

For example, Federal policies on disclosure of alcohol and drug abuse treatment records *[42 U.S.C. 4582 and 21 U.S.C. 1175]* differ from those applicable to records maintained under the Title XX program, which also funds alcohol and drug abuse treatment services. Thus, there has been confusion about what rules should be applied to a treatment provider who receives funding from Title XX as well as other Federal government sources.[21]

For another example, the statutes and regulations governing the provision of legal assistance under grants made by the Legal Services Corporation contain one provision relating to confidentiality, namely that:

> . . . neither the [Legal Services] Corporation or the Comptroller General shall have access to any reports or records subject to the attorney-client privilege. *[42 U.S.C. 2996h(d)]*

By contrast, the statute governing confidentiality of Title XX legal services records also limits permissible disclosures for non-Title XX purposes but permits the imposition of reporting requirements that would, in the opinion of some groups, violate the attorney-client privilege.

For a third example, family planning assistance is provided under Title X of the Public Health Service Act, and also under Title XX of the Social Security Act. Regulations implementing Title X provide that:

> Each grant award is subject to the condition that all information obtained by the personnel of the project from participants in the project related to their examination, care, and treatment, shall be held confidential, and shall not be divulged without the individual's consent except as may be required by law or as may be necessary to provide service to the individual. *[42 C.F.R. 59.10]*

This provision for confidentiality differs from the one found in the Title XX statute

Finally, regulations governing services to individuals under the Older Americans Act provide that:

> . . . the State agency will take steps to insure that no information

[21] Section 2003(f) of the Social Security Act currently provides that "The provisions of Section 333 of the Comprehensive Alcohol and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 [pertaining to the confidentiality of records] shall be applicable to services provided by any State pursuant to this title with respect to individuals suffering from drug addiction or alcoholism."

> about, or obtained from, an individual, and in possession of an agency providing services to such individual . . . shall be disclosed in a form identifiable with the individual without the individual's informed consent. *[45 C.F.R. 903.139]*

This regulation is significantly stricter than those applicable to records about senior citizens services provided under Title XX.

2) *By applying different disclosure criteria to federally assisted and non-federally assisted programs. Federal disclosure policies erect a statutory barrier that hampers the work of both.* For example, AFDC program records may circulate to other federally assisted programs, however remote in purpose from the AFDC program, but disclosure to a program funded solely by a State is prohibited without client consent, even when the aims of the State program are closely allied with those of AFDC. Similarly, Title XX records may be circulated freely among Title XX providers of quite unrelated services but not to a State-funded social services program without the client's consent.

3) *In all four main programs, the same disclosure restrictions apply to both factual data regarding an individual's eligibility and level of need (e.g., income, assets, resources, number of children), and the record of a client's physical or mental condition.* Thus, sensitive information regarding an AFDC recipient's physical incapacity may be disclosed just as freely as the simple fact that the recipient has three children. Failure to establish different criteria for different categories of information encourages either undue restriction of factual data needed for effective program administration, or inappropriate disclosures of sensitive material which may derive from subjective judgments.

The Commission found a need for a comprehensive policy on client record disclosures that would apply uniformly to all public assistance and social services records maintained by State and local government agencies, if the rights of clients are to be consistently protected and if welfare programs are to be effectively administered. It then addressed the question of how to formulate such a policy, and what it should cover.

The Commission considered recommending that Congress enact a detailed statute regulating disclosures of records maintained by all assistance and services agencies receiving Federal funds. It rejected this solution for several reasons:

- the differences in State programs and their administration made it unlikely that the Commission could formulate a workable single policy;
- a detailed Federal policy would tend to frustrate innovative State records-management practices, such as the development of multi-purpose application forms and integrated management information systems;
- any detailed Federal policy would undoubtedly conflict with State fair information practices statutes that apply to welfare records as well as to other State agency records; and
- a single policy could not reflect the different trade-offs

different States would make between confidentiality and other values.

Instead of a detailed Federal policy, the Commission has chosen to recommend broad Federal guidelines which leave latitude for the States to arrive at their own specific policies. Accordingly, the Commission recommends:

Recommendation (10):

That the Congress provide by statute that no disclosures of records about a public assistance or social services client may be made without the authorization of the client, unless disclosure has been specifically authorized by State statute, which must contain:

- **(a) provisions relating to the permissible uses and disclosures of individually identifiable information about clients for purposes related to the administration and enforcement of the specific program for which the information was acquired, as well as for purposes related to the administration and enforcement of other public assistance and social services programs for which the individual has applied, is required to apply, or may be eligible;**
- **(b) a prohibition on the disclosure of individually identifiable information about clients to members of the public and to legislative committees;**
- **(c) a prohibition on the use or disclosure of individually identifiable information about clients for purposes unrelated to the provision of public assistance and social services without the consent of the client, provided, however, that:**
  - **(i) disclosure necessary to assure the health or safety of the client or another individual in compelling circumstances may be permitted;**
  - **(ii) disclosure made pursuant to a court order may be permitted if the agency has contested the order, provided, however, that adequate notice and ability to participate in any action regarding the order has been provided the client if the client is the subject of the investigation or prosecution in furtherance of which the court order is issued; and**
  - **(iii) disclosure for a research or statistical purpose may be permitted, provided, however, that:**
    - **(A) the agency maintaining the information ascertains that use or disclosure in individually identifiable form is necessary to accomplish the purpose for which disclosure is made;**
    - **(B) further use or disclosure of the information or record in individually identifiable form is prohibited without the express authorization of the agency or the client;**

(C) reasonable procedures to protect the record or information from unauthorized disclosure are established and maintained by the recipient, including a program for removal or destruction of identifiers; and

(D) the agency determines that the research or statistical purpose for which any disclosure is to be made is such as to warrant risk to the individual from additional exposure of the record or information;

(d) provisions stating which redisclosures of individually identifiable information may be made by agencies or persons authorized to obtain such information; and

(e) a requirement that all permissible disclosures be limited to information that is necessary and relevant to the purpose for which disclosure is made, including those disclosures made for collateral verification purposes.

Finally, the Congress should provide that when enacted, the required State statute shall constitute the sole authority for disclosures of client records maintained by public assistance and social services agencies receiving Federal funding except that 42 U.S.C. 4582 and 21 U.S.C. 1175, regarding the confidentiality of alcohol and drug abuse treatment records, will continue to be in force.

The Commission feels that this recommendation outlines a sensible approach to the complex problem of handling the disclosure of client records. These recommendations seek to resolve problems created by inconsistency in Federal confidentiality policies by requiring each State to develop a comprehensive statute tailored to the State's particular needs, regulating disclosure of records about clients of *all* federally assisted programs operating in the State, as well as of other programs operated within the State by agencies that receive Federal funds. The Commission believes that the State, rather than the Federal government, is best able to define specifically the limits of permissible disclosure within broad limits set by Federal law for all the States. The Federal government cannot be expected to appreciate fully the particular needs which guide each of the 50 States in administering its programs, nor can the Federal government respond as effectively as the States to future changes in these particular needs.

On the other hand, the recommended measures do not give the States a license to ignore a client's right to be treated fairly. Three features of the recommendations seek to assure that the policies formulated by the States will be fair to the individual.

First, the recommended process for States to follow in formulating their policies provides for public participation. Specifying that the policies be enacted into statute means that their adoption must follow the legislative process, and that they will not be changed without public involvement. The Commission's general recommendations further require public hearings to precede enactment of such a State statute.

Second, the recommended measures require State statutes to be faithful to a key principle of fair information practice—that information acquired for one purpose should not be used for an unrelated purpose without the individual's consent, either actual personal consent or consent as collectively arrived at through the legislative process. Thus, the recommended measure requires that a State's statute forbid disclosures of public assistance and social services records without the consent of the individual to whom they pertain, unless such disclosure is specifically authorized by statute. The authorizations in the statute should be sufficiently specific so that clients will either know or can find out the particular purposes for which information about themselves will be used.

Finally, the recommended Federal statute would require States, in enacting their own statutes, to adhere to minimum standards regarding permissible disclosures. As long as a State's statute complies with these recommended standards, State legislators can incorporate into their statute those disclosure policies that reflect their own State's administrative needs and citizen concerns. The Congress could, of course, require that States enact provisions of law that permit Federal auditors to have access to welfare records. In that regard, the Commission urges the Congress to follow the recommendations set forth in Chapter 9 for government access to records.

The recommended measure allows States to enact statutes which permit disclosures without client consent *within* the welfare system. It would, however, prohibit disclosure of individually identifiable records to the general public or to legislative committees, or for purposes unrelated to the provision of public assistance and social services, except under certain narrow conditions. Disclosures of client records without authorization would be permitted under compelling circumstances affecting the health or safety of the client or another individual, and for use in research or statistical activities. In cases in which a court order is issued to an agency for a client record, the recommendation would permit disclosure in response to the court order only if the agency contested the order, and if the client who is the subject of the record were given notice and an opportunity to participate in any proceedings regarding the order. Notice to, and participation by, the client would be required only if he is the subject of the investigation or prosecution for which the court order is issued. Moreover, the Commission understands that the States, in enacting the recommended statute, may well wish to limit the number of record subjects who would receive notice when the record being sought contains information about all the members of an assistance unit or household.

These prohibitions on disclosure are generally consistent with existing Federal and State disclosure policies, except insofar as States are currently free to pass statutes making certain information about AFDC recipients available to the general public. The Commission found no compelling arguments supporting disclosure to the public that outweighed the possible harm or embarrassment that would result if a recipient's name and amount of assistance were publicly available.

Another recommendation—that States be required to apply the same

safeguards as in federally assisted programs to client records of programs that are not federally assisted but that are maintained by agencies receiving Federal funding—would assure consistency in all a State agency's public assistance and social services record-keeping activities. It would also facilitate necessary flows of information between federally assisted programs and those in which there is no Federal involvement.

The Commission believes that in enacting the recommended statute, States may wish to apply different—probably more restrictive—disclosure standards to subjective or judgmental information regarding a client's mental or physical health or status than to factual information regarding eligibility. The Commission would approve of an approach that takes into account the relative sensitivity of different types of information.

Another important principal reflected in *Recommendation (10)* is that no more information should ever be disclosed than the minimum necessary to accomplish the purpose for which disclosure is made. As noted earlier, this is crucial when collateral verification of information supplied to the agency by the client is necessary.

Examples of the benefits to be expected from adoption of the recommended measures are not hard to find. California, for example, has a State-funded program for providing cash assistance to intact families with an unemployed father or mother. The eligibility criteria for this State program are more liberal than those of the Federal AFDC-Unemployed program, which California also administers. A single family—whose situation with respect to employment may vary from month to month and thus who may qualify under different programs in successive months—may one month receive a check partially paid for out of Federal funds, and the next month one financed solely by the State treasury. The client may not realize who is footing the bill from month to month. There is only one case record about such a family—that is, there is not one record of the family's eligibility for Federal help and another of its eligibility for the State program. AFDC case records cannot, however, by Federal law, be used in the administration of a solely State-financed assistance program. The recommended measure would eliminate such problems of technical compliance with detailed Federal requirements and few people would argue that an outcome reinforcing present practice in this case would represent an unwarranted invasion of the client's privacy.

Another example concerns the development of multi-purpose application forms. Where there is a common set of data elements used to determine a client's eligibility for several programs, it would clearly be economical to collect such information on only one form. Such simplification would be welcomed by clients as well as by agencies. Some States, in fact, have been trying to develop such a form. Their efforts may be impeded by the fact that, for example, information about Food Stamp eligibility may not be disclosed to persons unrelated to the administration of the Food Stamp program, so that a multi-purpose application might violate the Federal Food Stamp disclosure law.

If the Commission's sampling of Federal confidentiality laws is a fair indication, the minimum protections guaranteed by the recommended

measure would not significantly reduce any protections individuals currently enjoy. In one special area, however, it might be argued that the form of the recommended measure might create the *risk* of undermining privacy rights. The argument concerns alcohol and drug abuse treatment records. Because these kinds of records are extremely sensitive, and because individuals with problems relating to use of alcohol and drugs must be encouraged to seek needed treatment, the Federal government has formulated very restrictive policies regarding permissible disclosures of alcohol and drug abuse treatment records. The Commission recommends that these policies not be modified, and further, that they continue to apply to alcohol and drug abuse treatment records maintained by every program receiving *any* Federal funds (including Title XX funds), whatever the provisions of State statutes.[22]

Notification of Rights

The Commission believes that in order for a client to exercise the rights its recommendations would establish, he must be cognizant of those rights, and of agencies' information management practices. Therefore, the Commission recommends:

Recommendation (11):

That the Congress require States to provide by statute that public assistance and social services agencies must inform each client in plain language of:

- **(a) the kinds of records that the agency maintains, and the purposes for which the information in those records may be used;**
- **(b) the client's right to see, copy, and request correction of a record about himself;**
- **(c) whether information requested of the client by the agency *must* be provided as a condition of eligibility for public assistance and social services, or whether providing it is voluntary;**
- **(d) of the agency's procedures regarding collateral verification** [as required by *Recommendation (4)*], **including its use of inter-agency and inter-jurisdictional data exchanges; and**
- **(e) the provisions of the State statute governing disclosure.**

Regulations currently applicable to the AFDC and Medicaid programs already provide that agencies must inform applicants about their rights and obligations under the program. They require that applicants be notified, either in written form, or orally when appropriate, of the coverage, eligibility, and scope of the program, of related services available to them, and the rights and responsibilities of applicants for and recipients of assistance. To fulfill this requirement agencies must develop bulletins and pamphlets which explain the rules of eligibility and appeals in simple,

[22] The statutory requirements for confidentiality of drug and alcohol patient records are found at 42 U.S.C. 4582 and 21 U.S.C 1175.

understandable language. Such bulletins or pamphlets must be publicized and available in quantity. *[45 C.F.R. 206.10(a)(2)(i)]*

Thus, there is already some precedent for requiring agencies to notify clients of their rights. Comments received by the Commission indicate that giving the recommended notice of an agency's record-keeping policies and practices would not create excessive administrative burdens for agencies. The Commission believes that the recommended notice should be made available to clients in their primary language wherever possible.

Subsection (c) of the above recommendation reflects the Commission's concern that to limit intrusiveness, clients should know whether they are required to disclose information about themselves as a condition of receiving assistance, or whether disclosure is voluntary.

Remedies for Violations of a State Statute

The Commission believes that a State statute regarding fair information practice in welfare record keeping would not be complete if it did not provide remedies and penalties for violation of its requirements. Accordingly, the Commission recommends:

Recommendation (12):

> **That the Congress require the States to provide by statute that appropriate remedies and penalties will be available in cases in which a public assistance or social services agency violates a provision of the State fair information practice statute.**

Although the Commission feels that the States are best able to determine what type of remedies and penalities are appropriate, it believes that its suggested amendments to the civil remedies and criminal penalties sections of the Privacy Act of 1974 represent a model for the kinds of statutory provisions the States would be required to enact.[23]

Child Support Enforcement

There is one area of public assistance and social services record keeping that seemed to merit the Commission's special attention: record keeping carried out in connection with Child Support Enforcement activities. The Commission promised to address this issue in its June, 1976 report on *Federal Tax Return Confidentiality*.

Although the recommendations thus far made in this chapter are intended to apply to Child Support Enforcement programs, they do not address all of the special record-keeping issues that arise in that particularly controversial area. Therefore, the Commission includes below a brief description of the program and several specific recommendations that apply only to it.

Part D of Title IV of the Social Security Act authorizes Federal grants

[23] See Chapter 13 for a discussion of the suggested revisions.

to the States for the purpose of locating absent parents who have defaulted on their child support obligations, for establishing the paternity of children for whom child support may be owed, and for enforcing child support obligations. To be eligible for Federal grants for these purposes, a State must establish a State Child Support Enforcement agency and a State Parent Locator Service within the agency. The agency's functions may be performed either by that agency or by law enforcement officials (e.g., district attorneys, State attorneys general) who have entered into cooperative agreements with the agency. The agency may also contract with private investigatory agencies for assistance in locating absent parents.

In addition to providing Federal financial assistance for State child support enforcement activities, Title IV-D established an Office of Child Support Enforcement within the Department of Health, Education, and Welfare to oversee States' administration of the program, as well as a Federal Parent Locator Service within that Office to aid in the location of absent parents. Although the primary purpose of the Child Support Enforcement program is to find the parents of children who are AFDC recipients and to see that they fulfill their parental obligations, the State Child Support Enforcement agencies and the Federal Parent Locator Service (PLS) may make their services available, for a fee, to individuals who are not AFDC recipients.

Title IV-D of the Social Security Act does not prescribe statutory standards for the safeguarding of information obtained by State Child Support Enforcement agencies. Federal regulations provide that States, pursuant to State statutes which impose legal sanctions, shall apply the same limitations on the use or disclosure of information concerning applicants and recipients of child support enforcement services as are prescribed for AFDC records. *[45C.F.R. 302.18]* Additionally, the regulations require that all requests for information from a State to the Federal Parent Locator Service shall include a statement, signed by the head of the State Child Support Enforcement agency or his designee, affirming both that information obtained from the Federal Parent Locator Service will be treated as confidential and safeguarded pursuant to the requirements of the AFDC confidentiality regulations, and that the State agency will take protective measures to safeguard information transmitted to and received from the Federal Parent Locator Service *[45 C.F.R. 302.70(e)(2) and (3)]*.

The Commission finds that these regulations do not adequately safeguard the information collected by State IV-D agencies about the individuals being sought. The regulations only place limits on the use and disclosure of information about absent parents obtained from the Federal PLS, and do not apply to information regarding absent parents obtained by State agencies from State and local sources.

Information on missing parents is collected by State and local AFDC offices, and by the State Child Support Enforcement agencies. Both ask a client for basic identifying information such as the name, address, and Social Security number of the absent parent. In addition, clients may be asked about the absent parent's work and social life. For example, in Michigan a "support specialist" responsible for locating an absent parent

must, as the first step of the location procedure, ask for information including, but not limited to, the absent parent's employment, occupational skills, work shift, date and place of marriage, physical description, names of creditors, names and addresses of friends or relatives, arrest record, and memberships in fraternal organizations. In addition to the information obtained from the client, and from the AFDC office, the record will include any information that can be gathered from other sources contacted in the course of the location effort.[24]

The Commission believes that the standards regarding confidentiality currently contained in regulations should be embodied in statute, so that they can be changed only by the legislative process, and not at the discretion of agencies. Moreover, the Commission believes that information about absent parents, as well as AFDC clients, should be subject to these statutory safeguards, and that the use of information about absent parents obtained from the Federal Parent Locator Service should be confined to the purposes for which the State acquired it.

Consistent with these findings, the Commission recommends:

Recommendation (13):

That the use and disclosure of information obtained on applicants for and recipients of child support services as well as on alleged absent parents should be subject to the same statutory disclosure policy called for by *Recommendation (10).* Furthermore, Congress should require by statute that information obtained by State agencies from the Federal Parent Locator Service regarding absent parents may not be disclosed for purposes unrelated to the establishment of paternity, the location of the parent, or enforcement of child support obligations, except to the extent that disclosures of such information result from court proceedings.

The Commission also believes that Section 454(8) of the Social Security Act, which mandates that States utilize all sources of information and available records should be qualified to except explicitly the classes of information which may not be disclosed under State or local laws. If, in the judgment of a State legislature, the nature of certain data warrants holding that data confidential, the State Parent Locator Service should be required to respect the legislature's judgment, and should not be held not to be in compliance with Federal law for doing so. For example, the Commission learned during its Tax Return Confidentiality hearings that an Ohio tax statute *[Ohio Revenue Code §5747.18]* holds data maintained by the State Department of Taxation confidential. The Ohio Department testified before the Commission that it refuses requests for information from the State PLS. In written testimony a representative of the Ohio Department of Taxation noted:

> . . . some provisions of the Federal welfare laws, specifically the parent-locator service provisions, encourage, if not require, efforts

[24] State of Michigan, Office of Standards and Investigation, Item CR-240, September 8, 1976.

to use State tax department files. This latter is a dangerous precedent, because once that first breach of confidentiality is legitimized, the legislative branch of both State and Federal governments will find it easier to create other special cases. Such legislation should not be encouraged.[25]

The Commission concurs with this opinion and therefore recommends:

Recommendation (14):

That the Congress amend Title IV-D of the Social Security Act to provide that the provision requiring States to "utilize all sources of information and available records" *[Section 454(8)]* **not be construed to override State and local laws prohibiting the disclosure of certain types of information unless these laws have made provision for disclosure to the State Parent Locator Service.**

The Commission also objects to Section 453(e)(2) of the Social Security Act which provides that, notwithstanding any other provision of law, Federal agencies shall supply information to the Federal Parent Locator Service (PLS). The only exceptions to this provision are for disclosures to the Federal PLS that would contravene national security or the confidentiality of census data.[26] The Commission believes that when other provisions of law dictate that the use or disclosure of certain information be restricted, and when such provisions do not explicitly allow, by exception, for release of information to the Federal PLS, the Federal PLS should not be permitted access to that information. Furthermore, the Commission strongly believes that Federal agency information available to the PLS should be limited to the minimum necessary to aid in the location of absent parents, and should not involve additional information regarding, for example, the individual's income or assets.[27] Accordingly, the Commission recommends:

Recommendation (15):

That the Congress amend Section 453(e)(2) of Title IV-D of the Social Security Act to provide that Federal agencies maintaining information which, by other provisions of law, has been deemed to be confidential, shall not be required to provide that information to the Federal Parent Locator Service (PLS), unless disclosure to the Federal PLS is specifically authorized by a Federal statute that specifies the agency that may disclose information to the PLS; and

[25] Written statement, *Federal Tax Return Confidentiality,* Hearings before the Privacy Protection Study Commission, March 12, 1976, p.3.

[26] In testimony before the Commission, Office of Child Support Enforcement officials testified that, although the Federal Parent Locator Service may utilize all Federal sources of information, it currently relies primarily upon the Social Security Administration, the Internal Revenue Service, and the Department of Defense.

[27] See Chapter 14 for a further discussion of this topic.

further, that the Congress limit disclosures of information by Federal agencies to the PLS to the minimum necessary to locate the absent parent (e.g., place of employment and home address).

These two recommendations reflect the Commission's conviction that no law regarding the gathering of information should override all other laws regarding confidentiality. Instead, policy makers formulating laws on the disclosure of the kinds of records that the PLS would find useful should be required to decide explicitly whether the PLS should have access to each type of record. Such a decision would require legislators to weigh all of the considerations involved, including the interests at stake in child support enforcement, and would assure that child support enforcement is not automatically viewed as paramount to all other considerations.

Technical Assistance for the States

Lacking any comprehensive Federal and State fair information practice policy, Congress and the Federal agencies have been compelled to develop policies in special areas where the absence of record-keeping policies is especially risky, most notably in the areas of alcohol and drug abuse treatment and child abuse and neglect prevention and treatment. In these two areas, Congress has enacted statutes and Federal agencies have developed regulations dealing with permissible uses and disclosure of records about individuals. The Commission's recommended measure on disclosure, *Recommendation (10),* would supersede other Federal policies on confidentiality, except in the case of alcohol and drug abuse treatment records, and would require States to enact their own comprehensive confidentiality statutes. Although some may contend that this measure would ultimately lessen privacy protection for clients, the Commission expects that States are as sensitive as the Federal government has been to the need to control carefully the dissemination of such information.

Nevertheless, not all of the States have had extensive experience in preparing this kind of legislation. Many Federal agency employees are intimately familiar with the policy issues that arise not only in the two areas cited above, but also in other areas where sensitive records are created with the help of Federal financing. The States, particularly those for which fair information practice is a novel concept, may find this experience most useful.

Therefore, the Commission recommends:

Recommendation (16):

That the Congress require the heads of all Federal agencies funding public assistance and social services programs to provide assistance to the States in developing their fair information practice statutes.

The Commission feels that such assistance could be provided by, for example, a committee made up of representatives of all appropriate Federal agencies which would meet with State legislators and other concerned

citizens to advise them in developing the State statutes required by the recommended measures. Assistance might also take the form of grants to consortiums made up of representatives of clients' groups, State and local government agencies, and State legislatures to serve as information clearinghouses, and to draft model statutes for the States.

* * * * * * *

Adoption of the Commission's recommendations with respect to public assistance and social services record keeping would, in the Commission's judgment, simplify the administration of the many programs and provide a reasonable balance between the demands of effective program administration and legitimate rights and interests of clients.

Personal Privacy in an Information Society

Excerpt from Chapter 7: Record Keeping in the Medical-Care Relationship

The Report of
The Privacy Protection Study Commission

July 1977

Fairness

Patient Access to Medical Records

As noted earlier, one of the issues on which medical-care providers are least in agreement is whether a patient should be allowed to see and copy a medical record about himself. Nine States currently grant a patient the right to inspect and, in some instances, obtain copies of his medical records. Colorado clearly has the most liberal statutes in that they apply not only to hospital records, but also to records kept by private physicians, psychologists, and psychiatrists. The Colorado statutes grant the patient the right to obtain a copy of his records for a reasonable fee, without resort to litigation, and without the authorization of physicians or hospital officials.[51] An Oklahoma statute permits the patient to inspect and copy his medical records in both the hospital setting and the physician's office.[52] The difference between the Oklahoma and Colorado laws lies in the status of psychiatric records. Colorado provides for patient access to psychiatric records following termination of treatment, while Oklahoma excludes psychiatric records altogether.

Other States recognize a much narrower right of access. Florida law gives the patient the right to obtain copies of all reports of his examination and treatment, but applies only to records maintained by physicians, with no mention of hospital records.[53] By contrast, the statutes of Connecticut,

[51] Colo. Rev. Stat. § 25-1-801.
[52] Okla. Stat. Ann. tit. 76, § 19.
[53] Fla. Stat. Ann. § 458.16.

Indiana, Louisiana, and Massachusetts cover only a hospital record, and make no mention of records maintained by physicians.[54] Mississippi and Tennessee require the patient to show good cause before he can have access to his hospital records.[55] Ten States (Illinois, Maine, Missouri, Montana, Nevada, New Jersey, New Mexico, North Dakota, Utah, and Wisconsin) have vaguely worded statutes or regulations[56] that allow a patient, relative, physician, or attorney access to the patient's medical records. Of these 10 states, Nevada and New Mexico apply only to mental-health records. In New York, the patient need be shown only enough of the hospital record to indicate which physicians have attended him,[57] and in Ohio the hospital determines how much of the medical record the patient may see.[58] In Arizona the administrator or attending physician must consent before a patient can inspect his hospital records.[59]

In several other States legislation is now pending that would create a right of access for a patient similar to the one provided by the Privacy Act of 1974, i.e., a right to *see and copy* a medical record about oneself except in special situations.

The subsection of the Privacy Act that specifically refers to medical records states:

> In order to carry out the provisions of this section, each agency that maintains a system of records shall promulgate rules . . . which shall . . . establish procedures for the disclosure to an individual, upon his request, of his record or information pertaining to him, including special procedures, if deemed necessary, for the disclosure to an individual of medical records, including psychological records pertaining to him. *[5 U.S.C. 552a(f)(3)]*

The Office of Management and Budget guidelines for implementing the Privacy Act quote the legislative history of this provision as follows:

> If in the judgment of the agency, the transmission of medical information directly to a requesting individual could have an adverse effect upon such individual, the rules which the agency promulgates should provide means whereby an individual who

[54] Conn. Gen. Stat. Ann. § 4.104 (1969); Ind. Code Ann. § 34-3-15.5-4; La. Rev. Stat. Ann. § 44.31 (1951); Mass. Gen. Laws Ann. ch. 111 § 70 (1971).

[55] Miss. Code Ann. § 7146-53 (Supp. 1971); Tenn. Code Ann. § 53-1322.

[56] Ill. Ann. Stat. ch. 51 § 71; Maine: Letter from Robert B. Calkins, Assistant Attorney General to the Secretary's Commission on Medical Malpractice, June 19, 1972; Missouri Division of Health, Hospital Licensing Law, ch. 197; Montana Board of Health Regulations, §31.106; Nev. Rev. Stat. §433.721; N.J. Stat. Ann. §30:4-24.3; N. M. Stat. Ann. §32-2-18; N.D.-Rules and Regulations for Hospitals and Related Institutions R. 23-16-8S.1-.3; Utah Code Ann. §64-7-50; and Wis. Stat. Ann. §269.57(4).

[57] N.Y. Official Compilation of Codes, Rules and Regulations, §§ 720.20(p)(1971).

[58] *Wallace v. University Hospital*, 171 Ohio St. 487, 172 N.E.2d 459 (1961).

[59] Arizona Hospital Association Consent Manual, 1969.

> would be adversely affected by receipt of such data may be apprised of it in a manner which would not cause such adverse effects.[60]

While the Privacy Act recognizes an individual's undeniable right to see and copy a medical record about him maintained by a Federal medical-care facility, it clearly allows special procedures where direct access could be harmful to him. The guidelines are vague about when special procedures are justified and silent about what they may be. Thus, it should not be surprising that the special procedures developed by the different agencies are not the same.

The Department of Health, Education, and Welfare has the most liberal procedures, providing for indirect access to records through a responsible individual, not necessarily a medical professional, designated by the patient. The Department of Defense procedure requires that arrangements be made for release of the record to a physician of the patient's choice. The Veterans Administration takes a middle ground, requiring that medical records containing "sensitive information" be "referred to a physician or other professional person with the necessary professional qualifications to properly interpret and communicate the information desired." The one caveat provided is that the selectee must either meet VA professional standards or be licensed in the appropriate professional specialty.[61]

The Commission's hearings failed to produce evidence that one procedure was more effective than another in protecting patients from any adverse consequences that might result from obtaining their medical records. Not one witness was able to identify an instance where access to records has had an untoward effect on a patient's medical condition. While the Department of Defense special procedure is clearly the most restrictive, DOD representatives estimated that the Department had released a record to a physician, rather than to the individual directly, in less than one percent of the cases where access had been requested.

The Commission considered a number of proposals for a special procedure to be followed when direct access might harm the patient. Some of these would stop short of the DHEW procedure allowing release of the record to any responsible person the patient may designate, whether the designee is a medical professional or not. Others would leave the patient's see-and-copy right unrestricted with respect to any information in his medical records that had been or might be disclosed for use in making non-medical decisions about him, but would prescribe special procedures in specified instances (e.g., psychiatric or terminal illness) when there is no possibility of such disclosure to third parties. In the end, however, the Commission concluded that no solution would be acceptable in the long run so long as it risks leaving the ultimate discretion to release or not to release in the hands of the patient's physician. In situations where the keeper of a medical record believes that allowing the patient to see and copy it may be

[60] Office of Management and Budget, *Privacy Act Guidelines*, issued as a supplement to Circular A-108, 40 *Federal Register*, 132, p. 28957.

[61] U.S. Veterans Administration, *Manual MP-1*, Part II, Chapter 21, Section 6.d.

injurious to the patient, the Commission concluded that it would be reasonable for the record to be given to a responsible person designated by the patient, with that person being the ultimate judge of whether the patient should have full access to it. In no case, however, should the physician or other keeper of the record be able to refuse to disclose the record to the designated responsible person, even where it is known in advance that the designated person will give the patient full access to it.

Accordingly, having weighed the evidence before it, and having considered the arguments pro and con, the Commission recommends:

Recommendation (5):

That upon request, an individual who is the subject of a medical record maintained by a medical-care provider, or another responsible person designated by the individual, be allowed to have access to that medical record, including an opportunity to see and copy it. The medical-care provider should be able to charge a reasonable fee (not to exceed the amount charged to third parties) for preparing and copying the record.

Although this recommendation stops short of guaranteeing that the patient will be allowed to see and copy everything in every medical record about him, it leaves the designee the option of giving the patient this guarantee. The Commission believes that the measure will encourage medical-care providers themselves to release records to patients whenever they can possibly do so in good conscience. In some sense, the recommended procedure harkens back to the time when family members and friends played a much larger role in patient care than they normally do today. In any case, it gives most patients a way of finding out what is in their medical records, and of knowing what others can learn about them from those records.

This discussion would be incomplete without a word about access to medical records by patients who are minors. As noted in Chapter 11 on the public assistance and social services relationship, most of the comments submitted to the Commission urged that a minor patient be given access to medical records concerning treatment he has sought on his own behalf, if State law permits him to obtain such treatment without the knowledge or consent of his parents. State laws usually deal with this question in connection with venereal disease, drug or alcohol abuse, pregnancy, and family planning, including abortion. The Commission believes that in these instances only the minors (and not their parents or guardians) should be given access to such records or portions of records so as not to discourage them from seeking necessary treatment.

The fee provision also raises a minor problem. *Recommendation (5)* would allow the medical-care provider to charge the individual a preparation or copying fee consistent with the fees it charges others for such services. This could mean anything from $1 to several hundred dollars. Obviously, the Commission would not want the right to see and copy a medical record to become a prerogative of the well-to-do, and thus urges

medical-care providers to develop fee schedules flexible enough to match the varying financial circumstances of patients.

Patient Access to Medical-Record Information

Elsewhere in this report the Commission recommends measures to assure an individual's right of access to a record maintained about him by an insurer, self-insurer, or insurance-support organization and further, that he be able to obtain on request a copy of all the information that served as the basis for an adverse insurance decision about himself. In another chapter, the Commission recommends that an employer voluntarily establish procedures whereby an individual can gain access to records the employer maintains about him. In the chapter on Public Assistance and Social Services, the Commission recommends enactment of a Federal statute requiring that the States, in turn, enact statutes permitting individuals to have access to records maintained by a public assistance or social service agency.

In all three instances, some of the records to which the individual would be given access are, or contain, medical-record information. The Commission would prefer that such third-party holders of medical-record information not distinguish it from any other information the individual asks to see and copy. The Commission recognizes, however, that as a practical matter an individual may not always find a medical record or a copy of medical-record information informative unless a medical professional interprets its technical language for him, and third-party keepers of medical-record information may not be able to provide such assistance. Thus, with respect to medical-record information, the Commission recommends:

Recommendation (6):

That upon request, an individual who is the subject of medical-record information maintained by an organization which is not a medical-care provider be allowed to have access to that information either directly or through a licensed medical-care professional designated by him.

It must be noted that this recommendation does not fall within the primary implementation strategy contained in *Recommendations (1), (2),* and *(3)* above. In the case of insurance institutions and insurance-support organizations, it would become part of the recommended general and specific rights of access to records to be established by Federal statute. In the private-sector employment situation, it would be implemented voluntarily by the employer. In the public assistance and social services area, it would become a right provided by State statute which, if the Commission's recommendations were followed exactly would have to distinguish between the social-services provider who is a medical-care provider—properly subject to the requirements of *Recommendation (5)* —and the social-services provider who is not a medical-care provider but who uses medical-record

information. As to the latter, the statute should guarantee *direct* access lest it retreat from the current practice of allowing an individual to see, before or during a hearing, information used to make an adverse eligibility determination about him. (See Chapter 11.)

Correction of a Medical Record

A main premise of a privacy protection policy is that an individual should be able to review the records made by others of information he has divulged, or has permitted to be divulged, and to correct any errors or amend any inadequacies in them. This premise is no less important for medical records than for other types of records, although much of the information in a medical record is put there by medical professionals. The individual may provide information, but he rarely enters it directly into the record; the medical professional normally does that. Thus, even with the most conscientious record keeping, there are ample opportunities for errors of fact or interpretation to creep into a medical record.

Within the medical-care relationship itself, such errors can usually be corrected before they do any harm. Once information has been disclosed to someone outside the relationship, however, not only is correction or amendment more difficult but the consequences of errors become increasingly difficult to avoid or reverse. This becomes a particular danger when, as previously noted, offhand comments and speculations which are irrelevant to a patient's medical history, diagnosis, condition, treatment, or evaluation are set down in medical records that become available for use in making a non-medical decision about him. Furthermore, while it is true that some portion of the information in a medical record may be beyond the patient's comprehension, not all of it will be. Accordingly, in recognition of the fact that the circulation of erroneous, obsolete, incomplete, or irrelevant medical-record information outside the confines of the medical-care relationship can bring substantial harm or embarrassment to the individual concerned, the Commission recommends:

Recommendation (7):

That each medical-care provider have a procedure whereby an individual who is the subject of a medical record it maintains can request correction or amendment of the record. When the individual requests correction or amendment, the medical-care provider must, within a reasonable period of time, either:

(a) make the correction or amendment requested; or
(b) inform the individual of its refusal to do so, the reason for the refusal, and of the procedure, if any, for further review of the refusal.

In addition, if the medical-care provider refuses to correct or amend a record in accordance with the individual's request, the provider must permit the individual to file a concise statement of the reasons for the

disagreement, and in any subsequent disclosure of the disputed information include a notation that the information is disputed and furnish the statement of disagreement. In any such disclosure, the provider may also include a statement of the reasons for not making the requested correction or amendment.

Finally, when a medical-care provider corrects or amends a record pursuant to an individual's request, or accepts a notation of dispute and statement of disagreement, it should be required to furnish the correction, amendment, or statement of disagreement to any person specifically designated by the individual to whom the medical-care provider has previously disclosed the inaccurate, incomplete, or disputed information.

The requirement to furnish a correction, amendment, or dispute statement to such previous recipients as the individual may designate evolves from a concern that medical-record information disclosed to third parties be as accurate, complete, and timely as possible. To expect a medical-care provider to convey a correction, amendment, or dispute statement to all previous recipients of information from a record would impose an unreasonable burden on the provider; yet the Commission is concerned that some steps be taken to minimize the extent to which medical-record information may become a source of unfairness to an individual. Therefore, it has recommended that only those specifically designated by the individual be furnished with the details of the correction, amendment, or statement of disagreement. The Commission believes this approach represents a reasonable balance. Moreover, because *Recommendations (10)* and *(14)* below call for two types of accountings of disclosures (notations and retained authorization statements), the Commission would expect those accountings also to be available to the individual to help him to decide to whom corrections, amendments, or statements of disagreement should be sent.

Correction of Medical-Record Information

As with its recommendations on patient access, the Commission also debated the correction, amendment, and dispute issues as they relate to keepers of medical-record information. The problem is largely one of information erroneously or incompletely reported by a medical-care provider, or erroneously copied or interpreted for or by the recipient. For example, an investigative-reporting firm under contract to an insurer may be authorized to acquire information from the physicians and hospitals named on an individual's insurance application. If the investigative firm representative makes a mistake in copying information from a medical record, neither his firm nor the insurer has any way of knowing it unless and until the error precipitates an adverse insurance decision and perhaps not even then. Even if the error is detected later, the information may have been disclosed in the meantime to other insurers (with the individual's authorization), or to the

Medical Information Bureau where it will be retained, and thus constitute a potential problem for the individual for many years.

The Commission recognizes that the number of mistakes of this sort can be minimized by having a medical-care professional review and interpret records for agents of third parties, or by using photocopying techniques. Not all medical records today can be organized to allow easy photocopying, however, and at the same time assure that the inquiring third party receives only as much information as the individual has authorized it to receive. Nor is it always possible to have a professional available when records are reviewed by third parties. Thus, in some unknown number of cases, either a medical professional will have to prepare special reports for the ultimate recipient—in this example, the insurer—or a certain amount of hand copying by persons who are not medically trained will unavoidably continue. Even when a medical record can be photocopied without revealing more information than is meant to be disclosed, there is the danger that the third party representative making the copy will overlook portions of the record which, if known, would alter the insurer's decision.

The simplest solution would, of course, be to allow the individual to correct or amend medical-record information where it rests, in the files of the recipient-user. Yet the simplest solution is not always the most practical one. The insurer (or employer, or whoever the third-party record holder happens to be) may elect not to give the individual direct access to medical-record information about himself. *Recommendation (6),* it will be remembered, gives the third-party record holder the option[62] of disclosing medical-record information either to the individual to whom it pertains, or to a licensed medical professional whom the individual designates. Hence, there may be no way for the third-party holder to cope with a correction or amendment request without, in effect, giving up its option to deal with the individual through a designated professional.

Moreover, despite what has been said about the tendency of some medical-care providers to record irrelevant information, it must be remembered that the medical record is a document to which unusual attention is given because it is created by persons who have special expertise. If an insurer could have confidence in an individual's own description of his medical situation, there would be no need to acquire information in his medical records. The insurer, however, cannot assume that the individual is either qualified or motivated to give an accurate description. The fact that the insurer cannot rely on the individual in this matter is both the reason why the insurer seeks to acquire medical-record information and the reason why the individual's claim that the information obtained is erroneous or otherwise inadequate cannot be taken at face value.

It may also happen that the medical-care provider who originally provided the contested information can no longer be consulted; for example, a physician may have retired, died, or moved out of reach, or the provider may simply not be willing to acknowledge that an error was made. In such situations, the Commission believes that the third-party holder of

[62] Except in the case of the social-service provider that uses medical-record information to make an (adverse) eligibility determination.

the allegedly inaccurate information should afford the individual a way of entering his corrections into the record as long as it also indicated that the changes were made without the concurrence of its original source. Accordingly, the Commission recommends:

IV

MATERIALS PERTAINING TO STERILIZATION

16

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PROPOSED REGULATIONS GOVERNING STERILIZATION

December 13, 1977

federal register

TUESDAY, DECEMBER 13, 1977
PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Care Financing Administration

Public Health Service

■

PROPOSED RESTRICTIONS APPLICABLE TO STERILIZATIONS FUNDED BY THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[4110-35]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Care Financing Administration

[45 CFR Part 205]

[42 CFR Part 50]

PROPOSED RESTRICTIONS APPLICABLE TO STERILIZATIONS FUNDED BY THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

AGENCY: Health Care Financing Administration, Public Health Service, Department of Health, Education, and Welfare.

ACTION: Proposed rules.

SUMMARY: The Department proposes new rules to govern Federal financial participation in sterilizations funded through various Departmental programs. These proposed rules are appropriate because of the Department's accumulating experience with the current rules governing sterilizations and in light of a recent court decision. The intended effect of these proposed rules is to specify the precise circumstances under which Federal Funds may be used for sterilization purposes. Current policies remain in full force pending adoption of these proposed rules.

DATES: Comments must be received on or before March 13, 1977.

FOR FURTHER INFORMATION CONTACT:

For the Public Health Service: Marilyn L. Martin, Room 722H (Hubert H. Humphrey Building), 200 Independence Avenue SW., Washington, D.C. 20201, 202-245-7581. For the Health Care Financing Administration: Emily J. Nichols, Room 4513, Switzer Building, 330 C Street SW., Washington, D.C. 20201, 202-245-0701 (HCFA).

SUPPLEMENTARY INFORMATION: The Department of Health, Education, and Welfare proposes new rules to govern Federal financial participation in sterilizations funded through various Departmental programs. These rules revise existing rules at 42 CFR 50.201-204 and 45 CFR 205.35, and supplant the current moratorium on sterilizations of people under 21 or mentally incompetent, first declared by the Secretary on July 27, 1973, see 38 FR 20930 (August 3, 1973). New rules are appropriate in light of the Department's accumulating experience with the current rules governing sterilizations and in light of the recent decision of the United States Court of Appeals for the District of Columbia Circuit in *Relf* v. *Weinberger*, No. 74-1797 (decided September 13, 1977). In that case, the court took note of the Department's professed intention to issue new rules and of its obligation to utilize informal rulemaking procedures.

STATUTORY PROVISIONS PERTAINING TO STERILIZATIONS

The Department funds family planning services, including sterilizations, under several Federal statutes. Three agencies within the Department are responsible for administering programs under which sterilizations are performed—the Medicaid Bureau (MMB) of the Health Care Financing Administration (HCFA), the Public Health Service (PHS), and the Administration for Public Services (APS) of the Office of Human Development Services (OHDS).

1. THE MEDICAID PROGRAM

The medical assistance (Medicaid) program under title XIX of the Social Security Act, 42 U.S.C. 1396, et seq., which is administered by MMB, provides for Federal matching of reimbursements for sterilizations pursuant to section 1902(a)(13) and 1905(a)(4)(C) of the Act, 42 U.S.C. 139a(a)(13) and 1396d(a)(4)(C). Those provisions require State Medicaid plans to provide "family planning services and supplies furnished (directly or under arrangements with others) to individuals of childbearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies * * *". The Medicaid Bureau has not defined family planning services by regulation; however, MMB policy has been to consider sterilization as a federally funded family planning service.

2. THE TITLE XX SOCIAL SERVICES PROGRAM

Title XX of the Social Security Act, which is administered by APS, authorizes grants to States for social services, including family planning services. See section 2002(a)(1) of the Act, 42 U.S.C. 1397a(a)(1). Regulations at 45 CFR 228.63, applicable to title XX published in the FEDERAL REGISTER at 42 FR 5861 (January 31, 1977), provide that "(c) where a State authorizes sterilization as a family planning service, it must comply with the provisions of 45 CFR 205.35."

3. THE AFDC PROGRAM IN THE 50 STATES AND THE DISTRICT OF COLUMBIA

While title XX itself does not mandate the provision of family planning services, title IV-A effectively does mandate such services in a State's title XX plan. In order for a State to qualify for Federal financial participation under title IV-A of the Social Security Act (Aid to Families with Dependent Children), the State's plan must provide that family planning services will be provided under title XX. Section 402(a)(15) of the Social Security Act, 42 U.S.C. 602(a)(15), as amended by Pub. L. 93-647 (the enacting title XX legislation), requires that the State's title IV-A plan provide:

> As part of the program of the State for the provision of services under title XX * * * for the development of a program, for (persons eligible for AFDC benefits) for preventing or reducing the incidence of births out of wedlock and otherwise strengthening family life, and for implementing such program by assuring that in all appropriate cases (including minors who can be considered to be sexually active) family planning services are offered to them and are provided promptly * * * to all individuals voluntarily requesting such services, but acceptance of family planning services provided under the plan shall be voluntary on the part of such members and individuals and shall not be a prerequisite to eligibility for or the receipt of any other services under the plan * * *

4. THE AFDC AND AGED, BLIND AND DISABLED PROGRAMS IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

In Guam, Puerto Rico, and the Virgin Islands, five titles of the Social Security Act are relevant to the provision of sterilizations. Titles I, X, XIV and XVI, providing for grants for assistance and services to the aged, blind and disabled, are now in effect only for Guam, Puerto Rico and the Virgin Islands. (In all other jurisdictions those titles have been superseded by the new title XVI (Supplemental Security Income) and title XX (Social Services.)) Each of those titles provides, at subsection (c)(1) of sections 3, 1003, 1403 and 1603, 42 U.S.C. 303(c)(1), 1203 (c)(1), and 1353(c)(1) and 381, respectively, that in order to qualify for Federal payments the State plan must provide that the State agency must make available "at least those services to help them attain or retain capability for [self-support or] self-care which are prescribed by the Secretary." (The bracketed words do not appear in title I.) 45 CFR 222.59, applicable to the original adult titles, authorizes family planning as an optional service under those titles. 45 CFR 222.7 (also applicable to the original adult titles) provides that "eligible individuals must be free to determine whether to accept or reject services from the agency."

Title IV-A reads virtually identically for Guam, Puerto Rico and the Virgin Islands as for the other States except that the provision in section 402(a)(15) referring to title XX does not apply. In these jurisdictions section 402(a)(15) requires that the title IV-A plan itself must provide for family planning services.

5. PROGRAMS ADMINISTERED BY THE PUBLIC HEALTH SERVICE

Title V of the Social Security Act, which is administered by PHS, requires each State, as a condition to the receipt of formula grant funds for maternal and child health and crippled children's services, to include in its State plan a program of family planning service projects. The program or project must offer reasonable assurance, particularly in areas with concentrations of low-income families, of satisfactorily helping to reduce the incidence of handicapping conditions caused by complications associated with childbearing and to reduce infant and maternal mortality. See section 505(a)(8) of the Act, 42 U.S.C. 705(a)(8)

The Public Health Service also funds sterilizations under title X of the Public Health Service Act, which authorizes the Secretary to make grants and contracts for family planning projects which offer a "broad range of acceptable and effective family planning methods." Section 1001(a), 42 U.S.C. 300(a). In addition, family planning services are included in the care offered by community health

centers under section 330 of the Public Health Service Act, 42 U S.C. 254c, and in the migrant workers health program under section 319 of the Act, 42 U.S.C. 247d.

Public Health Service personnel perform sterilizations in PHS hospitals, in the Indian Health Service, and in other direct programs. Although these rules govern only federally funded sterilizations, they will be made applicable to these direct programs by administrative directive.

Finally, section 205 of Pub. L. 94–63, 42 U.S.C. 300a–8, makes it a felony, punishable by a fine up to $1000, and by imprisonment of up to one year, or both, to coerce any person to undergo an abortion or sterilization through the threat of withholding any service or program receiving Federal financial assistance.

Current Policies

Departmental policies with regard to Federal financial participation in sterilizations are found in the existing rules, 42 CFR 50.201–50.204 and 45 CFR 205.35, and in the moratorium on any sterilization of individuals under 21 or legally incapable of consenting to be sterilized declared by the Secretary on July 27, 1973, 38 FR 20930 (August 3, 1973). These policies are still in effect and will remain in full force until the date these proposed rules become effective. In brief those policies are:

1. Federal financial participation is available only in the sterilization of people at least 21 years old who are mentally competent under State law. In other words, Federal funding is not available for any sterilization of a person who is either under 21 or who is mentally incompetent.

2. Federal financial participation is available in the sterilization of people over at least 21 years old only where informed consent, as defined and required by the current rules, is obtained. In all except so-called "therapeutic" sterilizations, informed consent must be obtained at least 72 hours prior to the sterilization.

Discussion of the Major Issues

1. The competing policies and the need for public comment

Regulation of Federal financial participation in sterilizations is governed by two principles. First, Congress, is enacting the various programs through which sterilizations are funded, recognized sterilization as a valid family planning technique and intended it to be freely available to the population eligible for family planning assistance. Equally significant, however, is that in virtually every provision in which the Congress authorized Federal funding of sterilization, it also required that the acceptance of such services be voluntary. See, e.g., Social Security Act sections 402, 508, and 1905(a), 42 U.S.C. 602, 708, and 1396(d), and Public Health Service Act section 1007, 42 U.S.C. 300a–5. See also S. Rep. No. 1230, 92d Cong., 2d Sess. 295–98 (1972) (legislative history to 1972 family planning services amendments to Social Security Act). Thus, the Congress wrote into law its determination that no person be coerced, through direct or devious means, into undergoing a sterilization.

The Department fully appreciates the importance each of these twin policies. Mature people, understanding the nature and consequences of sterilization procedures, should have access to sterilizations unimpeded by unnecessary procedural requirements. At the same time, the Department is aware of serious allegations of cases in which patients were coerced into being sterilized, and the Department is equally committed to preventing abuses wherever sterilizations are paid for with Federal funds. Thus, the Department seeks to prevent situations in which a patient decides to undergo a sterilization because of lack of information as to the nature and consequences of the procedure, because of lack of mental capacity to understand those nature and consequences, because of fear that refusal to be sterilized will result in reprisals such as withdrawal of Federal benefits, or because of susceptibility to duress at times of extreme stress associated with labor, childbirth or hospitalization. In drafting proposed rules, the Department has sought readily enforceable rules that minimize the opportunities for sterilization abuse. Consequently, the proposed rules contain few provisions for exceptions or allowances for special circumstances.

There is an inevitable tension between the dual policies of making sterilizations freely available and of preventing sterilization abuse. As a general matter, the greater the access to sterilizations the greater the possibilities for abuse. Similarly, stringent procedural requirements to control abuse may artificially inhibit patient demand for sterilizations, whereas the absence of such procedures may constitute an invitation for abuse. The policy balance must be struck separately with regard to virtually each and every regulatory option. Where to strike that balance, however, depends to some degree upon informed predictions as to its consequences, with regard to both sterilization availability and steriliaztion abuse.

The Department has found, however, that existing information does not permit precise predictions as to the effects of proposed choices. Indeed, there is serious question whether it is even possible to generate the type of comprehensive data that would permit "scientific" policy making in this difficult area. Systematic data on sterilization abuse, for exmaple, are extremely difficult to collect. First, there is the difficulty of defining sterilization "abuse"; some may argue that every violation, no matter how technical, of existing requirements constitutes abuse, while others might argue that only certain requirements are so fundamental that their violation is abusive. Second, assuming it is possible to define "abuse" satisfactorily, there is no mechanism whereby instances of abuse may be regularly and systematically identified, since abusers cannot be expected to report their conduct and those abused may not have the means or knowledge necessary to bring instances of abuse to the attention of those studying the problem.

The Department is therefore particularly eager to receive comments on these proposed rules, recognizing that individual case histories, no matter how compelling, with respect to both the need for sterilization and with respect to sterilization abuse may not accurately portray the actual consequences of alternative policy choices. Comments will be especially helpful if they are addressed to demonstrating why a particular balance between availability and abuse-prevention policies should be drawn at a given place. Comments should explain why any alternative choices are more likely to minimize overall hardships. Comments should explain why, for example, there would be more suffering because of the unavailability of sterilizations for people under 21 than there would be because of sterilization abuse if some lower minimum age were used in the final rules. The Department recognizes that such information may be difficult to provide, but to the extent available it would greatly inform the Department's exercise of its discretion. In the absence of systematic data, the Department will be forced to rely on anecdotal evidence and its own assessment of the risks and benefits of alternative policy choices. To be sure, however, the Department is also interested in receiving comments that reflect individual experiences and views with respect to these proposed rules. Finally, since the Department expects final rules to be applied administratively to programs in which the Department itself provides sterilizations as in the Indian Health Service, the Department solicits comments from people with an interest in those programs.

Among the issues as to which the Department seeks comments are:

1. The appropriateness of the definition of sterilization.

2. The appropriateness of excluding hysterectomy as a family planning technique.

3. The appropriateness of a 30-day waiting period.

4. The effectiveness of the consent procedures envisioned by the proposed rules.

5. The appropriateness of establishing 21 as the minimum age for Federally funded sterilizations.

6. The appropriateness of funding sterilizations of mental incompetents with the capacity to give informed consent.

7. The effectiveness of procedures in the proposed rules designed to ensure that mental incompetents are not sterilized without their informed consent.

8. The appropriateness of not financially participating in the sterilization of mental incompetents incapable of giving informed consent to be sterilized.

9. The appropriateness of extending special procedures to the sterilization of institutionalized people.

It is understood that this list of issues is by no means exhaustive, and the Department solicits comments of whatever nature on all aspects of these proposed rules.

2. SECTION-BY-SECTION ANALYSIS

Each section of the proposed rules is set out in this part of the Notice, followed by a brief discussion of its requirements. Generally, the text is set out as it will appear in both titles 42 and 45 of the Code of Federal Regulations, with the bracketed section numbers applicable to title 42. Where the text of the proposed rules differ, they are set out separately, with the title 45 rules appearing first.

§ 205.35–1 *Applicability.*

Text of proposed rule.

This section applies to programs administered under Titles I, IV–A, X, XIV, XVI, XIX, and XX of the Social Security Act.

§ 50.201 *Applicability.*

Text of proposed rule:

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

These paragraphs state the programs to which the proposed rules are applicable. It is anticipated that these rules will be made applicable by administrative directive to programs in which the Department directly provides sterilizations, as in the Indian Health Service.

§ 205.35–2 [§ 50.202] *Definitions.*

Text of proposed rule:

(a) "Sterilization" means any medical procedure or operation for the purpose of rendering an individual permanently incapable of reproducing.

The definition in the proposed rules makes no distinction between so-called "therapeutic" and "non-therapeutic" sterilizations. Any procedure performed for the purpose of rendering the patient permanently incapable of reproducing, regardless of whether the procedure is performed for medical reasons or for the convenience of the patient, will therefore be subject to the proposed rules. Thus, for example, a tubal ligation, whether performed because of concern that a pregnancy could endanger the health of the patient or because the patient did not wish to bear any more children would be subject to the procedures specified in the proposed rules.

The statutes authorizing Federal financial participation in sterilization nowhere distinguish between "therapeutic" and "non-therapeutic" sterilizations, and, as both the District Court and the Court of Appeals noted in the *Relf* case, it is unlikely that Congress intended that procedures designed to ensure informed consent would apply to one but not the other. *See Relf* v. *Weinberger*, No. 74–1797, slip. op. at 11 n.6 (D.C. Cir. September 13, 1977).

The Department thinks it unlikely, however, that Congress, by enacting legislation designed to promote family planning for convenience and other purposes, intended in doing so to impose identical procedural requirements on all medical procedures which have the effect of rendering a patient permanently incapable of reproducing. Some procedures ought not to be considered "sterilizations," even though sterility might result. Thus, for example, a removal of a cancerous uterus would not be deemed a sterilization, for it would not be performed for the purpose of rendering the patient incapable of reproducing, even though it would have that unavoidable effect.

The proposed rules do not define sterilization to include other forms of birth control, that is, procedures that render a person only temporarily incapable of reproducing.

Text of proposed rule:

(b) "Informed consent" (to a sterilization procedure) means a written authorization to be sterilized given by the person to be sterilized and given voluntarily and with an understanding of the nature and consequences of the procedure to be performed.

The definition of informed consent encompasses the two elements of voluntary action: (1) It must be knowing, that is the patient must fully understand the nature of the procedure and the significance of his/her action and (2) it must be entirely a product of the patient's free will. For purposes of these rules, informed consent must be given in writing in the manner specified by the rules.

Text of proposed rule:

(c) *"Consent form"* means a written document which states the requirements for informed consent as set forth in section 205.-35–3 [50.203].

Authorized consent forms must be used for giving informed consent under the proposed rules. Procedures for completing the consent forms are discussed elsewhere in this Notice.

Text of proposed rule:

(d)) "A mentally incompetent individual" means one who has been declared mentally incompetent by a Federal, State, or local court, or who is in fact mentally incompetent under Federal or State law.

This definition includes includes all people who have been adjudicated incompetent by Federal or State courts and those who are in fact incompetent under Federal or State law but who have never been so adjudicated.

Text of proposed rule:

(e) "A sterilization review committee" means a committee designated by the State Agency to review, approve, or deny applications for sterilization as required by this section. The committee must include a physician (other than the one proposing to perform the sterilization), attorney, social worker, and patient advocate.

And

50.202(e) "A sterilization review committee" means a committee designated by the program or project to review, approve, or deny applications for sterilization as required by this section. The committee must include a physician (other than the one proposing to perform the sterilization), attorney, social worker, and patient advocate.

Under one version of the proposed rules, sterilization review commitees would review applications for sterilizations by mentally incompetent patients and patients in institutions to determine their capability to give informed consent and whether they have in fact given their informed consent to be sterilized. Under another version, review commitees would review applications for sterilizations only by patients in institutions. The commitee would be composed of a physician, an attorney, a social worker, and another person who would advocate the patient's position. Because there is wide variation in conditions in various States with respect to such matters as the numbers and geographical dispersion of patients who, although mentally incompetent would nonetheless seek to be sterilized, and the presence of existing mechanisms to which a sterilization review committee could be appended, it is proposed to leave to the States, programs or projects the creation of mechanisms for the establishment and operation of such committees. In addition, procedures already required by State law may well be adequate to satisfy the review committee requirement. If at all possible, the Department does not desire to supplant or duplicate existing mechanisms.

The Department recognizes, however, that the nature and composition of sterilization review committees is a matter as to which there may be substantial variation of opinion. For this reason, the Department solicits comments on at least the following questions:

1. Is there a need for sterilization review committees, and if so, is the committee as envisioned by the proposed

2. Should the composition of the committee be in accordance with the formulation of the proposed rules?

3. Should final rules specify in greater detail the composition, responsibilities, and procedures for sterilization review committees? Specifically, should final rules specify such matters as the number of committees each State, program, or project must establish, their geographical location, whether they must be permanent or ad hoc bodies, and internal administrative procedures designed to ensure confidential treatment of patient records and effective liaison with State agencies and courts?

4. What State or local review committee procedures are now in effect, and how do they operate to prevent sterilization abuse?

5. Should the rule allow States, programs, or projects to utilize existing committee structures and procedures for the purpose of reviewing sterilization, subject to Departmental approval?

Text of proposed rule:

(f) "Hysterectomy" means a medical procedure or operation for the purpose of removing the uterus.

This item states the generally accepted medical definition of hysterectomy.

Text of proposed rule:

§ 50.202(g) The "Public Health Service" means the Health Services Administration, Health Resources Administration, National Institutes of Health, Center for Disease Control, Alcohol, Drug Abuse and Mental Health Administration, and all of their constituent agencies.

§ 50.202(h) The "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.

These definitions are self-explanatory.

§ 205.35–3. [§ 50.203] *Consent Procedures.*

Text of proposed rule:

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this paragraph.

This sentence states the general rule that for the purposes of these rules a person will not be deemed to have given his/her informed consent to be sterilized unless a consent form is completed in accordance with all the requirements of this section.

Text of proposed rule:

(a) *Preparing to Obtain Informed Consent.* An individual who obtains informed consent for a sterilization procedure must provide orally *all* of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw his/her consent to the procedure at any time prior to the sterilization without affecting his/her right to future care or treatment, and without loss or withdrawal of any Federally-funded program benefits to which the individual might be otherwise entitled;

(2) A description of available alternative methods of family planning and birth control;

(3) A full description of the benefits or advantages he/she may expect to gain as a result of the sterilization;

(4) Advice that the sterilization procedure is considered to be irreversible;

(5) A thorough explanation of the specific sterilization procedure to be performed;

(6) A full description of the discomforts and risks which may accompany and follow the performing of the procedure including an explanation of the type and possible effects of any anesthetic to be used;

(7) Advice that the sterilization will not be performed for at least 30 days; and

(8) An opportunity to ask and have answered any questions he/she may have concerning the sterilization procedure.

This item explains the information that a prospective patient must have for his/her assent to be sterilized to be deemed "informed". This provision, however, in no way limits the information that should be given to a patient seeking sterilization if in the judgment of the physician or the person who obtains the patient's consent form more information should be provided.

The patient's consent should be secured under circumstances free of pressure or coercion. Generally, a patient's consent should not be secured while the patient is in labor, during or immediately following delivery, or in conjunction with an abortion.

Although the patient will be provided much of the information in writing, the proposed rules require all information also to be given orally. Both the District Court in the *Relf* case and a recent report by the General Accounting Office concerning sterilization practices in the Indian Health Service concluded that essential information must be communicated orally, especially for people of limited literacy.

Foremost among the information that must be provided is the advice that a patient is free not to be sterilized. The patient must be advised that he/she is free not to consent or to withdraw consent previously given, and that a refusal to be sterilized will not result in the withdrawal of any Federally-funded program benefit, nor will such a refusal affect the patient's right to future care or treatment (including sterilization). It is expected that this advice will be communicated at the outset of any discussion of sterilization with a prospective patient.

The patient must be given all the important facts about sterilization. He/she must be told that sterilization is different from all other forms of birth control because it is irreversible. The patient must be told about both the advantages and disadvantages of sterilization, and about the nature and availability of alternative forms of birth control. Birth control information should include methods available to both the patient and his/her partner.

The patient must also be told of the nature of the surgical procedure that is proposed. This advice must contain a thorough explanation of the procedure and a full description of its discomforts and risks, particularly as compared to other sterilization procedures. The patient also should be adivsed about discomforts and risks that relate to the particular anesthetic to be used.

The patient should also be told that the sterilization will not be performed for at least 30 days, and that he/she may withdraw his/her consent at any time prior to the sterilization.

Finally, the patient must be offered an opportunity to ask and have answered any questions concerning the proposed sterilization.

The Department solicits comments concerning the necessity of providing patients with the foregoing information and as to what additional information, if any, should also be provided.

(b) *Filling out the consent form.*

The items in this paragraph are designed to ensure that the information required by the preceding paragraph is in fact communicated to the patient and that the patient's consent is in fact voluntary.

Text of proposed rule:

(1) *Language of the consent form.* The consent form should be in the primary language of the patient. If the consent form is not in the primary language of the patient, an interpreter must be made available to assist the individual.

Text of proposed rule:

(2) *Provisions for the handicapped.* Suitable arrangements must be made to ensure that consent information is effectively communicated to blind, deaf, and other handicapped patients.

These two items are designed to ensure that information necessary for informed consent is communicated to those whose primary language is other than English and to handicapped people. Where possible, the consent form should be in the primary language of the patient; if this is not possible, an interpreter must be made available. If the patient is blind, the consent form should be read to him/her, and similar arrangements must be made to ensure effective communication of consent material to deaf patients and to patients with other handicaps.

(3) *Signatures on the consent form.* The consent form must be signed and dated by:

(i) The patient; and

(ii) The interpreter, if one is provided; and

(iii) The individual who obtains the consent of the patient; and

(iv) The physician who will perform the sterilization procedure.

(4) *Required certifications.* (i) The person securing the patient's consent must certify by signing the consent form that, before the patient signed the consent form, he/she advised that patient had no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the elements of informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(ii) The physician performing the sterilization must certify by signing the consent form that, immediately prior to the performance of the sterilization, he/she advised the patient that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the elements of informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized. The physician will further certify that, to the best of his/her knowledge and belief, at least 30 days passed from the date upon which the patient signed the consent form until the date upon which the sterilization was performed.

(iii) The physician performing the sterilization must, in cases where court orders are required by this section, certify, by signing the consent form, that he/she was provided with a copy of the court order prior to the performance of the sterilization.

The proposed rules would require various signatures on the consent form to provide evidence that the requirements of the rules have been met. The patient's signature would be his/her expression of informed consent, and the interpreter's signature evidence that he/she had provided assistance to a patient whose primary language was not in English.

The proposed rules would also require the signature of the person who obtains the patient's consent, for example, a social worker in a family planning clinic or a physician's assistant. This person often plays a critical role in explaining sterilization to prospective patients, and the proposed rules would require him/her, by signing the consent form, to certify that he/she communicated the information necessary for a patient to give informed consent. The proposed rules

would allow the attending physican to obtain the patient's consent.

A person obtaining the patient's consent must attest to whether, to the best of his/her knowledge and belief, the patient in fact gave his/her informed consent to be sterilized. The person obtaining consent must also certify as to the patient's *appearance* of mental competence. It is not the intention of the proposed rules to place upon people obtaining consent the duty of conducting an independent inquiry into the mental competence of prospective patients seeking sterilization. Neither, however, is it the intention of the proposed rules to permit those obtaining consent to ignore clear evidence of a patient's mental incapacity.

Where a person obtaining the patient's consent is unable to make a required certification, under one version of the proposed rules the sterilization may not go forward. Under an alternative, where the sole issue is the patient's mental competence, the sterilization may go forward only if the requirements in section 205.35–5 (50.205), relating to sterilizations of mental incompetents, have been followed.

The proposed rules do not require an auditor/witness to be present or to sign the consent form. The Department believes that while a patient should be able to have another person present during counseling and consent sessions, respect for the patient's privacy dictates that the presence of a witness not be mandated.

Certification obligations would also be imposed upon physicians performing sterilizations, for physicians have a nondelegable responsibility to ensure that they perform sterilizations only upon patients who have given their informed consent. Consequently, physicians would be required to certify that, immediately prior to the performance of the sterilization, they orally communicated the information necessary for a patient to give informed consent and to certify further that the patient in fact gave informed consent. As with people obtaining patients' consent, physicians would be required to certify as to the patient's *appearance* of mental competence. The phyisican also would be required to certify that to the best of his/her knowledge and belief the required waiting period passed before the sterilization was performed. Ordinarily this last requirement would be satisfied by the physician noting that the sterilization was to be performed more than 30 days after the date appearing next to the patient's signature on the consent form. The required waiting period is discussed elsewhere in this Notice.

In cases where the sterilization is performed upon a person whom a court determined had given informed consent, the physician would be required to certify that he/she received a copy of the court's order prior to the sterilization. Among other purposes, this provision is designed to protect physicians from liability for performing unauthorized sterilizations.

Text of proposed rule:

(c) *Following State and local procedures.* In addition to the consent procedures required by this part, any requirement of State or local law, except one of spousal consent, must be followed.

This provision embodies the policy of the proposed rules not to supplant more stringent State and local requirements. Less stringent State and local requirements will of course be complied with through compliance with the proposed rules. Spousal consent requirements are excepted because of their almost certain unconstitutionality in light of *Planned Parenthood of Central Missouri* v. *Danforth*, 428 U.S. 52 (1976).

The Department is not certain about the extent to which existing State and local laws with respect to sterilization have the effect of denying access to sterilizations to those who would otherwise be eligible for them under these rules. Comments are solicited on the question as to the extent to which final rules should supplant State and local requirements.

§ 205.35–4 *Sterilization of a mentally competent individual aged 21 or older.*

Text of proposed rule:

Federal financial participation is available in expenditures for a sterilization of a mentally competent individual only when the following requirements have been met:

(a) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in section 205.35–3.

(b) At least 30 days have passed between the date of informed consent and the date of the sterilization.

(c) The individual is at least 21 years old.

and

§ 50.204 *Sterilization of a mental competent individual aged 21 or older.*

Text of proposed rule:

Programs or projects to which this subpart applies shall perform or arrange for the performance of a sterilization of a mental competent individual only when the following requirements have been met:

(a) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in section 50.203.

(b) At least 30 days have passed between the date of informed consent and the date of the sterilization.

(c) The individual is at least 21 years old.

These provisions set out the basic requirements for the vast majority of sterilizations in which Federal financial participation would be available under the proposed rules. The individual must have given his/her informed consent; at least 30 days must have elapsed between the date of informed consent and the date of the sterilization; and the patent must be at least 21 years old.

The requirements for informed consent have already been discussed in this Notice.

The 30-day Waiting Period. The Department is aware that there is substantial controversy over the length of time that should be required between rendition of informed consent and the sterilization operation. Some may argue that any "consent" obtained while a woman is hospitalized for childbirth or an abortion is necessarily involuntary. It may be asserted, in addition, that under any circumstances a hospital environment may be alien and frightening to patients and is therefore inherently coercive. The Department believes that any waiting period should be sufficient to remove the patient from the extreme emotional stress often associated with the latter stages of pregnancy as well as labor and delivery. Regardless of where informed consent is given, any waiting period also must be of sufficient duration to permit reflection and discussion with family and friends concerning this irreversible surgical procedure.

On the other hand, too long a waiting period might impose substantial inconvenience and additional expense if it is of sufficient duration as to require two hospitalizations. It may also be asserted that many women are reluctant to seek medical care and will not seek to be sterilized unless they can both choose and obtain sterilization incident to childbirth.

The Department has weighed these competing considerations, and its current thinking is that 30 days is the minimum period for necessary consultation and reflection. A waiting period of this duration, while sufficient to ensure that a decision to be sterilized is not made and effectuated during hospitalization for abortion or childbirth, will not necessarily result in multiple hospitalizations, since informed consent for sterilization can be obtained during pre-natal care or otherwise well in advance of delivery.

The Department has also considered proposing different waiting periods keyed to the type of sterilization and the place where it is to be performed, with different waiting periods for outpatient facilities and hospitals. Similarly, proposed rules could conceivably allow for waiver of the waiting period in exceptional circumstances, for example where a sterilization is arranged for over 30 days in advance of anticipated delivery date but there is a premature delivery. These alternatives may be in theory quite sound, but the Department is skeptical about their enforceability and concerned about the possibilities for abuse.

The Department does not consider a waiting period of less than 30 days as *necessarily* coercive; similarly, it understands that the failure of the proposed rules to provide for waivers or to differentiate between sterilization procedures and the environments in which they may be performed might result in individual cases of inconvenience and hardship. These factors are more than counterbalanced, however, in the Department's current view, by the need to ensure adequate time for reflection and consultation in an environment free from coercion. The Department is reluctant to introduce different standards based on factual circumstances that are not readily identifiable and verifiable on

a sample, audit basis. Consequently, differential waiting periods and waivers of waiting periods have been considered and rejected.

As with other issues with respect to sterilizations, reasonable people may hold strongly conflicting views. The Department therefore solicits the comments of interested parties on the issue of the waiting period, particularly with respect to the following questions:

1. What are the purposes of a waiting period?
2. What length of time is sufficient to accomplish those purposes?
3. What are the detriments of a lengthy waiting period?
4. What are the advantages or disadvantages of including waiting periods of varying duration depending on the type of sterilization procedure and the facility where performed (clinic or hospital)?
5. What are the advantages or disadvantages of permitting waivers of the waiting period in exceptional circumstances?
6. Can rules including waiting periods of varying duration be enforced, or would the result primarily be more instances of of abuse?

The Minimum Age of 21. As discussed above, the statutes themselves present an inevitable tension between two competing interests: assuring maximum availability of family planning services and at the same time assuring that those services are offered on a purely voluntary basis, free of coercion or pressure. To achieve a balanced accommodation between these two purposes, the regulations establish a Federal standard of voluntariness.

The United States Court of Appeals for the District of Columbia Circuit in its September 13, 1977 decision in *Relf* v. *Weinberger* recognized the Secretary's authority to set a uniform Federal standard:

> Where federal funds are authorized by Congress to be expended for sterilizations which are voluntary in nature, the question of what constitutes voluntariness in this context would appear to be one of federal law. In formulating standards for this purpose, it is surely true that state legal requirements cannot be controlling by their own force. A federal standard may still of course, to the extent the federal agency devising the standard finds wise or helpful, take note of state law and utilize available state legal mechanisms in designing and effectuating the federal standard. But how a federal statute is to be implemented remains a matter as to which federal law is supreme, and the agency charged by Congress with implementation is not bound to shape its concept of voluntariness to the contours of state law. *See generally* Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52 (1976); Wyatt v. Aderholt, 368 F. Supp. 1383, 1384 (M.D. Ala. 1974). *Relf* v. *Weinberger*, No. 74–1797 (D.C. Cir. September 13, 1977), slip. op. at 10 n.3.

Similar conclusions were reached recently by two Federal District Courts in decisions upholding the moratorium on Federal funding of sterilizations for those under 21 years old. *See Peck* v. *Califano*, U.S.D.C. D. Utah, Civil Action No. C 76–229 (June 30, 1977), and *Voe* v. *Califano*, U.S.D.C. Conn., Civil Action No. N–77–195 (July 14, 1977).

Given the Department's authority to establish uniform standards of voluntariness, three questions are raised with respect to age. First, should determinations of capacity with respect to age be made on a State-by-State or case-by-case basis, or should generally applicable standards be set? Second, if a minimum age is set, what should it be? Third, should Federal financial participation ever be available in sterilizations of people below the minimum age?

With respect to the first question, determinations of legal capacity to give informed consent made solely under State law would produce the anomalous result of the Department withholding funds for the sterilization of a 20-year-old in one State, while funding sterilizations of younger people in others. According conclusive effect to State law would also necessitate the extremely difficult determination of the age of consent for purposes of sterilization under varying State laws, some of which confer the status associated with the age of majority upon so-called emancipated minors or upon minors who have contracted a legal marriage, others of which confer competence for different purposes at a variety of ages. Moreover, it would be costly and perhaps impractical for the Department to mandate case-by-case inquiries into the maturity and judgment of prospective patients. Consequently, the Department believes that it has no alternative but to engage in line-drawing and set a single uniform standard, recognizing the inevitability that gross distinctions do not always adequately reflect differences of maturity and judgment.

A single standard necessarily divides persons who seek sterilizations into two groups: those over the the minimum age, for whom funds are made available; and those below it, for whom funds are withheld. This age classification is not, however, unconstitutional. The District Courts in *Voe* and *Peck*, discussed above, sustained against constitutional challenge the Department's current bar on funding sterilizations for individuals who are under age 21 or mentally incompetent. In doing so the courts relied heavily upon the Supreme Court's recent decision in *Maher* v. *Roe*, 45 U.S.L.W. 4787 (U.S. June 20, 1977), which held in essence that since the Constitution does not mandate the funding of medical care, governmental limitations on provision of such care must be upheld if they bear a rational relationship to a permissible legislative purpose. Thus, as in *Maher*, the proposed rules are not subject to the holding of *Roe* v. *Wade*, 410 U.S. 113 (1973), that the Constitution forbids the government to prevent or penalize the exercise of the right to procreative privacy. The age limitation does not interfere with an individual's decision whether to bear or beget a child, but merely withholds Federal funding of one particular means of effectuating the decision not to bear or beget a child.

Assuming the validity of a uniform minimum age, the second question, as to what is the appropriate minimum age, is one as to which reasonable people may have strongly disparate views. There is general agreement that at some age an individual is so immature and his/her judgment so uninformed that it is reasonable to presume that he/she is incapable of giving informed consent, and that therefore his/her assent to be sterilized cannot be said to be "voluntary" within the meaning of the family planning statutes. Moreover, minors have in the past been subject to sterilization abuse, although there may be some disagreement as to how widespread these abuses have been.

But beyond these general principles, there remains strong disagreement on the question as to where the line should be drawn. The Department is aware of the competing considerations: if the minimum is too high people needing sterilizations who might be able to give their informed consent will not be able to get them; but if the minimum age is too low, people without sufficient maturity or judgment to resist coercion may be forced into sterilizations they do not want. Resolving these tensions has proven to be quite difficult and vexing. Much of the evidence of hardship due to unavailability of sterilizations and hardship due to sterilization abuse is extremely compelling. But it is also only anecdotal. In the absence of substantial and systematic evidence as to where the balance of hardship lies, the Department is proposing 21 as the minimum age, recognizing the imperfection of any age chosen, in the belief that there is reason to be concerned whether people under that age generally have the judgment, experience and maturity to make voluntary decisions to be sterilized.

The third question is whether the proposed rules should provide for sterilization of people below the minimum age under extraordinary circumstances, and if so, what should those circumstances be? Although recognizing that severe hardships can befall a person under 21 who cannot use other forms of birth control if sterilization is unavailable, the Department is proposing that Federally-funded sterilizations not be available, under any circumstances, to people under 21.

There is serious question, given the presumption of lack of capacity on the part of a person under 21 to consent to be sterilized, whether the Department has the legal authority to fund any sterilizations of people below that age, since the family planning statutes require that the receipt of sterilization services be "voluntary." The issue is not free from doubt, since the doctrine of substituted consent, in which parents or guardians are empowered to make decisions on behalf of those incapable of doing so themselves, has been occasionally accepted with respect to other critical decisions. Equally important is that any exception would be difficult to monitor and could create substantial possibilities of abuse. Without evidence

of widespread compelling need, and without reason to believe that substantial incidents of abuse would not occur, the Department is reluctant to participate financially in the sterilization of people under 21.

The Department is eager to receive comments on the question of minimum age. It would be helpful if the comments could address themselves to the following issues, among others:

1. What is the evidence of sterilization abuse of people under 21 (or 18)?
2. Is there evidence that substantial numbers of people under 21 (or 18) have been denied necessary sterilization services under the current moratorium?
3. What form does sterilization abuse of people under 21 (or 18) take?
4. What are the circumstances under which it might be appropriate to fund sterilizations of people below the minimum age specified in the proposed rules? How could such exceptions be monitored to avoid abuse?

205.35–5 *Sterilization of a Mentally Incompetent Individual Aged 21 or Older; Sterilization of an Institutionalized Individual Aged 21 or Older*

Text of proposed rule:

(a) Federal financial participation is unavailable in expenditures for a sterilization of a person who has been declared mentally incompetent by a Federal, State, or local court, or who is in fact mentally incompetent under Federal or State law.

(b) Federal financial participation is unavailable in expenditures for a sterilization of any individual institutionalized in a correctional, or mental or other facility *unless*:

(1) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in section 205.35–3;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205. 35–3(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a), and that the patient has voluntarily consented to be sterilized.

or

(a) Federal financial participation is unavailable in expenditures for a sterilization of a mentally incompetent individual, or any individual institutionalized in a correctional, mental or other facility *unless:*

(1) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in section 205.35–3;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a), and that the patient has voluntarily consented to be sterilized.

(b) Federal financial participation is unavailable in expenditures for the sterilization of a mentally incompetent individual who does not understand the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a).

and

§ 50.205 *Sterilization of a mentally incompetent individual aged 21 or older; sterilization of an institutionalized individual aged 21 or older*

Text of proposed rule:

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any person declared mentally incompetent by a State, Federal or local court, or who is in fact mentally incompetent under Federal or State law.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any individual institutionalized in a correctional, mental or other facility unless:

(1) The individual has voluntarily given his/her informed consent in accordance with the procedure prescribed in section 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure, as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized.

or

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of a mentally incompetent individual or any individual institutionalized in a correctional, mental or other facility *unless:*

(1) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in section 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure, as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of a mentally incompetent individual who does not understand the nature and consequences of the proposed sterilization procedure as set forth in section 50.203(a).

These provisions embody two alternative responses to the issue of suitability of funding sterilization for two groups of people particularly vulnerable to sterilization abuse—mentally incompetent people and people in mental, correctional or other institutions.

Mental Incompetents. Two alternative formulations are proposed with respect to people who are mentally incompetent under Federal or State law. Under the first version, Federal funds would not be available for the sterilization of any person declared incompetent by a Federal, State, or local court, or incompetent in fact under Federal or local law. This is the Department's current policy, embodied in the moratorium in effect since 1973, on the funding of sterilization of mental incompetents.

The advantages of the moratorium have been its relative simplicity, consequent ease of application and its apparent prevention of substantial sterilization abuse of mentally incompetent people. Further, the Department has not been made aware of significant hardships traceable to the moratorium.

The current moratorium, however, has some serious disadvantages. It is possible that the moratorium results in substantial unnecessary suffering by denying access to sterilizations by people who want them and who—regardless of label imposed upon them by a finding of incompetence—are fully capable of understanding the nature and consequences of and voluntarily consenting to a sterilization. Indeed people may be adjudicated incompetent for limited purposes only, such as the conduct of financial affairs, and yet are fully capable of rendering informed and voluntary consent to be sterilized. In addition, continuing the absolute bar to the funding for sterilization of persons incompetent in fact but not so adjudicated leaves the physician

in an impossible dilemma and without any avenues of redress. Being uncertain as to the patient's competence, and without access to a review committee and court hearing, the physician will decline to sterilize the patient. It may be that the moratorium thereby has the unintended effect of denying sterilizations to people who would not be adjudicated incompetent but whom physicians are reluctant to sterilize because of possible liability.

The Department stresses that it does not have adequate data on the numbers of mentally incompetent people who desire and are capable of consenting to sterilizations. Should comments uncover evidence of substantial desire for sterilizations among the mentally incompetent capable of consent, a system of safeguards would need to be constructed to avoid creating a serious potential for sterilization abuse. The second alternative proposed in these rules is intended to construct such a system.

The Department seeks to avoid any coerced sterilizations of the mentally incompetent. Because mental incompetents are presumptively incapable of informed consent, the procedures under this alternative are directed to the end of assuring that assent to sterilization is indeed voluntary and informed. The Department intends to re-evaluate this section in light of the comments received to determine whether these—or any procedures will be adequate to forestall coerced sterilizations.

As with respect to setting minimum ages, the Department, in interpreting the Federal statutory standard of voluntariness, has the legal authority to administer a single, uniform standard of mental competence. See *Relf* v. *Mathews*, supra.

The fact that a patient has been adjudicated incompetent under State law would not settle the issue of Federal law as to whether the patient had voluntarily consented to be sterilized. If the Department decides to fund sterilization of mentally incompetent patients it would do so only if the patient "understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a)" and had given informed consent in accordance with the proposed rules. This standard by necessity calls for case-by-case determination.

Under this alternative regulation, persons adjudicated incompetent or incompetent in fact would be eligible for Federally funded sterilizations if they are capable of rendering informed and voluntary consent to be sterilized. Thus, for example, a patient as to whom a physician had any serious question as to his/her mental competence could be sterilized in accordance with the procedures mandated by this subsection.

Mental incompetents seeking to be sterilized would first give their informed consent to a proposed sterilization in the manner prescribed in section 205.35–3 [50.203] As with all other sterilizations—and for the same reasons—no federally funded sterilization could go forward before the expiration of 30 days after informed consent had been given, and no federally funded sterilization could be performed on a patient less than 21 years old.

Following the initial steps, the proposed sterilization would be presented to the sterilization review committee described earlier in this Notice. As previously indicated, the Department currently intends to leave the method of convening and the procedures for operating sterilization review committees to the States, programs, or projects. Existing procedures under State law may also be adequate to satisfy the review committee requirement. The rules do, however, require the presence of a physician, (other than the one proposing to perform the sterilization) lawyer, social worker and patient advocate.

The sole inquiry for the sterilization review committee would be whether the patient had the capacity to give and had in fact given his/her informed consent; it would not be empowered to consider the wisdom of the patient's choice. If informed consent had indeed been given, the committee would not be empowered to override the patient's choice on the basis of his/her "best interests." The committee would likewise not be empowered under these rules to consider whether sterilization would be in the "best interest" of one who could not understand the nature and consequences of the proposed sterilization.

The patient, as the proponent of the sterilization, would be required to demonstrate to the review committee that all the requirements for informed consent had been met, that he/she understood the nature and consequences of the proposed sterilization, and voluntarily consented to be sterilized. This inquiry subdivides into two parts: The question of patient's capacity to understand and appreciate the information given to him/her as part of the consent process, and the question whether the patient had in fact voluntarily given informed consent in the manner prescribed by these rules. The proposed rules specify the "nature and consequences" that the patient must understand; they are those delineated by section 205.35–3(a) as the minimum information the patient must receive if his/her consent can be said to be "informed."

The Department believes that, in addition to the patient advocate, legal counsel is necessary to protect the patient's rights. Since the inquiry is by definition into the patient's capacity, however, and circumstances will vary, it is difficult to predict whether the attorney would be acting in the best interests of his/her client in arguing for or against the proposed sterilization. Because of this unpredictability the Department believes that counsel would be most helpful to the patient and the review committee by marshalling and presenting the evidence both for and against the proposed findings.

If a sterilization review committee does not make the findings that would be required under the proposed rules, the sterilization could not be federally funded. Where the committee makes the required findings, the matter would then be presented to a court for its de novo consideration.

The proposed rules envision a rather limited role for courts to which petitions from review committees would be presented. The sole issue before the court would be whether the patient had the capacity to and did give informed consent to be sterilized. The proposed rules could not and would not requrie or empower courts to order federally funded sterilizations, so there is no reason for State courts to fear liability for ordering sterilizations. *Cf. Spartman* v. *McFarlin*, 522 F.2d 172 (7th Cir.), cert. granted, ____ U.S. ____ (1977).

A related issue is whether State courts would in fact assert jurisdiction over petitions from sterilization review committees. The Department, of course, has no power to create jurisdiction in State courts, and State courts may not exercise jurisdiction they do not have. However, since determinations of incompetence and commitment to institutions are often made by courts, it is believed that State courts have jurisdiction over the incompetent and institutionalized individuals to empower inquiry into the presence of informed consent for a sterilization.

Proceedings before courts reviewing petitions from sterilization review committees would be the same as those earlier described with respect to review committees. Thus, the proponent of the sterilization would bear the burden of proof, and the patient and the court would be assisted by counsel presenting the evidence for and against the required findings.

As with other strelization issues, the Department understands that there may be divergent views on the proper treatment of mental incompetents. Comments are therefore solicited, particularly with respect to the following issues:

1. Should the Department fund sterilizations of people who are mentally incompetent under State law? Under what circumstances?

2. Should the class of those requiring special protection be more broadly defined to include those, who although not incompetent, are mentally impaired? How would this group be described?

3. What have been the effects of the current moratorium upon people who would be eligible for sterilization under this section of the proposed rules?

4. What reason is there to believe that funding sterilizations of mental incompetents under any circumstances would result in sterilization abuse?

5. What reason is there to believe that the procedures required by this subsection of the proposed rules will be adequate to prevent coerced sterilizations or sterilizations of those unable to give informed consent? Would other procedures, such as resort to the American Arbitration Association, be more effective?

The mentally incompetent without the capacity to give informed consent. Under

either proposed version of the rules with respect to the funding of sterilization of the mentally incompetent, no funds would be available for sterilization of people who lack the mental capacity to give informed consent. This is the Department's current position on this issue. For purposes of these rules, people who cannot understand the nature and consequences of a proposed sterilization—that is, the minimum information set out in section 205.35–3(a) that must be understood for consent to be deemed "informed"—are considered to lack the mental capacity to consent to a sterilization. There are classes of people so profoundly retarded as to be unable to utilize temporary forms of contraception and for whom the bearing or begetting of a child may bring only confusion, fear, or indifference. The profoundly retarded may be totally incapable of caring responsibly for their children, many of whom may be profoundly retarded themselves. Instead, the burden may be shifted to parents, guardians or other custodians, perhaps raising burdens to intolerable limits and increasing the pressures for institutionalization of people who might be otherwise better served in non-custodial environments. In short, there is a class of people whose continued fertility may be against their best interests and that of society.

There are, however, compelling countervailing considerations. Although the issue is not free from doubt, there is serious question whether the Department has the legal authority to fund sterilizations for people who lack the mental capacity themselves to satisfy the statutory standard of voluntariness. Even assuming the validity of the doctrine of substituted consent in this context, the statutes give no guidance as to the circumstances under which a guardian could request sterilization in the patient's name. Without explicit congressional guidance in this sensitive and troubling area, the Department is reluctant to conjecture as to the circumstances under which Congress intended the Department to fund sterilizations of those without the mental capacity to give their informed consent.

In addition, there is reason to fear that any exception for sterilization of the profoundly retarded would create myrid possibilities for sterilization abuse. The Department wishes to avoid wholesale sterilization of mental incompetents for the convenience of their guardians and custodians, and fears that any exception to a ban on Federal financial participation in the sterilization of the profoundly retarded would prove extremely difficult to police. Finally, as previously discussed, there have been few reports of hardships occasioned by the present moratorium on payment for sterilization of mental incompetents.

These issues are deeply troubling, and the Department welcomes the comments of interested parties. Comments may be directed to the following issues, among others:

1. What is the Department's legal authority to fund sterilizations of people who lack the mental capacity to give informed consent?

2. Has the present moratorium on federally funded sterilizations of mental incompetents produced severe hardships? Of what nature?

3. If the Department were to fund sterilizations of the profoundly retarded, under what circumstances should it do so?

4. Would funding sterilizations of the profoundly retarded under exceptional circumstances inevitably lead to substantial sterilization abuse?

People in institutions. Under both proposed versions of this part of the rules, special procedural protections would be required for the sterilization of people in mental, correctional or other institutions. Although the Department is uncertain as to the number of institutionalized people seeking sterilizations, is is imperative that this group, no matter how small, be accorded special protections to counteract the enhanced opportunities for coercion inherent in a custodial environment.

The procedures proposed are the same as those proposed for mental incompetents, and they are directed towards the same goal—determining whether the patient has in fact given informed consent to a proposed sterilization. The Department believes that these procedures, described earlier in this Notice, are generally properly tailored to protect people in institutions.

One possible exception concerns the role of counsel for the institutionalized patient at committee and court proceedings. Since, unlike the situation with respect to mental incompetents, the inquiry would not be focused primarily on the issue of the patient's mental capacity, there is little reason to fear that an attorney supporting his client's request for a sterilization will not be acting for his client. But there may be some benefit, as a check upon abuse, in having an attorney present evidence against a finding that the patient in fact consented to be sterilized. For this reason, the Department has proposed that counsel for the institutionalized patient at committee and court proceedings present evidence for and against the requisite findings.

The Department solicits comments on the proper treatment of proposed sterilizations of people in institutions, including comments directed at the following issues:

1. What is the evidence of sterilization abuse of people in institutions?

2. Are identical procedures necessary or appropriate to protect the interests of mentally incompetent people and people in institutions?

3. What should be the role of counsel, if any, at committee and court proceedings?

§ 205.35–6 *Sterilization of a mentally competent or incompetent individual under the age of 21.*

Text of proposed rule:

Federal financial participation is unavailable in expenditures in the sterilization of individuals under 21 years old.

and

§ 50.206 *Sterilization of a mentally competent or incompetent individual under the age of 21.*

Text of proposed rule:

Programs or projects to which this subpart applies shall not perform or arrange for the performance of sterilizations of individuals under 21 years old.

These sections state the absolute rule, for the reasons discussed earlier in this Notice, that Federal financial participation would be unavailable in the sterilization of individuals under 21 years old.

§ 205.35–7 *Sterilization by hysterectomy.*

Text of proposed rule.

Federal financial assistance for family planning purposes is unavailable for participation in any hysterectomy performed for the purpose of rendering an individual permanently incapable of reproducing, unless [exception, with appropriate safeguards, to be added if comments describe circumstances in which sterilization by hysterectomy is generally accepted as the appropriate method].

and

§ 50.207 *Sterilization by hysterectomy.*

Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy for the purpose of rendering an individual permanently incapable of reproducing, unless [exception, with appropriate safeguards, to be added if comments describe circumstances in which sterilization by hysterectomy is generally accepted as the appropriate method].

The statutes under which the proposed rules are being issued authorize the expenditure of Federal funds for "family planning" services. In enacting these statutes, Congress clearly imposed upon the Department the responsibility to determine what services fall within the statutory authorization. For example, section 1001(a) of the Public Health Service Act, 42 U.S.C. 300(a), authorizes the Secretary to arrange for the provision only of "acceptable and effective" family planning methods. The Department believes that it has no less of a responsibility to fund only "acceptable and effective" family planning methods under its other programs; indeed, section 1903(a)(5) of the Social Security Act, 42 U.S.C. 1396b(a)(5), imposes this same duty upon the Department in the Medicaid program by providing for a special rate for Federal matching of State family planning expenditures.

There is virtual unanimity within the medical profession that hysterectomy, in the adsence of other clinical indications, is not an appropriate or even acceptable

means of sterilization. It is widely accepted that hysterectomy is a much more dangerous form of female sterilization than the various types of tubal ligations. One study, for example, concluded that "the complication rate of simple vaginal hysterectomy was 10 to 20 times higher than the complication rate of tubal sterilization procedures." L. Hibbard, Sexual Sterilization by Elective Hysterectomy, 112 Am. J. Obstet. Gynecol. 311, 317 (1972). It is believed that a comparison of mortality rates would be similarly striking.

Hysterectomies are also many times more expensive than other female sterilization procedures. A tubal ligation can be performed usually within a one-day hospital stay, and in some cases on an outpatient basis. In contrast, hysterectomy is a more drastic surgical procedure, often requiring hospitalization for as much as 5 to 7 days.

Because of these considerations, hysterectomy is virtually universally decried when used for sterilization purposes alone. The American College of Obstetricians and Gynecologists, for example, takes the position that whenever a hysterectomy is performed solely for sterilization purposes, the case automatically should be referred to a physician's committee for peer review. *See* ACOG, Model Screening Criteria, 18 (1977). Other authorities have concluded that hysterectomy is not a valid sterilization technique. *See, e.g.*, Dyck, F. Murphy & J. Murphy et al. Effect of Surveillance on the Number of Hysterectomies in the Province of Saskatchewan, 296 N.E.J. Med. 1326, 1328 (1977); Testimony of Kenneth J. Ryan, M.D., Chairman, Department of Obstetrics and Gynecology, Harvard University School of Medicine, in Hearings on Important Cost and Quality Issues of Health Care Before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, 95th Cong., 1st Sess. at 350 (1977).

On the basis of these authorities, and in the belief that they represent the overwhelming preponderance of opinion in the medical profession, the Department is proposing not to fund sterilizations by hysterectomy. In spite of this apparent unanimity, however, the proposed rules have been written so as to provide for Federal financial participation in hysterectomies for family planning purposes under exceptional circumstances, of which the Department is presently unaware, in which sterilization by hysterectomy would be medically appropriate, should any such circumstances be described in public comments received by the Department. If such an exception is added to this provision, the Department will have to consider possible safeguards to protect against abuse. Such safeguards might include additional documentation requirements or a required consultation with an additional physician. In any event, sterilizations by hysterectomy for which there might be non-family planning justifications could still be Federally funded if they meet the criteria of other provisions authorizing funding for medical assistance.

The Department solicits comments on the appropriateness of sterilizations by hysterectomy, including comments directed at the following issues:

1. Are there any circumstances under which performing a hysterectomy for sterilization purposes is generally accepted as appropriate?

2. Should any other mechanism, for example requiring additional documentation or second physician consultations, be utilized to deal with the question of sterilization hysterectomies?

Text of proposed rule:

(b) Federal financial participation is available in a hysterectomy the purpose of which is other than to render the patient permanently incapable of reproducing, provided that:

(1) The individual who secures the usual authorization from the patient or her representative, if any, to perform the hysterectomy has informed the patient and her representative, if any, orally and in writing, that the hysterectomy will render the patient permanently incapable of reproducing; and

(2) The patient or her representative, if any, has signed a written acknowledgment of receipt of the foregoing information.

and

(b) Programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy the purpose of which is other than to render the patient permanently incapable of reproducing, provided that:

(1) The individual who secures the usual authorization from the patient or her representative, if any, to perform the hysterectomy has informed the patient and her representative, if any, orally and in writing, that the hysterectomy will render the patient permanently incapable of reproducing; and

(2) The patient or her representative, if any, has signed a written acknowledgment of receipt of the foregoing information.

Even though hysterectomy is not acknowledged as an acceptable family planning technique, it undeniably always has the effect of rendering a patient permanently incapable of reproducing. The Department wishes to ensure that patients fully understand the family planning consequences of hysterectomies.

To accomplish this end, the proposed rules require that whenever a Federally-funded hysterectomy is performed, the person securing the patient's authorization for the surgery (or, where applicable, the authorization of the patient's representative) inform the patient and her representative that the hysterectomy will render the patient permanently incapable of reproducing. To ensure compliance with this provision, the proposed rules further require the patient or her representative to acknowledge, in writing, receipt of the information that the hysterectomy will render the patient permanently incapable of reproducing.

It should be noted that this provision imposes no requirements as to the circumstances under which authorization for a hysterectomy must be obtained or the people from whom it must be obtained. The Department at present does not have reason to believe that authorization for hysterectomies, like all other purely medical procedures, is not routinely and properly obtained. The proposed rules, therefore, would require the provision and acknowledgment of receipt of the requisite information only on the same basis and under the same circumstances as upon which authorization is already being obtained.

Comments are solicited with respect to this provision, particularly with respect to the following questions:

1. Is the proposed rule adequate to ensure that patients are apprised of the inevitable consequencies of hysterectomies?

2. Are existing procedures adequate to ensure that patients are apprised of the inevitable consequences of hysterectomies?

§ 205.35–8 *State Agency Requirements.*

Text of proposed rule:

(a) A State plan under Title I, IV–A, X, XIV, XVI, XIX, or XX of the Social Security Act must provide, with respect to sterilization procedures or hysterectomies for which payment is made under the plan, (1) that all requirements of this section be met; and (2) that the State will provide legal counsel for the patient at all review committee and court proceedings described in this section.

(b) The State Agency shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The State Agency shall submit other reports as required and when requested by the Secretary.

and

§ 50.208 *Program or project requirements.*

Text of proposed rule:

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, (1) meet all requirements of this subpart: and (2) provide legal counsel for the patient at all review committee and court proceedings described in this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

The proposed rules provide that a State plan under title I, IV–A, X, XIV, XVI, XIX, or XX of the Social Security Act, with respect to sterilization procedures or hysterectomies for which payment is made under the plan, and a program or project, with respect to sterilization procedures or hysterectomies supported by the Public Health Service, must provide (1) that all requirements of this section be met; and (2) that the State, program, or project will provide legal counsel for the patient at all sterilization review committee and court proceedings described in this section. The State Agency, or program or project, must maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years. The appro-

priate State Agency, program, or project must submit other reports as required and when requested by the Secretary.

§ 205.35–9 *Federal financial participation.*

Text of proposed rule:

(a) Federal financial participation is not available in expenditures for sterilization procedures unless a facsimile of the consent form appended to this section or another form approved by the Secretary is used for purposes of this section.

(b) Federal financial participation under title XIX of the Social Security Act is unavailable in any sterilization or hysterectomy for which the State Agency has paid without first having received documentation showing that the requirements of this section have been met. Documentation includes consent forms, review committee certifications, court orders, and acknowledgements of receipt of hysterectomy information.

(c) Federal financial participation is available in expenditures for the review committee and legal counsel where required by this section.

and

§ 50.209 *Use of Federal financial assistance.*

(a) Federal financial assistance administered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this subpart or another form approved by the Secretary is used for purposes of this section.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, review committee certifications, court orders, and acknowledgements of receipts of hysterectomy information.

(c) Federal financial assistance administered by the Public Health Service may be used for the expenditures for the revivew committee and legal counsel where required by this section.

The proposed rules provide that Federal financial participation would not be available in expenditures for sterilization procedures unless the consent form contained in the appendix to the regulations or another form approved by the Secretary is used for purposes of this section. To facilitate enforcement, the appropriate State Agency, program, or project may not pay for any sterilization procedure or hysterectomy without first receiving documentation showing that the requirements of these rules have been met. Documentation includes consent forms, sterilization review committee certifications, court orders, and acknowledgements of receipt of the information that a hysterectomy will render the patient permanently incapable of reproducing. The proposed rules also provide that Federal financial participation is available in expenditures for the sterilization review committee and legal counsel where required by the regulations.

INVITATION TO COMMENT

Interested persons are invited to submit written comments, suggestions or objections concerning the proposed regulations to, for the Public Health Service, Marilyn L. Martin, Room 722H (Hubert H. Humphrey Building), 200 Independence Avenue SW., Washington, D.C. 20201 and, for the Health Care Financing Administration, Administrator, HCFA, P.O. Box 2366, Washington, D.C. 20013, on or before March 13, 1977. All comments received in timely response to this Notice will be considered and will be available for public inspection at the following offices during regular business hours.

Public Health Service, Room 722H (Hubert H. Humphrey Building), 200 Independence Avenue, SW., Washington, D.C. 20201.

Health Care Financing Administration, Room 5225, Switzer Building, 330 C Street, SW., Washington, D.C. 20201.

It is proposed to make these rules effective upon republication in the FEDERAL REGISTER.

NOTE.—The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A–107.

It is therefore proposed to amend 42 CFR Part 50 Subpart B, and 45 CFR, Chapter II, Part 205 as set forth below.

Dated: November 30, 1977.

JULIUS B. RICHMOND,
Assistant Secretary for Health.

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

NOVEMBER 30, 1977.

Approved: December 1, 1977.

JOSEPH A. CALIFANO, Jr.,
Secretary.

1. Section 205.35, Part 205, Chapter II, Title 45 of the Code of Federal Regulations is revised to read as set forth below:

§ 205.35–1 Applicability.

This section applies to programs administered under Titles I, IV–A, X, XIV, XVI, XIX, and XX of the Social Security Act.

§ 205.35–2 Definitions.

(a) "Sterilization" means any medical procedure or operation for the purpose of rendering an individual permanently incapable of reproducing.

(b) "Informed consent" (to a sterilization procedure) means a written authorization to be sterilized given by the person to be sterilized and given voluntarily and with an understanding of the nature and consequences of the procedure to be performed.

(c) "Consent form" means a written document which states the requirements for informed consent as set forth in Section 205.35–3.

(d) "A mentally incompetent individual" means a person who has been declared mentally incompetent by a Federal, State, or local court, or who is in fact mentally incompetent under Federal or State law.

(e) "A sterilization review committee" means a committee designated by the State Agency to review, approve, or deny applications for sterilization as required by this section. The committee must include a physician (other than the one proposing to perform the sterilization), attorney, social worker, and patient advocate.

(f) "Hysterectomy" means a medical procedure or operation for the purpose of removng the uterus.

§ 205.35–3 Consent procedures.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this paragraph.

(a) *Preparing to obtain informed consent.* An individual who obtains informed consent for a sterilization procedure must provide orally *all* of the following information or advice to the individual who is to be sterilized:

(1) Advice that the individual is free to withhold or withdraw his/her consent to the procedure at any time prior to the sterilization without affecting his/her right to future care or treatment, and without loss or withdrawal of any Federally-funded program benefits to which the individual might be otherwise entitled;

(2) A description of available alternative methods of family planning and birth control;

(3) A full description of the benefits or advantages he/she may expect to gain as a result of the sterilization;

(4) Advice that the sterilization procedure is considered to be irreversible;

(5) A thorough explanation of the specific sterilization procedure to be performed;

(6) A full description of the discomforts and risks which may accompany and follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(7) Advice that the sterilization will not be performed for at least 30 days; and

(8) An opportunty to ask and have answered any questions he/she may have concerning the sterilization procedure.

(b) *Filling out the consent form.*—(1) *Language of the consent form.* The consent form should be in the primary language of the patient. If the consent form is not in the primary language of the patient, an interpreter must be made available to assist the individual.

(2) *Provisions for the handicapped.* Suitable arrangements must be made to ensure that consent information is effectively communicated to blind, deaf, and other handicapped patients.

(3) *Signatures on the consent form.* The consent form must be signed and dated by:

(i) The patient; and

(ii) The interpreter, if one is provided; and

(iii) The individual who obtains the consent of the patient; and

(iv) The physician who will perform the sterilization procedure.

(4) *Required certifications.* (i) The person securing the patient's consent must certify by signing the consent form that, before the patient signed the consent form, he/she advised the patient

that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the requirements for informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(ii) The physician performing the sterilization must certify by signing the consent form that, immediately prior to the performance of the sterilization, he/she advised the patient that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the elements of informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized. The physician will further certify that, to the best of his/her knowledge and belief, at least 30 days passed between the date upon which the patient signed the consent form and the date upon which the sterilization was performed.

(iii) The physician performing the sterilization must, in cases where court orders are required by this section, certify, by signing the consent form, that he/she was provided with a copy of the court order prior to the performance of the sterilization.

(c) *Following State and local procedures.* In addition to the consent procedures required by this part, any requirement of State and local law, except one of spousal consent, must be followed.

§ 205.35–4 Sterilization of a mentally competent individual aged 21 or older.

Federal financial participation is available in expenditures for a sterilization of a mentally competent individual only when the following requirements have been met:

(a) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in § 205.35–3.

(b) At least 30 days have passed between the date of informed consent and the date of the sterilization.

(c) The individual is at least 21 years old.

§ 205.35–5 Sterilization of a mentally incompetent individual aged 21 or older; sterilization of an institutionalized individual aged 21 or older.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any person declared mentally incompetent by a State, Federal or local court, or who is in fact mentally incompetent under Federal or State law.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any individual institutionalized in a correctional, mental or other facility unless:

(1) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in § 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure, as set forth in section 50.203(a), and that the patient has voluntarily consented to be sterilized.

or

(a) Federal financial participation is unavailable in expenditures for a sterilization of a mentally incompetent individual, or any individual institutionalized in a correctional, mental or other facility unless:

(1) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in § 205.35–3;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in section 205.35–3(a), and that the patient has voluntarily consented to be sterilized.

(b) Federal financial participation is unavailable in expenditures for the sterilization of a mentally incompetent individual who does not understand the nature and consequences of the proposed sterilization procedure as set forth in § 205.35–3(a).

§ 205.35–6 Sterilization of a mentally competent or incompetent individual under the age of 21.

Federal financial participation is unavailable in expenditures in the sterilization of individuals under 21 years old.

§ 205.35–7 Sterilization by hysterectomy.

(a) Federal financial assistance for family planning purposes is unavailable in any hysterectomy performed for the purpose of rendering an individual permanently incapable of reproducing, unless [exception, with appropriate safeguards, to be added if comments describe circumstances in which sterilization by hysterectomy is generally accepted as the appropriate method].

(b) Federal financial participation is available in a hysterectomy the purpose of which is other than to render the patient permanently incapable of reproducing, provided that:

(1) The individual who secures the usual authorization from the patient or her representative, if any, to perform the hysterectomy has informed the patient and her representative, if any, orally and in writing, that the hysterectomy will render the patient permanently incapable of reproducing; and

(2) The patient or her representative, if any, has signed a written acknowledgement of receipt of the foregoing information.

§ 205.35–8 State Agency requirements.

(a) A State plan under Title I, IV–A, X, XIV, XVI, XIX, or XX of the Social Security Act must provide, with respect to sterilization procedures or hysterectomies for which payment is made under the plan, (1) that all requirements of this section be met; and (2) that the State will provide legal counsel for the patient at all review committee and court proceedings described in this section.

(b) The State Agency shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The State Agency shall submit other reports as required and when requested by the Secretary.

§ 205.35–9 Federal financial participation.

(a) Federal financial participation is not available in expenditures for sterilization procedures unless a facsimile of the consent form appended to this section or another form approved by the Secretary is used for purposes of this section.

(b) Federal financial participation under title XIX of the Social Security Act is unavailable in any sterilization or hysterectomy for which the State Agency has paid without first having received documentation showing that the requirements of this section have been met. Documentation includes consent forms, review committee certifications, court orders, and acknowledge-

ments of receipt of hysterectomy information.

(c) Federal financial participation is available in expenditures for the review committee and legal counsel where required by this section.

2. Sections 50.201–204, Subpart B, Part 50, Chapter I, Title 42 of the Code of Federal Regulations are revised to read as set forth below:

§ 50.201 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service.

§ 50.202 Definitions.

As used in this subpart:

(a) "Sterilization" means any medical procedure or operation for the purpose of rendering an individual permanently incapable of reproducing.

(b) "Informed consent" to a sterilization procedure means a written authorization to be sterilized given by the person to be sterilized and given voluntarily and with an understanding of the nature and consequences of the procedure to be performed.

(c) "Consent form" means a written document which states the requirements for informed consent as set forth in § 50.203.

(d) "A mentally incompetent individual" means a person who has been declared mentally incompetent by a Federal, State, or local court, or who is in fact mentally incompetent under Federal or State law.

(e) "A sterilization review committee" means a committee designated by the program or project to review, approve, or deny applications for sterilization as required by this section. The committee must include a physician (other than the one proposing to perform the sterilization), attorney, social worker, and patient advocate.

(f) "Hysterectomy" means a medical procedure or operation for the purpose of removing the uterus.

(g) The "Public Health Service" means the Health Services Administration, Health Resources Administration, National Institutes of Health, Center for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and all of their constituent agencies.

(h) The "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.

§ 50.203 Consent procedures.

Informed consent does not exist unless a consent form is completed voluntarily and in accordance with all the requirements of this paragraph.

(a) *Preparing to obtain informed consent.* An individual who obtains informed consent for a sterilization procedure must provide orally *all* of the following information or advice to the individual who is to be sterilized.

(1) Advice that the individual is free to withhold or withdraw his/her consent to the procedure at any time prior to the sterilization without affecting his/her right to future care or treatment, and without loss or withdrawal of any Federally-funded program benefits to which the individual might be otherwise entitled;

(2) A description of available alternative methods of family planning and birth control;

(3) A full description of the benefits or advantages he/she may expect to gain as a result of the sterilization;

(4) Advice that the sterilization procedure is considered to be irreversible;

(5) A thorough explanation of the specific sterilization procedure to be performed;

(6) A full description of the discomforts and risks which may accompany and follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used;

(7) Advice that the sterilization will not be performed for a least 30 days; and

(8) An opportunity to ask and have answered any questions he/she may have concerning the sterilization procedure.

(b) *Filling out the consent form.* (1) *Language of the consent form.* The consent form should be in the primary language of the patient. If the consent form is not in the primary language of the patient, an interpreter must be made available to assist the individual.

(2) *Provisions for the handicapped.* Suitable arrangement must be made to ensure that consent information is effectively communicated to blind, deaf and other handicapped patients.

(3) *Signatures on the consent form.* The consent form must be signed and dated by:

(i) The patient; and

(ii) The interpreter, if one is provided; and

(iii) The individual who obtains the consent of the patient; and

(iv) The physician who will perform the sterilization procedure.

(4) *Required certification.* (i) The person securing the patient's consent must certify by signing the consent form that, before the patient signed the consent form, he/she advised the patient that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the requirements for informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief, appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(ii) The physician performing the sterilization must certify by signing the consent form that, immediately prior to the performance of the sterilization, he/she advised the patient that no Federal benefits may be withdrawn because of the patient's decision not to be sterilized, that he/she explained orally the requirements for informed consent as set forth on the consent form, and that the patient, to the best of his/her knowledge and belief appeared mentally competent and knowingly and voluntarily consented to be sterilized. The physician will further certify that, to the best of his/her knowledge and belief, at least 30 days have passed between the date upon which the patient signed the consent form, and the date upon which the sterilization was performed.

(iii) The physician performing the sterilization must, in cases where court orders are required by this section, certify, by signing the consent form, that he/she was provided with a copy of the court order prior to the performance of the sterilization.

(c) *Following State and local procedures.* In addition to the consent procedures required by this part, any requirement of State and local law, except one of spousal consent, must be followed.

§ 50.204 Sterilization of a mentally competent individual aged 21 or older.

Programs or projects to which this subpart applies shall perform or arrange for the performance of sterilization of a mentally competent individual only when the following requirements have been met:

(a) The individual has voluntarily given his/her informed consent in accordance with all the procedures prescribed in section 50.203.

(b) At least 30 days have passed between the date of informed consent and the date of the sterilization.

(c) The individual is at least 21 years old.

§ 50.205 Sterilization of a mentally incompetent individual aged 21 or older; sterilization of an institutionalized individual aged 21 or older.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any person declared mentally incompetent by a State, Federal or local court, or who is in fact mentally incompetent under Federal or State law.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any individual institutionalized in a correctional, mental or other facility *unless*:

(1) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in § 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of the sterilization;

(3) The individual is at least 21 years old;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that

all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in § 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure, as set forth in § 50.203 (a), and that the patient has voluntarily consented to be sterilized.

or

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of a mentally incompetent individual, or any individual institutionalized in a correctional, mental or other facility *unless*:

(1) The individual has voluntarily given his/her informed consent in accordance with the procedures prescribed in § 50.203;

(2) At least 30 days have elapsed between the date of informed consent and the date of sterilization;

(3) The individual is at least 21 years;

(4) The sterilization review committee has certified to a court, after a hearing at which counsel representing the patient has presented the evidence for and against such a certification, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in § 50.203(a), and that the patient has voluntarily consented to be sterilized; and

(5) The court has found, after a hearing at which counsel for the patient has presented the evidence for and against such a finding, that all of the requirements for sterilization have been met, that the patient understands the nature and consequences of the proposed sterilization procedure as set forth in § 50.203 (a), and that the patient has voluntarily consented to be sterilized.

(b) Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of a mentally incompetent individual who does not understand the nature and consequences of the proposed sterilization procedure as set forth in § 50.203 (a).

§ 50.206 Sterilization of a mentally competent or incompetent individual under the age of 21.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of sterilizations of individuals under 21 years old.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any hysterectomy for the purpose of rendering an individual permanently incapable of reproducing, unless [exception with appropriate safeguards, to be added if comments describe circumstances in which sterilization by hysterectomy is generally accepted as the appropriate method].

(b) Programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy the purpose of which is other than to render the patient permanently incapable of reproducing, provided that:

(1) The individual who secures the usual authorization from the patient or her representative, if any, to perform the hysterectomy has informed the patient and her representative. If any, orally and in writing, that the hysterectomy will render the patient permanently incapable of reproducing; and

(2) The patient or her representative, if any, has signed a written acknowledgment of receipt of the foregoing information.

§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure or hysterectomy it performs or arranges, (1) meet all requirements of this subpart; and (2) provide legal counsel for the patient at all review committee and court proceedings described in this subpart.

(b) The program or project shall maintain sufficient records and documentation to assure compliance with these regulations, and must retain such data for at least 3 years.

(c) The program or project shall submit other reports as required and when requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance administered by the Public Health Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary is used for purposes of this section.

(b) A program or project shall not use Federal financial assistance for any sterilization or hysterectomy without first receiving documentation showing that the requirements of this subpart have been met. Documentation includes consent forms, review committee certifications, court orders, and acknowledgments of receipt of hysterectomy information.

(c) Federal financial assistance administered by the Public Health Service may be used for the expenditures for the review committee and legal counsel where required by this section.

APPENDIX: REQUIRED CONSENT FORM

NOTICES Your decision at any time not to be sterilized will not result in the withdrawal or withholding of any benefits provided by programs or projects receiving Federal funds.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from _____ (doctor or clinic)

When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment and I will not lose any help or benefits from programs receiving Federal funds such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I understand that the sterilization must be considered permanent and not reversible. I have decided that I do not want to become pregnant, bear children or father children.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and freely chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least thirty days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by Federally funded programs.

I am _____ years old. I was born on ____ day _____ _____ month year

I, _____, hereby consent of my own free will to be sterilized by _____ _____ by a method called _____ _____.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health, Education, and Welfare or

Employees of programs or projects funded by that Department but only for purposes of research or for determining if Federal laws were observed.

You are requested to supply the following information, but it is not required:

Race and ethnicity designation (please check)

Black (not of Hispanic origin) _____

Hispanic _____

Asian or Pacific Islander _____

American Indian or Alaska native _____

White (not of Hispanic origin) _____

_____ ____ ____/ ___/____

Patient's Signature Date: Month Day Year

Where the consent form is not in the primary language of the patient:

I have read the consent form to_____ _____ in _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Interpreter Date

Before _____ signed this consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

name of individual

I counseled the patient that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the patient that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the patient is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.

Signature of person obtaining consent Date

Facility

Address

PHYSICIAN'S STATEMENT

Immediately before I performed a sterilization operation upon ----------

Name of patient

I explained to him/her the nature of the sterilization operation ----------, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the patient that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the patient that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief at least thirty days have passed since the patient consented to the sterilization.

To the best of my knowledge and belief the patient is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

Physician

Date

Alternative final paragraph for use where court order is required:

To the best of my knowledge and belief the patient is at least 21 years old. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequences of the procedure. I have been provided with a copy of the attached court order.

Physician

Date

[FR Doc.77-35424 Filed 12-12-77;8:45 am]

[4110-35]

Public Health Service

[42 CFR Part 50]

[45 CFR Part 205]

PROPOSED RESTRICTIONS APPLICABLE TO STERILIZATIONS FUNDED BY THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

CROSS REFERENCE: For a document proposing rules on restrictions applicable to sterilizations funded by the Department of Health, Education, and Welfare, See FR Document 35424 under Health Care Financing Administration in Part III of this issue.

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COMMENT OF THE
NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS
ON
PROPOSED RULEMAKING GOVERNING
STERILIZATIONS FUNDED BY DHEW

March 29, 1978

Comment of the

National Commission for the Protection of Human Subjects

on

Proposed Rulemaking Governing

Sterilizations Funded by DHEW

March 29, 1978

Historically, the medical profession and the law have excessively restricted or, in some instances, promoted sterilization of men and women in the United States. To determine whether or not sterilization services would be provided, persons desiring to be sterilized have been required in the past to satisfy formulas developed and endorsed by medical organizations and based upon the number of living children and age of the patient. Such persons have legally been required to obtain the consent of their spouses in order to be sterilized. On the other hand, many women, particularly the poor and members of minority groups, have complained that they have been unduly influenced to agree to sterilization. Others have claimed that they were sterilized without their knowledge or permission. There is also evidence that hysterectomy has been performed inappropriately, solely as a means of sterilization. Laws in some states have compelled the sterilization of mentally retarded persons or refused to permit the procedure, without taking into account the needs and desires of the persons involved.

The medical and legal restrictions on sterilization of competent adults have by now largely been terminated. Sterilization has become a very popular means of contraception, being employed in this country by almost as many couples as those choosing to use the contraceptive pill. A potential for abuse exists, however, in the form of undue influence or coercion of vulnera-

ble persons to agree to be sterilized, the performance of sterilization without the knowledge of the patient, or sterilization by means of unneeded hysterectomy. Those who receive their health care under publicly-funded programs may be especially vulnerable to such abuse. Thus, the challenge to DHEW in administering its health care programs is to make sterilization freely available on a voluntary basis while guarding against any abuse that can be controlled by regulation.

Recognizing that protective measures will necessarily restrict access to sterilization, DHEW has sought public comment on the appropriateness of such measures, and Secretary Califano has requested that the National Commission for the Protection of Human Subjects provide its views on the proposed regulations. This assignment is within the mandate of the Commission to consider the applicability of guidelines for the conduct of research involving human subjects to the delivery of health care under programs conducted or supported by DHEW. In addition, the Commission's consideration of research involving children and those institutionalized as mentally infirm has acquainted it with many of the issues addressed in the proposed sterilization regulations.

The Commission affirms that appropriate steps should be taken to prevent performance of sterilization under conditions of coercion or inadequate consent. In this context, the Commission notes that the availability of sterilization services at the same time abortion services are being sharply curtailed under DHEW programs may have the appearance of coercion. The Commission recognizes, too, that sterilization is an accepted part of medical care and is being requested by increasing numbers of men and women. Any undue

limitation on access to sterilization would lower the standard of care available to persons dependent upon DHEW health programs.

The Commission is pleased to note that DHEW has attempted, in its proposed regulations governing sterilization, to balance the conflicting goals of protecting beneficiaries of its programs while assuring their access to desired medical services. The Commission has reviewed the proposed regulations and concludes that, although DHEW has generally proposed appropriate means to protect against abuse, it has failed to recognize certain conditions and circumstances warranting exceptional treatment. Providing protection by regulations that are easy to administer has been accomplished by imposing absolute prohibitions that may unduly limit access to sterilization in such exceptional circumstances.

Some of the proposed provisions, such as the requirement for a meaningful consent process, are excellent protective measures and may even be strengthened. Other provisions, such as the mandatory 30-day waiting period and the blanket prohibition of sterilization for persons who are under 21 or mentally incompetent and unable to give informed consent, are more stringent than necessary and may result in the denial of access to proper medical care. The inescapable burden created by the need to protect against abuses should not be made to fall too heavily on the potentially abused. Although rules without exceptions may be easier to administer, failure to provide for exceptional circumstances may place an unfair burden on those for whom protection is sought. The appropriate goal of the sterilization regulations and of the government programs to which they apply should be to provide the dependent population

with health services of quality and quantity equal to those available for other persons, while facilitating individuals' abilities to make decisions about their reproductive capacity and protecting them against coercion.

The Commission's comments on the specific provisions follow.

Definition of Sterilization (205.35-2 and 50.202)

The proposed definition of sterilization does not distinguish between medically-indicated and elective sterilization. Such a distinction is necessary, the Commission believes, in light of the proposed prohibition on sterilization of persons who are under 21 or unable to give informed consent because of mental incompetence. DHEW argues, citing court decisions, that "it is unlikely that Congress intended that procedures designed to ensure informed consent would apply to one [elective sterilization] but not the other [medically-indicated sterilization]." Therefore, DHEW concludes, no distinction should be made. However, this argument wrongly assumes that distinguishing medically-indicated sterilization would necessarily result in the abandonment of protective measures in instances where sterilization is medically indicated. To the contrary, as will be shown below, the protective procedures may merely be adjusted in exceptional cases, so that adequate protection against abuse is maintained while appropriate medical care is provided.

Medical indications for sterilization would include, for example, severe diabetes or kidney or heart disease in a sexually active woman for whom non-permanent forms of contraception are either medically contraindicated or not sufficiently effective. When these conditions occur in women who are under

21 or unable to give informed consent because of mental incompetence, sterilization would be absolutely prohibited under the proposed regulations. The Commission believes that exceptions to the general prohibition should be made in such instances, provided there are alternative protective measures. Such exceptions would require a separate definition of medically-indicated sterilization. (The Commission suggests below that the minimum age of 21 be reduced to 18; if this suggestion is followed, the exception for medically-indicated sterilization should apply in the case of women who are under 18.)

Further, hysterectomy may be performed on severely or profoundly retarded women, before or after age 21, to alleviate the serious problems presented by their menstrual care, and may make the difference between home care and institutionalization. The definition of sterilization should be explicitly clarified to provide that hysterectomy for this purpose is not done for the purpose of sterilization and falls in the same category as hysterectomy for medical indications such as uterine cancer or metrorrhagia unresponsive to hormone therapy. When performed for this purpose, hysterectomy should be fundable under consent conditions required for other medical procedures involving such patients.

Consent Procedures (205.35-3 and 50.203)

The Commission generally favors and applauds the proposed measures for assuring that patients will be informed of the ramifications of sterilization and alternatives thereto, that consent will be sought in circumstances free of pressure or coercion, and that patients will be told that government bene-

fits will not be withheld if they do not consent to sterilization. The list of essential information that must be given to patients orally appears comprehensive, but several additional facts should be included if the patients are to be adequately informed. First, when patients are advised that withholding consent will not result in loss of federal benefits, they should also be told that, under present law, should alternative means of birth control fail, benefits are not available to pay for an abortion except in limited circumstances. Second, the description of alternative methods of family planning and birth control should be required to include information on the risks (including failure rates) and benefits of those methods. Such information should include the warnings that have been issued by the Food and Drug Administration regarding risks associated with use of the contraceptive pill and the intrauterine device. Third, the description of the risks and discomforts of the sterilization procedure should be required to include mention of the rare possibility that the procedure may fail to produce sterility, and of the need to use another means of contraception for a short time after the procedure as a precaution. Finally, the Commission disagrees with the requirement for a mandatory 30-day wait, as discussed below.

The Commission supports the decisions not to require the presence of a witness or spousal consent, and the requirement for an interpreter when the consent form is not in the patient's primary language. There is no objection to the required certifications so long as they are based on "the best of [the certifier's] knowledge and belief."

The Commission notes that two purposes are comingled in the "Required Consent Form" set forth in the Appendix to the proposed regulations. This

form, as drafted, constitutes not only a consent to be sterilized but also a consent to the release of the form (including some requested, but not mandatory, information) and the patient's medical records "for purposes of research or for determining if Federal laws were observed." The Commission has two comments on this form: first, separate forms should be employed for the consent to sterilization and the consent to release of information, and the patient should be able to refuse to give permission for the release of information about him or her for research purposes. Second, it should be made clear that under no conditions will information be released for the purpose of determining if state laws or Federal laws unrelated to the provision of sterilization services have been observed, and that every attempt will be made to protect patient privacy, including the use of aggregate or unidentified data whenever that would be sufficient for the research purposes.

Sterilization of a Mentally Competent Individual Aged 21 or Older (205.35-4 and 50.204)

30-Day Waiting Period

The proposed regulations impose a mandatory 30-day waiting period between the time of consent and the performance of a sterilization. DHEW notes that the

> proposed rules could conceivably allow for waiver of the waiting period in exceptional circumstances, for example where a sterilization is arranged for over 30 days in advance of anticipated delivery date but there is a premature delivery. These alternatives may be in theory quite sound, but [DHEW] is skeptical about their enforceability and concerned about the possibilities for abuse.

The Commission agrees that a 30-day waiting period, although chosen arbitrarily, may be reasonable to assure sufficient time for consultation and reflection. However, the Commission suggests that such a period not be adopted unless DHEW plans to conduct research to determine whether the 30-day wait is justified, taking into consideration both the protection afforded by the wait and the unwanted pregnancies that result. Further, the Commission strongly disagrees with the position of DHEW that shortening the waiting period in exceptional circumstances is not warranted or enforceable. The very example given in the DHEW statement -- prearrangement of sterilization followed by a premature delivery -- constitutes an exceptional circumstance that the Commission believes should justify a shortening of the waiting period. Failure to provide for such an exception would result in an otherwise unnecessary second hospitalization of patients who deliver prematurely and who have consented to sterilization at least 30 days prior to the anticipated delivery date.

DHEW appears to be more concerned about the enforceability than the justification of a provision for exceptions. However, DHEW has apprently failed to consider than an anticipated delivery date can be based on factual circumstances that are readily identifiable and verifiable upon audit. The patient's records will provide an objective basis for determining whether it was reasonable to believe, at the time the consent form was signed, that confinement would not occur for at least 30 days.

The Commission notes that DHEW has adduced no evidence of failure of the present 72-hour waiting period to prevent abuse of the consent process;

many reported deficiencies, such as absence or insufficiency of documentation, would not be affected by the requirement of a waiting period. In the absence of such evidence, a significantly longer waiting period should not be rigidly imposed without provision for exceptional circumstances. The Commission believes that the reasonableness of the longer, 30-day waiting period would be enhanced by a provision for exceptions, as discussed above.

(One member of the Commission, Dr. Donald W. Seldin, wished to have noted his strong belief that an exception to the 30-day waiting period should also be provided whenever a woman undergoing cesarean section or emergency abdominal surgery for reasons such as ectopic pregnancy or a ruptured uterus, requests sterilization and gives informed consent.)

Minimum Age of 21

The proposed regulations impose a blanket prohibition on sterilization of persons under 21 years of age. To support this provision, DHEW argues that (1) determination of capacity to give informed consent under state law would produce anomalous results; (2) it is questionable whether persons under 21 have the judgment, experience and maturity to make voluntary decisions to be sterilized; and (3) any exception to the minimum age would be difficult to monitor and subject to abuse.

With respect to the first argument, the Commission notes that state laws regarding the age of majority are not nearly so diverse as DHEW appears to believe. Forty-two states and the District of Columbia have adopted 18 as the age of majority; only two states remain at the traditional age of 21, three states are at 19, and three states are below 18 (see the Commission's Report and Recommendations: Research Involving Children, pp. 85-87). Thus,

adoption of a minimum age of 18 would be consonant with current practice in all but a few jurisdictions. Although the constitutionality of the present moratorium on sterilization of persons under 21 has been upheld in cases cited by DHEW, the judge in one of these cases (Voe v. Califano) clearly indicated in his decision that he considered the regulation unjust. He accepted a 20-year-old woman's consent as informed and valid, and directed his clerk to send a copy of the decision to the Secretary of Health, Education, and Welfare, in hope that her "poignant cry . . . could not fail to be heard by those with discretion to grant relief."

DHEW admittedly has no evidence that persons under 21 lack sufficient judgment, experience and maturity to consent voluntarily to sterilization; in view of the lower age of majority adopted by almost all the states, such inability or lack of capacity should not be presumed. Therefore, the Commission recommends that the regulations should permit persons to consent to elective or medically-indicated sterilization at age 18 rather than 21. Below the age of 18, medically-indicated sterilization should be permitted with the permission of the parents of the patient and either her assent, or when assent is not possible, with appropriate procedural safeguards and court approval.

Sterilization of a Mentally Incompetent Individual Aged 21 or Older; Sterilization of an Institutionalized Individual Aged 21 or Older (205.35-5 and 50.205)

DHEW has proposed alternative regulations governing sterilization of mentally incompetent and institutionalized individuals. The first alternative would prohibit sterilization of any person who has been declared mentally incompetent by a court or is in fact mentally incompetent under law.

Under the second alternative, a mentally incompetent person would be treated in the same manner as an institutionalized person, i.e., sterilization could be performed only if a review committee and a court had independently found that the patient understood the nature and consequences of the sterilization and had voluntarily consented to be sterilized. Sterilization could not be performed under the second alternative if the review committee or court found that the patient was incapable of consenting.

Of the two alternatives, the Commission prefers the second, which is more consonant with the Commission's approach in its recommendations on research involving those institutionalized as mentally infirm (see Report and Recommendations: Research Involving Those Institutionalized as Mentally Infirm, pp. 1-22). Rather than prohibit the participation of such persons in research on the grounds that they cannot give legally valid informed consent, the Commission has recommended that the "assent" of such persons be recognized under appropriate conditions. By "assent" the Commission refers to a functional capacity to understand basic information about proposed research and to volunteer freely to participate. This would appear analogous to the proposed functional standard for "consent" that a review committee and court must apply in the case of a mentally incompetent or institutionalized person wishing to be sterilized. Since this standard is functional rather than legal, the terms "informed consent" and "consent" should be replaced with the term "assent" in this section of the regulations. Adoption of the second alternative with amended terminology would enable appropriate recognition to be given to the functional ability of mentally incompetent persons and, in view of the independent determinations that must be made by a review committee and a court, would be unlikely to lead to abuse.

The Commission believes, however, that the second alternative is inadequate in two respects. The proposed regulation fails to provide for the performance of sterilization of mentally incompetent persons who are incapable of assenting. In the case of medically-indicated sterilization, the presence of conditions such as severe diabetes, or kidney or heart disease, which are easily verifiable, should be sufficient to overcome reluctance to accept consent by a parent or guardian, provided a review committee and court find that sterilization is in fact medically indicated and alternative means of contraception are not feasible. Although courts may be unwilling to accept jurisdiction in such cases, there is no reason to believe that they would be less willing to make a finding of medical necessity than to find that a patient had the capacity to and did give informed consent.

Sterilization "in the best interests" of a mentally incompetent woman incapable of assenting presents more problems than medically-indicated sterilization of such an individual, because of the many possibilities for abuse in this area. Nevertheless, the Commission believes that such sterilization should at least be available, although the Commission does not endorse its general use. As a condition for sterilization in the best interests of a woman who is mentally incompetent and cannot assent, a parent or guardian should approve the operation and both the review committee and the court should find (1) that alternative means of contraception are not feasible, (2) that the patient has participated in the decision regarding sterilization to the extent of her competence and does not object, and (3) that the patient will benefit from the sterilization. What constitutes a "benefit" to the patient cannot easily be defined. Those who must make this determination should distinguish between benefit to the caretaker or society and benefit to the patient; sterilization should not be used as a substitute for good care. On the other

hand, sterilization in anticipation of nonprotective care might be considered a possible benefit to the individual prior to placement in the community; in such instances, however, alternative means of contraception should be considered first.

The Commission notes that hysterectomy is sometimes performed on severely or profoundly retarded females for the purpose of eliminating difficulties associated with menstruation. In such instances, hysterectomy should not be considered sterilization as defined in the proposed regulations, since the purpose of the procedure is not to render the patient permanently incapable of reproducing, even though it would have that unavoidable effect. Thus, it should be available under the same requirements for determination of the need for the procedure and consent as for other medical treatments of such patients.

Sterilization of a Mentally Competent or Incompetent Individual Under the Age 21 (205.35-6 and 50.206)

The Commission has discussed its opposition to this proposal above under sections 205.34-4 and 205.35-5.

Sterilization by Hysterectomy (205.35-7 and 50.207)

Although hysterectomy performed solely for sterilization is inappropriate medical treatment, the Commission believes that hysterectomy should be recognized as an acceptable means of sterilization, under certain carefully defined guidelines, when uterine abnormalities are present. Many women requesting sterilization are found to have certain conditions which, in and of themselves, are not sufficient indications for hysterectomy, but which taken together with their desire for sterilization indicate that

hysterectomy is the most desirable means of sterilization for them. Among such abnormalities are uterine descensus, premalignant diseases of the cervix and endometrium, severe dysmenorrhea, and chronic menorrhagia. Thus, when sterilization is requested under conditions where hysterectomy would best serve the medical interests of the patient, an exception to the general prohibition of funds for sterilization by hysterectomy should be made. In this situation it would be reasonable to require a concurring judgment by a second independent physician that the combination of circumstances is such that hysterectomy sterilization is warranted.

The Commission supports the requirement that women undergoing hysterectomy for any reason be advised that it will render them incapable of bearing children.

State Agency, or Program or Project Requirements (205.35-8 and 50.208)

These requirements seem appropriate, provided adequate steps are taken to protect the privacy of the patients by limiting access to the consent forms on file.

Federal Financial Participation and Assistance (205.35-9 and 50.209)

These measures seem appropriate, provided that if there is to be a federal requirement for review committees and legal counsel, there is also a federal commitment to meet the resulting costs through increased appropriations rather than by diverting funds from health care services.

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