Initial Development of National Guidelines for Health Planning

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THE NATIONAL GUIDELINES FOR HEALTH PLANNING are a new approach to health policy development. They seek to provide direction to local and State health planning. They aim to contribute to the development and coordination of national health policy.

The first section of the National Health Planning and Resources Development Act of 1974 (Public Law 93–641) calls for the Secretary of Health, Education, and Welfare (HEW) to issue such guidelines. The law specifies that they include (*a*) standards respecting the appropriate supply, distribution, and organization of health resources and (*b*) a statement of national health planning goals.

The law also indicates that these guidelines are to be promulgated in regulations and revised periodically. They are an integral and critical part of the new nationwide health planning program; the program's essential purpose and nature and its focus on voluntary planning have been reviewed in Public Health Reports (*1*) and elsewhere (*2, 3*).

The statute prescribes that the effort to develop such guidelines must give "priority consideration" to the 10 national health priorities that Congress identified in Section 1502 of the Health Planning Act (see National Health Priorities, page 408). The statute also provides that, "goals, to the maximum extent practicable, shall be expressed in quantitative terms." The achievement of "equal access to quality health care at a reasonable cost" is set as the principal purpose.

The guidelines are to be the product of widespread public consultation. The Secretary is specifically instructed to consult with and solicit recommendations and comments from local and State health planning bodies, associations and specialty societies representing medical and other health care providers, and with the National Council on Health Planning and Development. The National Council was established by the law as a 15-member advisory body; its first responsibility is to advise the Secretary on the development of the national guidelines.

The guidelines are to be used by local health systems agencies (HSAs) in developing their health systems plans (HSPs). They also are to be applied in formulating criteria and standards for the review of existing and planned health services and facilities and in preparing State health plans. The HSPs are to take into consideration the statements of national health goals and are also to be consistent with the standards respecting the supply, distribution, and organization of health resources.

The guidelines provide a framework and benchmarks for local analyses and decision making. They can increase objectivity and equity in the allocation of health resources. As discussed subsequently, the relationships between national statements and local actions are complex, and some have already been a subject of considerable controversy; these interactions are likely to be a critical and evolving aspect of the future of the guidelines.

This paper is a report on the initial legislative and administrative development of the National Guidelines for Health Planning. It chronicles experiences between the spring of 1974 and the spring of 1978 and identifies progress made and problems encountered.

Congressional Phase

When the Nixon Administration introduced its proposal for a new health planning act in March 1974, the bill did not mention national guidelines for health planning. Administration witnesses testified that they felt such guidelines were neither necessary nor desirable since existing mechanisms of health policy development appeared adequate.

A number of interested Congressmen, however, introduced bills which called for the drafting of national health guidelines and listed several health priorities. The lead bill, introduced by Representative James Hastings of New York, proposed an independent council on health policy with responsibilities for issuing guidelines and developing

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"NATIONAL HEALTH PRIORITIES"

"SEC. 1502. The Congress finds that the following deserve priority consideration in the formulation of national health planning goals and in the development and operation of Federal, State, and area health planning and resources development programs:

"(1) The provision of primary care services for medically underserved populations, especially those which are located in rural or economically depressed areas.

"(2) The development of multi-institutional systems for coordination or consolidation of institutional health services (including obstetric, pediatric, emergency medical, intensive and coronary care, and radiation therapy services).

"(3) The development of medical group practices (especially those whose services are appropriately coordinated or integrated with institutional health services), health maintenance organizations, and other organized systems for the provision of health care.

"(4) The training and increased utilization of physician assistants, especially nurse clinicians.

"(5) The development of multi-institutional arrangements for the sharing of support services necessary to all health service institutions.

"(6) The promotion of activities to achieve needed improvements in the quality of health services, including needs identified by the review activities of Professional Standards Review Organizations under part B of title XI of the Social Security Act.

"(7) The development by health service institutions of the capacity to provide various levels of care (including intensive care, acute general care, and extended care) on a geographically integrated basis.

"(8) The promotion of activities for the prevention of disease, including studies of nutritional and environmental factors affecting health and the provision of preventive health care services.

"(9) The adoption of uniform cost accounting, simplified reimbursement, and utilization reporting systems and improved management procedures for health service institutions.

"(10) The development of effective methods of educating the general public concerning proper personal (including preventive) health care and methods for effective use of available health services."

recommendations for a national health policy. Somewhat similar bills were introduced by Congressman Paul Rogers of Florida, Congressman William Roy of Kansas, and Senator Edward Kennedy of Massachusetts.

Interest in these provisions appeared largely motivated by analyses of the experiences of earlier health planning efforts. William Hiscock of Baltimore, representing the American Association for Comprehensive Health Planning, testified before a Senate committee that "one of our biggest problems in areas and States, charged with developing and implementing unified coherent health policy plans for those areas and States, is the absence of a similar national health policy planning vehicle" (*4*).

Dr. Donald Smith of Michigan's Comprehensive Health Planning Agency testified before a House committee: "Establishment of a national health policy is . . . one of the most important provisions (of the bill). . . . Health policy in the U.S. today is characterized by a conglomerate of highly specific laws, independently interpreted and implemented at several government levels . . . We believe that formulation of a national health policy should be an integral part of this legislation" (*5*).

Supporting testimony was offered by various hospital associations, the Blue Cross Association, the Association of State and Territorial Health Officials, and others (*6*). A study of previous health planning programs by Prof. Herbert Klarman of New York University concluded that a serious negative factor had been "the deliberate posture adopted by the federal government of refraining from formulating a national health planning policy or anything that might resemble one and from furnishing guidelines to local health planners" (*7*).

The bills reported by the House Committee on Interstate and Foreign Commerce in September 1974 and the Senate Committee on Labor and Public Welfare in November 1974 included provisions for national health guidelines. The House bill called for a national council for health policy to develop and recommend "a quantifiable statement of national health goals;" the report indicated that "the guidelines respecting the appropriate supply, distribution, and organization of health resources are intended to provide a general framework for the more detailed planning efforts of the Federal government and the State and areawide health planning agencies . . ." (*8*) The Senate bill called for the HEW Secretary to develop national guidelines for health planning; the report emphasized that such statements would be especially timely "in view of the increasing Federal

involvement in and responsibility for the provision and assurance of health care services to the American people" (*9*).

After the bills were passed by the House and Senate, the conference committee met to resolve differences. Its report, in December 1974, assigned the responsibility for developing national guidelines to the HEW Secretary; the first guidelines were to be issued within 18 months of the enactment of the law. A broad process of public consultation was specified. The conference committee also made several changes in the national health priorities, emphasizing the importance of organized health care systems and prevention activities in line with the Senate bill. The bill was signed into law by President Gerald Ford on January 4, 1975.

The statute provided that local HSAs are to give "appropriate consideration," as they develop local health systems plans, to the national guidelines and the national health priorities. Further, local HSPs were not only to be responsive to the unique needs and resources of the local area but were also to "take into account" and be "consistent with" the national guidelines for health planning policies respecting the supply, distribution, and organization of health resources and services.

Initial Administrative Actions

The DHEW staff undertook to implement the new law with Department-wide participation in policy development (table 1). An intra-departmental committee, co-chaired by the Assistant Secretary for Health, Dr. Theodore Cooper, and the Deputy Assistant Secretary for Planning and Evaluation/Health, Dr. Stuart Altman, was organized to oversee the development of policies on all aspects of the new health planning program. The Task Force on the National Guidelines, composed of staff from all six agencies of the Public Health Service (PHS), was established to help prepare and review materials for the national guidelines. Leadership and coordination responsibilities regarding the development of the guidelines were assigned to my office, the Office of Planning, Evaluation, and Legislation of the Health Resources Administration. The Bureau of Health Planning and Resources Development was established in the Health

Table 1. Chronology of initial administrative actions

April 1975	Establishment of Intra-Departmental Committee on Public Law 93–641
May 1975	Establishment of Task Force on the National Guidelines
June 1975	Publication of Notice in the Federal Register
June 1975	Issuance of contracts regarding potential criteria and standards
July 1975	Communications to professional and public organizations and local and State agencies
July 1975	Commissioning of first issue papers
Summer 1975	Three meetings at the Harvard School of Public Health
November 1975	Followup communications to professional and public organizations and local and State agencies
December 1975	Meeting of the first members of the National Council on Health Planning and Development
January 1976	Conference with WHO consultants on health goals and standards
January 1976	Meeting in San Francisco sponsored by University of California School of Public Health
July 1976	Distribution of initial draft of potential guidelines
July 1976	Workshops at American Association of Comprehensive Health Planning meeting in Miami
September 1976	Publication of first volume of "Papers on the National Health Guidelines"
October 1976	Distribution of revised draft of potential guidelines
Fall 1976	National Health Policy Issues Forum, DHEW Region IX
Winter 1976	Local and regional meetings on the draft National Guidelines
January 1977	Publication of second volume of "Papers on the National Health Guidelines"
Spring 1977	Local and regional meetings on the draft National Guidelines
July 1977	Health Resources Administration conference on financial and economic indicators
September 1977	Publication of third volume of "Papers on the National Health Guidelines"
September 1977	Publication of notice of proposed rulemaking on initial issuance of the National Guidelines in the Federal Register
September 1977	First full meeting of National Council on Health Planning and Development
November 1977	Five public meetings on the proposed guidelines
December 1977	Meetings of the National Council on Health Planning and Development to make recommendations on proposed guidelines
January 1978	Publication of revised proposal on the initial issuance of the National Guidelines in the Federal Register
March 1978	Publication of final rules on initial issuance of the National Guidelines in the Federal Register
April 1978	Publication of fourth volume of "Papers on the National Health Guidelines"

Resources Administration to administer the new program.

To help initiate the process of guidelines development, a notice was published in the Federal Register on June 12, 1975, calling attention to the law's provisions regarding the national guidelines and soliciting ideas and recommendations on how best to carry out this new task. The Assistant Secretary for Health sent a similar message to some 80 professional and public agencies and existing local and State health planning agencies. About 100 comments were received.

A more focused effort was the commissioning of papers on health policy issues related to the statutory mandate. Some were prepared by staff, and others by consultants. Formal conferences to discuss pertinent issues were held in Boston, Miami, and San Francisco. Numerous informal sessions were held with individual persons and groups—both providers and consumers—expressing interest in the subject. Products of these analyses and exchanges were later published in "Papers on the National Health Guidelines": Volume I. "Baselines for Setting Health Goals" (*10*), Volume II. "The Priorities of Section 1502" (*11*), and Volume III. "Conditions for Change in the Health Care System" (*12*).

These deliberations made clear that the development of a comprehensive set of national guidelines was likely to be a long-term task. Analyses of available publications and other materials from health commissions, professional agencies, public groups, health planning bodies, and others indicated there was little consensus on health goals. Seldom had agreement been reached on specific program aims; usually conclusions and recommendations urged further expansion of health resources and services of particular concern.

Similarly, the state-of-the-art in developing resource standards was found to be primitive in most cases. A series of studies concerning 16 specialized medical services and other technological advances, funded by the Bureau of Health Planning and Resources Development, addressed such subjects as pediatrics, obstetrics, diagnostic radiology, ambulatory surgery, computed tomographic (CT) scanning, and multiphasic health testing (*13*). The reports were made available for information and review by interested agencies, without endorsement, through the National Health Planning Information Center. An evaluation of the early operations of State certificate of need programs documented the importance of review criteria and standards in achieving credibility and fairness (*14*).

Draft Guidelines

An initial draft of potential guidelines was distributed in July 1976. It included 24 goal statements on such subjects as infant mortality, communicable disease, health education, and health care costs. This draft was distributed for review and comment to local and State health planning agencies and other groups. Approximately 200 comments were received.

A more extended draft, published in October 1976, presented four goals with related subgoals and standards. The four goals focused on improving health status, advancing health prevention, strengthening health services, and extending health care financing. The October draft was widely distributed throughout the country. The HEW Secretary, Dr. David Matthews, decided, though, it was premature to publish the material as a notice of proposed rulemaking in the Federal Register. Instead, a series of meetings on the draft guidelines was organized in the winter of 1976–77, some in local communities and others on a regional basis.

More than 1,000 comments were received on the October draft. Reviewers were requested to complete a scorecard indicating whether they agreed with the proposed statements, agreed with changes, or disagreed. These responses were extensively analyzed. (*15*). Examples of reactions to certain proposed goals and standards are indicated in table 2.

These efforts were aimed at identifying the extent and nature of interest in and support for different approaches to the formulation of goals and the development of standards. As many commentators pointed out, the initial drafts included a variety of approaches, some specific and others general. The October draft presented 7 principles, 4 goals, 17 subgoals, and 25 resource standards. While the guidelines were relatively complex, they omitted some important subjects. A primary purpose of distributing this document was to elicit popular interest and preferences in order to help identify those subjects most appropriate for initial issuance and those deserving further analysis and elaboration.

Some HSAs found the draft material helpful in developing their initial health systems plans and annual implementation plans. After being organized, the 205 conditionally designated agencies concentrated on the preparation and adoption of their plans, a necessary step to full designation. To assist this work, guidelines for plan development by HSAs were issued by the Bureau of Health Planning and Resources Development in December 1976 (*16*).

Initial Issuance of Guidelines

In considering extension of the health planning program in the spring and summer of 1977, the congressional committees expressed concern that the initial issuance of the National Guidelines for Health Planning, scheduled for the summer of 1976, had not yet been published. They noted that a draft had been circulated, but expressed concern that the draft included few standards respecting the appropriate supply, distribution, and organization of health resources. They emphasized that such standards were needed by health planning agencies to guide them in making proper plans and decisions. The new Administration was urged to devote early and aggressive efforts to this task.

In August 1977, the Office of the HEW Secretary decided to focus the initial issuance of the guidelines on short-term opportunities for containing hospital costs and improving the quality of certain hospital services. Through containment of the relatively rapid increases in hospital costs, scarce resources could be preserved to help attain goals with higher priority. It was planned to address goals in later issuances of the guidelines.

Intensive staff effort was devoted to developing additional statements concerning proposed standards for certain specialized services. The October 1976 draft had included proposed statements on the supply and occupancy of general hospital beds. The monographs prepared earlier regarding specialized medical services, as well as many other studies and reports, were analyzed and used in developing potential statements.

Proposed statements were published in the Federal Register, as a notice of proposed rulemaking, on September 23, 1977 (*17*). They concerned 11 subjects:

I. General hospitals—bed-population ratio
II. General hospitals—occupancy rate
III. Obstetrical services
IV. Pediatric inpatient services—number of beds
V. Pediatric inpatient services—occupancy rates
VI. Neonatal intensive care units
VII. Open heart surgery
VIII. Cardiac catheterization unit services
IX. Radiation therapy
X. Computed tomographic scanners
XI. End-state renal disease services

All these statements were standards respecting the supply, distribution, and organization of health resources. There were no statements of health planning goals; however, the aim of reducing the rate of increase in hospital costs through constraints on hospital capacity was implicit.

Table 2. Response to some statements in the July and October 1976 draft guidelines

Item	Agree as is		Agree with changes		Disagree		Other [1]	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Infant mortality rate should be less than 12 per 1,000 live births	739	57	201	15	77	6	283	22
Deaths from accidents and violence should be less than 60 per 100,000 persons	733	56	204	16	109	8	262	22
Health promotion should be extended through individual and community actions	741	67	72	7	24	2	262	24
Knowledge and capabilities of persons to obtain an adequate diet should be increased.	938	71	227	17	58	4	104	8
Every person should have access to emergency and primary health care services and to appropriate specialized, long-term and rehabilitative services	743	59	191	15	36	3	288	23
Health care services should be linked to other social and human services	879	65	216	16	112	8	154	11
Sources of primary medical and dental care should be available within 30 minutes, except under extraordinary circumstances	697	57	184	15	140	12	195	16
There should be no less than 1 primary care physician per 3,500 persons, except under extraordinary circumstances	681	56	161	13	124	10	257	26
The ratio of non-Federal short-term hospital beds to population should be less than 4 beds per 1,000 persons, except under extraordinary circumstances	545	45	133	11	172	14	369	30

[1] No opinion and no response. Totals differ since all items were not in both drafts.

Coincidentally, the National Council on Health Planning and Development met formally for the first time the day of publication of the Federal Register notice. The organization of the Council had been delayed substantially because of difficulties in identifying members who met the various characteristics for affiliation with the local and State planning activities set forth in the law. The proposed guidelines were presented to the new Council for consideration and review. The timing of these events led to questions concerning the commitment to advance consultation with the National Council.

A 60-day period was set for public review and comment. During that period, five public meetings were held in Washington, D.C., to discuss the proposed standards; panels of professional and consumer representatives provided comments and then the meetings were opened to public participation. Toward the end of the 60 days, it became apparent that an unanticipated amount of controversy was developing. Hundreds and then thousands of letters poured in, indicating concern about the proposed guidelines. Most writers were rural residents and were alarmed that the only local hospital might be closed.

Other writers objected strenuously to the rigidity that was perceived in the proposed standards. These critics were concerned that HEW might be attempting to impose uniform and arbitrary standards across the nation without regard for special local conditions and needs. Many objected that the Secretary was extending his role and authority in ways that would upset and might destroy local health planning.

Still other writers objected to particular features of individual standards included in the proposed materials. Many were especially disturbed by the suggested standard for obstetrical services; respondents anticipated that many small maternity units might be closed and that pregnant women might be forced to travel substantial distances for needed services.

Objections to other proposed standards frequently indicated concern about the quantitative levels and questioned the data and analytical bases of the suggested standards. Some repeated the observation set forth in the Preamble to the Federal Register notice itself: "The state of the art of establishing specific quantitative resource standards is still in infancy" and concluded that all or many of the proposed standards were being issued prematurely.

Many commentators also wrote their Congressmen, Senators, and the President. It was reported that some Congressional offices received 10,000 or more letters. As a result, interest in the proposed guidelines grew in the Congress. The House Subcommittee on Health and Environment of the Committee on Interstate and Foreign Commerce, chaired by Congressman Rogers, held a special oversight hearing on October 19, 1977. During the session, many questions were raised about the bases of the proposed guidelines and their potential application in different localities, especially in rural areas. Concerns were also voiced about the adequacy of the consultation process and the delay in issuing statements of national health goals.

Toward the end of the 60 days, numerous letters—especially those from Congressmen and some national agencies—requested additional time so that all interested parties would have an opportunity to express their views. On the 59th day, the comment period was extended for an additional 17 days, through December 9, 1977.

In a November 30, 1977, letter to each member of Congress, the HEW Secretary, Joseph A. Califano, Jr., attempted to alleviate the major concerns. He wrote:

> *Rural and community hospitals*—The guidelines currently provide for exceptions for rural hospitals and exempt such hospitals from the standards if they provide services to patients who would otherwise be more than 45 minutes travel time from a hospital. In response to the comments we have received, we intend to clarify and broaden the exceptions applicable to rural and community facilities. . . . Our objective is to improve access to needed, high quality health care for those living in rural and other underserved areas.
>
> *Obstetrical units*—The Department recognizes that the currently proposed standard for obstetrical units may be too strict. We intend to review this standard carefully and to revise it appropriately to take into account the objections that have been raised.
>
> *Local control*—Nothing in the National Health Planning Act or in the proposed guidelines would or could take decisions concerning individual facilities out of local hands. The guidelines give local and State agencies national benchmarks to help in drawing up local and State plans. The plans should, and indeed must, recognize special local circumstances and requirements, and the guidelines will provide for recognizing such circumstances.

The Secretary's letter also emphasized:

> These guidelines are directed at guiding the development of local plans concerning the organization and delivery of health services. They do not include any Federal authority to close any hospitals or to eliminate any services. Neither the Act nor the guidelines can require any local agency, any State Agency, or the Secretary to close any hospital or hospital services.
>
> The planning process established by the National Health Planning Act represents a critical element in our hopes to ensure access to quality health care and to hold down costs. Strong workable national guidelines are critical to that process. We intend to evaluate carefully all the comments on the proposed guidelines and to revise them in a careful and responsible manner.

On December 6, the House of Representatives

passed, by a vote of 357 to 0, a Concurrent Resolution on this subject. The resolution stated: "It is the sense of Congress that the National Health Planning Guidelines should include sufficient flexibility to allow a Health Systems Agency to recognize special characteristics in rural areas and, on the basis of those special characteristics, to establish a health systems plan that varies from the national guidelines, in order to provide necessary health care services to rural residents." On December 5, a letter with the signatures of 49 Senators was sent to the HEW Secretary expressing similar sentiments.

Altogether, some 55,000 comments were received by HEW. About 43,000 (80 percent) were from persons who appeared to be consumers (table 3). Most of them lived in small towns and rural areas. Some were form letters and others included similar language. Many appeared to have been prompted by newspaper reports and advertisements and State or community campaigns organized by hospital associations and others. Class projects to petition HEW were organized by some teachers of elementary classes and high school students.

Almost 80 percent of the public comments were from three States—Texas, Iowa, and Montana (table 4). In many areas of these States the threat of closing the local hospital (perhaps following earlier losses of schools, post offices and businesses) seemed to endanger the economic survival of the community and upset existing arrangements for health care.

About 1,000 comments were received from national, State, and local health agencies. These included statements from about 60 national associations, about half the State and local health planning bodies, and the hospital associations and medical societies in the majority of States. The HEW staff extensively reviewed the public comments, and a series of reports by a contractor tabulated and categorized them for analysis (*18*). A series of potential modifications were drafted.

Table 3. Responses to Federal Register notices by type of respondent

Type of respondent	Sept. 23, 1977 notice		Jan. 20, 1978 notice	
	Number	Percent	Number	Percent
Consumers	50,266	91	380	44
Providers	3,709	7	244	28
Health associations	307	1	115	13
Planning agencies	204	1	65	8
Other	578	1	64	8
Total	55,064	101	868	101

The National Council on Health Planning and Development, which, as noted, had first reviewed the proposed guidelines on September 23, 1977, concentrated on them during meetings in October, November, and December. It passed 11 resolutions providing recommendations to the Secretary. Its major recommendation was to add a "general exception" provision that would specifically indicate that local health systems agencies might make adjustments in the nationally promulgated standards to meet special local conditions and circumstances (*19*).

On January 20, 1978, a revised notice on the national guidelines was published (*20*). Although it had been planned to issue the revised material as regulations, the HEW Secretary decided that it would be best, "in view of the earlier concerns and responses," to issue them as a second notice of proposed rulemaking and to provide an additional period of 30 days for public comment. This approach was commended by many and helped further to relieve the tension.

The revised notice included major revisions. A general provision was added emphasizing the responsibilities of local health systems agencies to analyze and consider carefully the application of the guidelines to local conditions and needs and that indicated that:

whenever a health systems agency concludes, on the basis of a detailed analysis, that development of a Health Systems Plan

Table 4. Responses to Federal Register notices by geographic areas

Geographic areas	Sept. 23, 1977 notice		Jan. 20, 1978 notice	
	Number	Percent	Number	Percent
Texas	22,632	41	311	36
Iowa	11,058	21	96	11
Montana	9,923	18	5	1
Other Mid-western States (HEW Regions 5 and 7)	5,590	10	199	23
Other Southwestern States (HEW Region 6)	2,634	5	18	2
Western States (HEW Regions 8, 9, and 10)	1,345	2	65	8
Southern States (HEW Region 4)	836	1	43	5
Eastern States (HEW Regions 1, 2, and 3)	514	1	128	15
Other	532	1	3	—
Total	55,064	100	868	101

consistent with one or more of the standards . . . would result in:

1. residents . . . not having access to necessary health services;
2. significantly increased costs of care for a substantial number of patients in the area; or
3. the denial of care to persons with special needs resulting from moral and ethical values;

. . . the agency may include in the Health Systems Plan a special adjustment of the standard or standards which will avoid this result."

It was also specified that the plan should include detailed justification for the adjustment and documentation of related circumstances, and that proposed adjustments are to be reviewed by the State health planning and development agency and the statewide health coordinating council; the council determines whether the adjustment will be part of the State health plan.

The general provision also required adjustment to take into account (*a*) the special needs and circumstances of health maintenance organizations and (*b*) the services available to local residents from Federal health care facilities. The first adjustment reflected a specific congressional intent and the second responded to the criticism that the original issuance had not adequately considered Federally managed health care institutions.

There was discussion, in the preamble to the new notice, of the likelihood that some local HSAs might need to adjust a quantitative standard upward or downward to meet special local situations. The importance of basing such adjustments on careful analyses was emphasized. It was indicated that the Secretary and HEW staff would not act on individual adjustments, but rather their review would focus on patterns of changes to determine whether the local agencies were performing their planning functions in conformance with the law. The Preamble pointed out: "The initial Guidelines thus reflect a careful balance between the Federal role in providing national health planning leadership and guidance and the needs of local and State agencies to take account of local health conditions and requirements."

Other changes addressed the concerns of rural areas. Specific changes were made in 7 of the 11 standards to clarify or broaden the provision dealing with rural conditions. For example, in the standard concerning hospital bed supply, the special provision for rural areas was changed to refer to 30 minutes' travel time rather than 45 minutes. The standard dealing with pediatric inpatient services was limited to urbanized areas.

A number of individual standards were also changed in important ways. For example, the standard for obstetrical services was revised substantially to emphasize regionalized systems of care and give major attention to more complicated services provided in more expensive facilities. A similar approach was adopted for neonatal special care units. The standard for CT scanners was modified to focus on a minimum number of medically necessary patient procedures and to encourage utilization review systems. Throughout the notice, the bases and rationale for the standards were elaborated on (*21*).

The public response to the second notice was much less extensive; there were about 900 comments. Some commended the changes made and endorsed the new guidelines; for example, an editorial in the Des Moines Register concluded: "The modified proposals strike a reasonable balance between local management and the Federal government's proper concern for waste and inefficiency in the health care system." However, the majority of comments expressed continued concern about either the general approach or particular provisions or questioned the capacity of local agencies to make appropriate analyses and adjustments. More professionals than consumers responded in the second round (table 3). The geographic distribution of commentators changed somewhat (table 4).

In response to these further comments a few additional modifications were made. A general provision was added indicating that, if a State set higher minimum target levels or lower maximum levels, they are to be used. It was emphasized that hospital occupancy rates should be based on medically necessary hospital care and that the standard should be applied so that increases in occupancy rates result from decreases in bed use and supply to the maximum extent possible. The standard concerning open heart surgery was modified to recognize a single team working in a number of institutions. The standard concerning CT scanners was extended to clarify the definition of "patient procedures" and to review further the considerations involved in formulating the standard; the changing character of the field was noted, and a commitment was made to monitor developments carefully and to make changes as indicated, preferably toward a population-based standard. Confidence was expressed in the abilities of local HSAs to make the necessary analyses, especially in view of recent increases in staff.

The initial guidelines (see pp. 416-17) were issued as regulations on March 28, 1978 (*22*). They are to be reflected in health systems plans established after December 31, 1978. To facilitate discussions and

analyses of these guidelines, a series of conferences was planned through the 10 Centers for Health Planning during the summer and fall of 1978. The regulations were documented in the fourth volume of Papers on the National Guidelines for Health Planning (*23*).

Further Issuances

The second issuance of the national guidelines is to be concerned with health planning goals. As noted, the first issuance of the guidelines focused entirely on resources standards. The second is to focus on the other aspect of the statutory definition of national guidelines, that is, statements of national health planning goals.

As discussed previously, the draft of October 1976 proposed 4 goals and 17 subgoals. In the fall of 1977, a PHS task force reevaluated and revised these materials in light of the comments received and later information. It was decided to focus the first statement of goals on three subjects—health status, health promotion and disease prevention, and access to services at a reasonable cost.

The National Council on Health Planning and Development reviewed the proposed goals in draft form at its January and February 1978 meetings and passed five resolutions with recommendations. At its April meeting, the Council recommended that priority consideration be given to a smaller number of subgoals in which measurable gain might be achieved in the near future and that further attention be given to the development of strategies for achieving these goals. These priorities included:

First group
- Reducing infant mortality
- Increasing immunization rates
- Preventing communicable diseases
- Extending organized systems of care

Second group
- Strengthening preventive health services
- Reducing the incidence of alcoholism
- Assuring the effectiveness and safety of clinical procedures

Congressional committees considering the extension of the Health Planning Act in the spring of 1978 reviewed the development of the national guidelines. While no fundamental changes were proposed by the committees, modifications were recommended to emphasize the importance of advanced consultation with the public and the National Council, to require periodic progress reports and an annual review involving feedback from local and State plans and implementation, and to relax the requirement that local plans be consistent with the national guidelines. Extension of the national health priorities was also proposed to emphasize cost containment and improve efficiency, the discontinuation of unneeded services and facilities, and the strengthening of community mental health services (*24, 25*).

Issues

Experience has confirmed that the development of National Guidelines for Health Planning is difficult. The first issuance was about 22 months late. Future experiences will tell whether it is a useful effort.

The issuance of such material by regulation is without precedent. Many earlier bodies have attempted to contribute to national health policy, but usually they have viewed only a small part of the broad world of health affairs (*10a*). Two recent national conferences reviewed current conditions concerning national health policy and issued reports, but neither attempted to define specific health goals or resource requirements on a systematic basis (*26, 27*).

Congress has usually been jealous of its prerogatives in setting policy. The first Senate Committee Report on the new Health Planning Act pointed out: ". . . the Committee wishes to reemphasize ultimate Congressional authority and responsibility for developing the basic framework for Federal health policy through legislative action . . ." Congress has passed a proliferation of health laws in recent years; there have been about 150 major national health laws since 1935 (*10b*). The programs that these laws established have tended to be categorical and independent, while mechanisms for coordination and integration have been very weak.

Recent Presidents have frequently stated their health policies in formal messages. These statements usually are designed to serve the immediate interests and objectives of the Executive, and lack of continuity and permanence has usually not been viewed as a serious shortcoming. Occasionally, a HEW Secretary or an Assistant Secretary for Health has attempted to issue statements on national health policy (*28, 29*), but these efforts have tended also to be ephemeral.

Efforts to establish an ongoing mechanism for formulating and articulating health policy are not without risks (*10*). Some have argued it is futile to attempt to order goals and priorities in the complex, pluralistic health world of the United States. Others have argued it is unwise even to try, mischievous at best, and dangerous at worst. Formal efforts may help entrench existing arrangements; they can oversimplify or focus on the wrong issues; they can be too broad in a search for consensus or too narrow

in the pursuit of success. Goal setting can be a diversion from needed actions.

However, there can be offsetting benefits. Goals and standards can help focus attention on societal and program aims and values. They can help measure progress, further accountability, and improve coordination. They can stimulate reexamination and redirection of resource allocation and help ensure that incremental actions are aimed at desired ends.

Goal setting and standards development need not be perfect to be useful. A leader in health planning has given this prescription: "National goals should be stated in sufficient detail to provide meaningful guidance but brief enough so that they become widely known and understood. They should be sufficiently specific to be useful, but not so specific as to serve to impede progress, initiation, initiative, and innovation" (*30*).

The process of developing National Guidelines for Health Planning is influenced by, and also contributes to, four more general issues. The brief review of these issues that follows may encourage more extended consideration of these topics.

Policy development. The congressional mandate to formulate National Guidelines for Health Planning indicates that previous planning efforts have been inadequate. What is there about the current undertaking, though, that makes success or progress more likely? Perhaps the key feature is the apparent commitment in the legislation to a long-term, reiterative process.

The initial development of the national guidelines has inevitably been incomplete and imperfect. For example, little attention was given to facilities and services providing long-term care, and most standards are not population based. If a commitment to the development of such guidelines is maintained, though, future issuances can reflect corrections and refinements based on accumulating experience, knowledge, and understanding.

The original drafts of the national guidelines,

Initial Issuance of National Guidelines for Health Planning

§ 121.201—General Hospitals—Bed Supply

(a) *Standard.* There should be less than four non-Federal, short-stay hospital beds for each 1,000 persons in a health service area except under extraordinary circumstances.

§ 121.202—General Hospitals—Occupancy Rate

(a) *Standard.* There should be an average annual occupancy rate for medically necessary hospital care of at least 80% for all non-Federal, short-stay hospital beds considered together in a health service area, except under extraordinary circumstances.

§ 121.203—Obstetrical Services

(a) *Standard*

(1) Obstetrical services should be planned on a regional basis with linkages among all obstetrical services and with neonatal services.

(2) Hospitals providing care for complicated obstetrical problems (Levels II and III) should have at least 1,500 births annually.

(3) There should be an average annual occupancy rate of at least 75% in each unit with more than 1,500 births per year.

§ 121.204—Neonatal Special Care Units

(a) *Standard*

(1) Neonatal services should be planned on a regional basis with linkages with obstetrical services.

(2) The total number of neonatal intensive and intermediate care beds should not exceed 4 per 1,000 live births per year in a defined neonatal services area. An adjustment upward may be justified when the rate of high-risk pregnancies is unusually high, based on analyses by the HSA.

(3) A single neonatal special care unit (Level II or III) should contain a minimum of 15 beds. An adjustment downward may be justified for a Level II unit when travel time to an alternate unit is a serious hardship due to geographic remoteness, based on analyses by the HSA.

§ 121.205—Pediatric Inpatient Services—Number of Beds

(a) *Standard.* There should be a minimum of 20 beds in a pediatric unit in urbanized areas. An adjustment downward may be justified when travel time to an alternate unit exceeds 30 minutes for 10% or more of the population, based on analyses by the HSA.

§ 121.206—Pediatric Inpatient Services—Occupancy Rates

(a) *Standard.* Pediatric units should maintain average annual occupancy rates related to the number of pediatric beds (exclusive of neonatal special care units) in the facility. For a facility with 20-39 pediatric beds, the average annual occupancy rate should be at least 65%; for a facility with 40-79 pediatric beds, the rate should be at least 70%; for facilities with 80 or more pediatric beds, the rate should be at least 75%.

§ 121.207—Open Heart Surgery

(a) *Standard*

(1) There should be a minimum of 200 open heart procedures performed annually, within three years after initiation, in any institution in which open heart surgery is performed for adults.

(2) There should be a minimum of 100 pediatric heart operations annually, within three years after initiation, in any institution in which pediatric open heart surgery is per-

adopted a "buffet" approach to policy development. In view of the uncertain nature and direction of the new enterprise, a variety of offerings of different character and tastes were presented. This approach was aimed at testing the nature and extent of the nation's interests and preferences. It also sought to provide a relatively full, if mixed, plate of options for future consideration.

Six criteria were articulated to assist in selecting guidelines for initial development:

1. A statement must be relevant to the statutory mission, that is, it must lead in some way to improved access, better quality care, or cost containment;
2. It should address an important health issue;
3. It should be consistent with other health policy statements in Federal law or regulation;
4. It should be susceptible to achievement through program action;
5. It should be potentially useful to Health Systems Agencies and others and;
6. It should be timely as a national statement.

As in other aspects of health planning, a key aspect of guideline development is a high degree of public visibility and a broad scope of public participation. Extensive involvement, even beyond that required by the law, was sought early in the process. To the extent that the controversy over the initial issuance of the guidelines extended interest in and understanding of this process, the long-term impact of the controversy can be positive.

The law provides that the Secretary shall revise the guidelines periodically. The final preamble to the first issuance indicated a commitment to "periodic review and revision as knowledge is increased concerning the most appropriate configuration of resources to provide services which meet the health needs of the population with a minimum of duplication." Such a concept can be a key to continuing progress and meaningful impact.

Technology assessment. The development of resource standards, a principal feature of the national guidelines, depends upon knowledge of the appropriate

formed, of which at least 75 should be open heart surgery. (3) There should be no additional open heart units initiated unless each existing unit in the health service area(s) is operating and is expected to continue to operate at a minimum of 350 open heart surgery cases per year in adult services or 130 pediatric open heart cases in pediatric services.

§ 121.208—Cardiac Catheterization

(a) *Standard*

(1) There should be a minimum of 300 cardiac catheterizations, of which at least 200 should be intracardiac or coronary artery catheterizations, performed annually in any adult cardiac catheterization unit within three years after initiation.

(2) There should be a minimum of 150 pediatric cardiac catheterizations performed annually in any unit performing pediatric cardiac catheterizations within three years after initiation.

(3) There should be no new cardiac catheterization unit opened in any facility not performing open heart surgery.

(4) There should be no additional adult cardiac catheterization unit opened unless the number of studies per year in each existing unit in the health service area(s) is greater than 500 and no additional pediatric unit opened unless the number of studies per year in each existing unit is greater than 250.

§ 121.209—Radiation Therapy

(a) *Standard*

(1) A megavoltage radiation therapy unit should serve a population of at least 150,000 persons and treat at least 300 cancer cases annually within three years after initiation.

(2) There should be no additional megavoltage units opened unless each existing megavoltage unit in the health service area(s) is performing at least 6,000 treatments per year. (3) Adjustments downward may be justified when travel time to an alternate unit is a serious hardship due to geographic remoteness, based on analyses by the HSA.

§ 121.210—Computed Tomographic Scanners

(a) *Standard*

(1) A Computed Tomographic Scanner (head and body) should operate at a minimum of 2,500 medically necessary patient procedures per year, for the second year of its operation and thereafter.

(2) There should be no additional scanners approved unless each existing scanner in the health service area is performing at a rate greater than 2,500 medically necessary patient procedures per year.

(3) There should be no additional scanners approved unless the operators of the proposed equipment will set in place data collection and utilization review systems.

§ 121.211—End Stage Renal Disease (ESRD)

(a) *Standard.* The Health Systems Plans established by HSAs should be consistent with standards and procedures contained in the DHEW regulations governing conditions for coverage of suppliers of end-stage renal disease services, 20 CFR Part 405, Subpart U.

Note

Discussion of the standards, including their rationale and the bases for potential adjustments, may be found in the Federal Register of March 28, 1978 (Part IV) or in the fourth volume of Papers on the National Health Guidelines, "National Guidelines on Health Planning." DHEW Publication No. (HRA) 78-643, U.S. Government Printing Office, Washington, D.C., 1978.

and efficient use of existing and new technology. The initial issuance of the guidelines recognized that "the state of the art of establishing specific quantitative resource standards is still in its infancy."

The importance of this deficiency has been increasingly recognized in recent years (*12a, 31*). Widespread uncertainty, combined with a cultural tendency to assume that more resources are probably better, has had an extraordinary impact on health care costs. HEW is planning to strengthen substantially its technology review and assessment activities (*32*).

The initial issuance of the resource standards for the national guidelines took place after extensive review of available data and public comments. The capacities of the National Library of Medicine and the National Health Planning Information Center were used. Earlier work of the Institute of Medicine, the Committee on Perinatal Health, the Inter-Society Commission on Heart Disease Resources, and the American College of Radiology were especially important. The Department concluded that "while it recognized that the process of developing quantitative standards is still in its early stages, the Department believes that sufficient progress has been made to support the standards as issued" (*20*).

The difficulties of developing and applying resource standards effectively are great (*33*). Since much contemporary medical practice depends upon the availability of substantial institutional resources, the standards can have an important impact. They need to be directly linked to related activities of the Medicare program, the Food and Drug Administration, the National Institutes of Health, and Professional Standards Review Organizations.

Changing conditions and knowledge require continuing reevaluation of both new and existing technologies and practices. Although standards are aimed at disciplining planning and decision making in the health field by emphasizing resource constraints, they are not intended to become barriers to desirable innovations. Perhaps the most important impact of the initial efforts will be to increase the attention and analyses devoted to these complex matters.

Intergovernmental relations. Both the national guidelines and the health planning program as a whole require balancing of national, State, and local activities and interests. They also depend upon actions by numerous private groups, in line with the pluralistic quality of the American health scene. Such an approach is in the tradition of most major social programs in the United States, but it involves continuing tensions and new accommodations.

As discussed, a principal concern of the authors of the statutory provision calling for national guidelines was that coherent statements of national health policy be available to assist local and State health planners since the lack of such guidance had been a serious deficiency of earlier health planning programs. Many persons felt that the initial issuance of the guidelines threatened to upset the appropriate balance of national and local activities and roles; some feared that HEW would close local services or cut off Medicare payments unless there was strict compliance. There was much concern that "top-down" dictation might replace "bottoms-up" planning. There was fear that local voluntary participation might be negated and that local agencies might become largely agents of the Federal Government.

Subsequent releases attempted to alleviate these anxieties and concerns. The critical role of local HSAs in planning and in the analysis and application of the guidelines was strongly reemphasized. The purpose of the guidelines to provide benchmarks for local planning was clarified.

State agencies also have critical roles in considering and using the guidelines (*34*). State health plans and State medical facilities plans are to reflect their use, as will the criteria adopted by each State and by local agencies for certificates of need, review of new institutional health services and the appropriateness of existing institutional health services, and other mandated reviews. Studies of intergovernmental relations have indicated that Federal programs can significantly affect the agenda of local and State agencies even though they seldom result in radical or rapid changes in their objectives or activities (*35*).

Public Law 93–641 calls for health systems agencies to develop health plans that are both "responsive to the unique needs and resources of the area" and "which take into account and (are) consistent with the national guidelines . . . respecting supply, distribution and organization of health resources and services." Thus, the agencies are challenged to balance local and national factors, a feat which often calls for a high level of analytical and negotiating skills.

The history of the Federal system has demonstrated that the balancing of national and local interests is not only feasible but that such accommodations can be valuable sources of ideas and vitality. Thus, the development of national guidelines and the health planning program can contribute to the enrichment of the ongoing American constitutional experiment (*36*).

Social learning. Changes in complex social systems are not easily attained. Established agencies and activities confront new interests and demands. However, change is inevitable as knowledge expands and conditions and values alter. Opportunities for public learning become critical in helping society learn to identify, analyze, and solve its problems (*37*).

The national guidelines, as well as other aspects of the health planning program, provide instruments for society to learn better ways of dealing with health matters. The Preamble to the guidelines emphasizes "that Health Systems Plans can and should be important occasions and vehicles for advancing public understanding of (health) issues and other factors contributing to rises in health care costs and other pressing health problems. Health Systems Plans will be of little value if they do not seriously address these issues."

For example, one of the most important outcomes of the initial issuance of the national guidelines may be the concentration of additional attention and efforts on the development of standards. The discussions and debates over this material provide occasions to learn the shortcomings, as well as the strengths, of past and current attempts to assess existing and new medical technologies and practices.

Similarly, the increased use of and dependence on professional health services, a major contributor to the expansion of health expenditures, requires broad public and professional reexamination. Many look to the health system for support that others provided, in less expensive and no less effective ways, in the past. A recent poll indicated notable discrepancies between the opinions of the public and health leaders regarding needs for hospital beds (table 5). Discussions and debates about the national guidelines and health plans can further public learning about the appropriate allocation and extension of health resources and the national wealth.

The Health Planning Act sets "the achievement of equal access to quality health care at a reasonable cost" as a national priority. Many believe there are irreconcilable contradictions in this statement. If these aims are to be reconciled, the nation must learn new ways to organize and provide health services in an economical manner that achieves both equity and quality (*38*). To this end, the first statement of the goals emphasizes the importance of strengthening preventive and ambulatory services.

Conclusion

The initial development of the national guidelines has consumed 3 years of substantial effort. The process has attracted increasing interest and attention among health professionals and the public. It has involved episodes of bureaucratic delay and considerable controversy.

National guidelines have now been issued for widespread consideration and future application throughout the nation. These actions, though, are but the first steps of a long, continuing process. In the future, these guidelines will need to be modified, refined, and extended.

If the guidelines are to be most meaningful and useful, they will require the attention and efforts of private and public groups across the nation. They can help advance learning about and action on health issues of importance. In turn, they can respond to and reflect changing attitudes and knowledge.

Table 5. Views on the supply of hospital beds. Responses (in percentages) to two questions

1. Some people say there are more beds available than are really needed, and this increases the costs of hospital care. Other people say that all the beds are necessary. On balance, which do you agree with?
2. Would you support or oppose a policy which would reduce costs by reducing the number of hospital beds in your community if this meant that, on occasion, people would have to wait to get a bed?

Type of respondent	Question 1			Question 2		
	Too many beds	All beds are needed	Not sure	Support	Oppose	Not sure
Public	12	71	17	21	65	14
Hospital administrators	38	54	8	58	42	...
Hospital trustees	49	49	2	51	46	3
Physicians	38	53	9	50	44	7
Health insurers	97	3	...	93	7	...
Congress	79	15	7	66	30	5

Source: Hospital Care in America. A National Opinion Research Survey of Consumers, Government Officials, and Health Care Community Attitudes Toward Health and Hospital Care. Conducted by Louis Harris and Associates, April 1978.

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