Regulatory and Review Functions of Agencies Created by the Act

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A MAJOR RESPONSIBILITY for planning for health care delivery within their respective geographic areas is given to the agencies created by the National Health Planning and Resources Development Act of 1974. The act, however, goes beyond merely giving these agencies the responsibility of putting together comprehensive and viable plans—it also provides the tools by which the agencies can implement these plans. Among these tools are the regulatory and review activities that the agencies are required to perform. Grouped into four major areas, these activities are (*a*) review of new institutional health services, (*b*) review of existing institutional health services, (*c*) regulation of rates for provision of health care, and (*d*) review of proposed uses of funds provided by Federal programs.

Review of New Institutional Health Services

The large increase in health care costs during the past decade has attracted attention at both State and Federal levels. From 1960 to 1973 the national expenditure for health care more than tripled, and its overall percentage of the GNP rose from 5.2 to nearly 8 percent. In 1974, expenditures for personal health care exceeded $100 billion; approximately $40 billion of this amount was contributed by Federal, State, and local governments (*1*). These major increases in costs were accompanied by strong demands for public regulation of the health care industry.

The large increases in hospital costs appear to stem in large part from the creation of an excess of hospital beds, which in turn has led to under-utilization. The operation of a hospital bed, full or empty, each year costs an estimated one-third of its initial cost, owing to the high overhead costs of hospitals (*2*). The availability of Federal and other reimbursement has provided a significant financial incentive for hospital construction. Under the widely used cost-reimbursement systems, the cost for each bed—used or unused—is figured into the allowable rate paid to hospitals. As a result, most States have an oversupply of beds, in excess of the number allowed for emergency situations, seasonal fluctuations, and the like. Moreover, the duplication of special hospital units, such as those for open heart surgery or cancer irradiation, has significantly increased costs and possibly decreased the quality of available care. The quality consideration comes about because health care personnel may not have a sufficient number of patients to maintain a high level of proficiency for an underused service.

In response to the rising costs of health care, oversupply of inpatient beds, and unnecessary duplication of services, a number of States enacted certificate of need statutes. Most of these statutes sought to control the building of new health facilities or the expansion of existing ones by withholding licensure if a need could not be justified. The majority of these States relied on the State and areawide comprehensive health planning agencies, established by the 1966 Partnership for Health Act (Public Law 89–749), to certify the need for proposed construction.

The first of the State laws was the Metcalf-McCloskey Act passed by the State of New York in 1964 as the result of a study by a joint legislative committee. Often with support from State hospital associations, other State certificate of need laws followed New York's lead. Maryland and Rhode Island enacted such statutes in 1968, and Connecticut and California followed in 1969. Since that time, 25 additional certificate of need laws have been enacted. The North Carolina statute was overturned by the State Supreme Court in early 1973, thus reducing the number to 29, as of September 30, 1975.

With the passage of the Social Security Amendments of 1972, the Federal Government for the first time became formally engaged in the certificate of need concept. Under section 1122 which this law added to the Social Security Act, States were permitted to designate State agencies to determine the consistency or inconsistency of a capital expenditure proposed by a health care facility or health maintenance organization with areawide or State plans. When the State agency found that such proposed capital expenditures were inconsistent with these plans, the Secretary of DHEW could withhold a portion of the health facility's reimbursement under the Medicare, Medicaid, or Maternal and Child Health Programs. The portion permitted to be withheld is only that attributable to the capital expenditure for the unneeded construction and might be a relatively small amount, especially in the case of existing facilities considering moderate expansion. Beyond this, however, the review requirement appears to have had an impact on the availability of capital because commercial lenders and governmental loan programs usually require "1122 approval" before agreeing to help finance a health facility construction project.

The section 1122 review program began to operate in a few States in early 1973, although the final Federal regulations for its implementation were not published until November 1973, and most States did not begin to sign agreements to implement the law until early 1974. A few States, including some with strong certificate of need laws, elected not to sign an agreement with the Secretary. The States with certificate of need statutes and section 1122 programs as of September 30, 1975, are shown in the table. Only West Virginia had neither program as of that date.

The enactment of the National Health Planning and Resources Development Act in January 1975 gave an increased impetus to the certificate of need concept.

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States with certificate of need statutes and section 1122 programs, as of September 30, 1975

State	Year certificate of need enacted	Effective date of section 1122 agreement
Alabama	....	9/18/73
Alaska	....	4/01/74
Arizona	1971	.....
Arkansas	1975	7/01/73
California	1969	.....
Colorado	1973	3/01/74
Connecticut	1969	.....
Delaware	....	7/01/73
Florida	1972	1/01/73
Georgia	1974	2/27/74
Hawaii	1974	8/16/73
Idaho	....	2/01/74
Illinois	1974	.....
Indiana	....	7/01/73
Iowa	....	3/07/73
Kansas	1972	.....
Kentucky	1972	3/15/74
Louisiana	....	5/16/73
Maine	....	3/01/73
Maryland	1968	2/15/74
Massachusetts	1971	.....
Michigan	1972	12/14/73
Minnesota	1971	2/25/74
Mississippi	....	6/25/73
Missouri	....	6/16/73
Montana	1975	2/26/74
Nebraska	....	2/26/73
Nevada	1971	3/15/74
New Hampshire	....	4/01/73
New Jersey	1971	2/28/74
New Mexico	....	7/01/73
New York	1964	2/28/73
North Carolina	....	4/02/73
North Dakota	1971	2/28/74
Ohio	....	6/28/74
Oklahoma	1971	2/27/74
Oregon	1971	3/01/74
Pennsylvania	....	3/01/73
Rhode Island	1968	.....
South Carolina	1971	3/15/74
South Dakota	1972	.....
Tennessee	1973	.....
Texas	1975	.....
Utah	....	2/26/74
Vermont	....	1/02/75
Virginia	1973	7/01/73
Washington	1971	2/01/74
West Virginia	....	.....
Wisconsin	....	9/01/73
Wyoming	....	2/28/74
Total	29	39

Section 1523 of this act requires that a State health planning and development agency, as one of its mandated functions, must "administer a State certificate of need program which applies to new institutional health services proposed to be offered or developed within the State and which is satisfactory to the Secretary." This section further specifies that the certificate of need program shall provide for review and determination of need "prior to the time such services, facilities, and organizations are offered or developed or substantial expenditures are undertaken in preparation for such offering or development, and provide that only those services, facilities, and organizations found to be needed shall be offered or developed in the State." It further establishes a two-level review system by specifying that the State agency "shall consider recommendations made by health systems agencies."

The definition of "institutional health service" is provided in the law as "the health services provided through health care facilities and health maintenance organizations (as such facilities and organizations are defined in regulations prescribed under section 1122 of the Social Security Act) and includes the entities through which such services are provided."

The Division of Regulatory Activities, a component of the Bureau of Health Planning and Resources Development, has developed the proposed regulation setting forth the minimum requirements which a State certificate of need program must meet to be "satisfactory to the Secretary," in the words of the statute. This proposed regulation, published in the Federal Register in late 1975, addressed such concerns as the minimum coverage of services offered in violation of the program, the procedures to be followed by the State in conducting its review, and the criteria to be considered before a new service could be deemed necessary. The Division is now preparing the final regulation based on comments received on the proposed rules. States, of course, are free to administer certificate of need programs that are more comprehensive or more stringent than the minimum Federal requirement.

Review of Existing Health Services

One of the more controversial of the review and regulatory functions required by the National Health Planning and Resources Development Act is the requirement for periodic reviews to determine the appropriateness of all existing institutional health services. To date, there have been few, if any, similar activities with such purpose or scope. The term "appropriateness" itself is not clearly defined but must be determined in accordance with social, economic, geographic, and political factors. The health systems agency must view appropriateness as a systemwide measure rather than as a measure confined to a single service or institution. An existing service may be duplicative on a systemwide basis and thus inappropriate for the population served by the health systems agency.

The law requires health systems agencies to perform reviews to determine the appropriateness of all existing institutional health services offered within their health service areas at least every 5 years and to complete the first cycle of such reviews within 3 years of full designation of the agency. These reviews will result in a recommendation to the State agency concerning the appropriateness of the service.

The State health planning and development agency is also required to review all existing institutional health services offered in the State at least every 5 years and, after considering recommendations submitted by the health systems agencies, to "make public its findings." The State agency must complete its findings on the appropriateness of any existing institutional health service about which a health systems agency has made a recommendation within 1 year of that recommendation.

Since the Federal regulation for the review process is still at a formative stage, the health systems agencies may have several options in terms of methods of review. For example, a review may be performed for each service on an areawide basis, on an individual institutional basis, or on the basis of a single service offered in one institution. The health systems agency and the State health planning and development agency will be required to develop and publish plans for administering this review. These plans will include the review procedures that the agencies plan to use and the methods by which they will report and use the findings of this review.

The purpose of a review for appropriateness is to identify existing problems and to correct these problems through suggestions for change. The absence of any sanction in the law indicates that Congress intended that this review have the positive effect of molding the health care system to meet areawide and State health needs. Both the Senate and House committees that developed this legislation stated clearly that the State health planning and development agency and the health systems agency were to provide assistance to institutions so that they could bring their services into conformity with areawide needs. Federal regulations pertaining to this review activity are expected in the summer of 1976.

Rate Regulation for Provision of Health Care

In addition to the regulation of proposed new health services, a major approach to controlling the cost of institutional care concerns the use of various mechanisms which affect reimbursement for this care. Traditionally, reimbursement by public and private purchasers of health care has been by (*a*) payment of reasonable costs retrospectively, (*b*) payment of charges on an indemnity basis by private insurance carriers, or (*c*) payment by individuals of the entire cost of their health care or of the costs above insurance coverage. Most States now use retrospective cost reimbursement to pay for services purchased by programs they administer.

Through the authorization of grants for rate regulation to a maximum of six State health planning and development agencies, Congress intended to give the State agencies financial assistance to demonstrate the effectiveness of mechanisms which they establish to regulate health care charges in their States. These mechanisms must meet the minimum requirements stated in the law for such a program; the most important of these are that only a fully designated State health planning and development agency is eligible for this grant, and that such an agency must obtain a recommendation from the appropriate health systems agencies before it conducts its review. The program of rate regulation contained in the National Health Planning and Resources Development Act closely parallels the prospective reimbursement authority contained in the Social Security Act. Therefore, the Department intends to implement the rate review demonstration program in conjunction with the existing activities of the Social Security Administration. The Social Security Administration has already prepared an inventory of States that have indicated their intention to regulate rates, and it is developing the regulation and procedures governing the submission of grant applications by the States.

Review of Proposed Uses of Federal Funds

The National Health Planning and Resources Development Act mandates that each health systems agency shall review and approve or disapprove each proposed use of certain Federal funds within its health service area. These Federal funds are those available through the grants, contracts, loans, or loan guarantees for programs authorized under the Public Health Service Act, the Community Mental Health Centers Act, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 for the "development, expansion, or support of health resources."

Health systems agencies are also required to review and approve or disapprove funds made available in their health service areas by the State—from a Federal allotment to the State under the forementioned acts—for grants or contracts for the development, expansion, or support of health resources. The law, however, specifically bars health systems agencies from exercising this function with respect to Federal funds appropriated for grants or contracts by the National Research Institutes (title IV), for Health Research and Teaching Facilities and Training of Professional Health Personnel (title VII), and for Nurse Training (title VIII) under the Public Health Service Act, *unless* the grant or contracts support "the development of health resources intended for use in the health service area" or support "the delivery of health services." Also, health systems agencies must review, but may only comment on, any similar proposed use of Federal funds by an

Indian tribe or intertribal Indian organization located within or specifically serving a federally-recognized Indian reservation, any land area in Oklahoma which is held in trust by the United States for Indians or which is a restricted Indian-owned land area, or a Native village in Alaska (as defined in the Alaska Native Claims Settlement Act).

The law provides further that applicants for these Federal funds may appeal to the Secretary of HEW to overturn any disapproval decision by a health systems agency. In such cases, the Secretary may not make the funds available until he has consulted the State health planning and development agency concerned and given that agency at least 30 days to comment. The funds may then be made available only if the health systems agency is given a detailed statement of the reasons for the funding despite its disapproval.

Statewide health coordinating councils have similar review and approval or disapproval responsibilities under the new program. Statewide health coordinating councils are required to review annually and to approve or disapprove any State plan and any application for allotment funds made to States under the forenamed acts. If the statewide health coordinating council disapproves a State plan and application, the Secretary may overturn the decision upon request of the Governor of the State or of another agency of the State.

Health systems agencies are given their authority to review and approve or disapprove the use of health funds in local communities "to assure appropriate coordination of the Department's health activities with the planning activities of community planning agencies," as expressed in the House committee report on the proposed legislation which became the National Health Planning and Resources Development Act (*3*). The House committee also expressed hope that "similar reviews of proposed Federal health activities . . . outside the jurisdiction of the committee will be undertaken by those responsible for them." Specifically mentioned were activities of the Departments of Labor and Defense and the Veterans Administration.

To assure that local activities funded directly by the Department are consistent with and will promote the planning and development of activities of the State and areawide health planning agencies, the health systems agency and Statewide health coordination council must do more than simply review applications. They must also work actively with persons applying for funds in the development of applications to assure that the proposed projects will meet community needs. Applicants for funds subject to review also have responsibilities in the review process. They must demonstrate that their proposals conform with the adopted plans and criteria of the health systems agencies and statewide health coordinating councils, and they should begin to work with these agencies in the early stages of development of their applications to better achieve this conformity.

The Division of Regulatory Activities is presently developing regulations to further explain these review activities. The regulations are expected to be published in the Federal Register early this year. Before they are published, however, the specific Public Health Service programs that are subject to review and approval or disapproval by the health systems agencies must be identified. Discussions are presently underway with the PHS agencies that fund programs and activities not primarily directed toward the development of health resources or the delivery of health services in particular health service areas. It is necessary to come to some agreement with these agencies to enable the health systems agencies to properly perform their mandated functions without interfering with the research and training efforts of the PHS agencies. It is anticipated that there will be many more issues to resolve when the activities of health systems agencies and statewide health coordinating councils begin to influence the distribution of Federal funds in their areas.

Conclusion

In view of the expected passage of some form of national health insurance, Congress has taken the initiative to coordinate existing health care planning and regulatory functions and to create new ones as a result of its findings concerning the status of health care delivery in the United States. The increased demand for health services that will accompany national health insurance will necessitate effective planning which can both anticipate and develop the type and quantity of services needed.

Rapidly escalating health care costs, apparently inherent in our health care delivery system, have prompted increasing Federal concern and efforts to contain these costs. Although planning agencies will continue to be concerned with promoting health care capacity in underserved areas, they will increasingly focus their regulatory and review functions on (*a*) promoting alternative methods of health care and (*b*) discouraging the growth of health care facilities where that growth will unnecessarily increase the cost of health care to the Federal Government and to the American people.

References

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