REPORT OF THE COMMITTEE

STUDYING

THE CERTIFICATE OF NEED PROCESS

February, 1982

MEMBERS:

Sen. Barbara A. Gill, Chair
Sen. Beverly M. Bustin
Rep. Sandra K. Prescott
Rep. Alfred Brodeur
Rep. Mary H. MacBride
Rep. Merle R. Nelson
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I. INTRODUCTION

In 1978, the Maine Legislature passed and the Governor signed the Maine Certificate of Need Act (PL1977, c.687). This action was necessary to comply with Federal mandates established in the National Health Planning and Resources Development Act of 1974 (PL93-641). That law requires review by a state agency of hospital expenditures for capital development, purchase of equipment and development and provision of new services. In addition to meeting the Federal requirement, the Maine Legislature intended this law to provide for quality health care at the lowest possible cost, to avoid duplication of health facilities and health services and to assure the most effective and appropriate use of State funds.

The review process established in the Certificate of Need law (CON) requires participation by various groups recognized (or required) by the Federal government: the State Health Planning and Development Agency (SHPDA), a bureau within the Department of Human Services, the Health Systems Agency (HSA) and the State Health Coordinating Council (SHCC). All three have statutorily established state or federal components and tasks; the SHCC and the HSA groups include citizen participation, with representation from both consumer and provider sectors. The SHPDA has both planning and review functions: the SHCC is primarily a planning group; and the HSA also does both planning and review.

The 1978 law established the process, the criteria for

review, and gave the Department of Human Services the authority to promulgate rules, and penalties for violating them.

Since passage of the initial Federal legislation, there have been varying efforts to have states alter their CON laws to come into conformity with the Federal laws and regulations. The compliance requirement is enforced by sanctions such as the cut-off of Federal funds for the planning process. It was this impending Federal action in the winter of 1980-81 which led to the development of legislation in the First Regular Session of the 110th Legislature to modify Maine's CON law.

There were 4 bills proposed in 1981, all of which addressed various aspects of the law, and which added varying interpretations of what needed to be done to achieve compliance - or to use the opportunity to amend other parts of Maine's law. Finding fundamental disagreement between the provider groups (mostly represented through the Maine Medical Association and the Maine Hospital Association) and the Department of Human Services, the Committee on Health and Institutional Services, which heard the bills, asked the two groups to come up with compromises which could be offered to the Committee, along with appropriate explanations and rationales.

During deliberations in the spring of 1981 among the Maine Bureau of Health Planning and Development, the Maine Health Systems Agency, Maine Blue Cross-Blue Shield, Maine Hospital Association and the Maine Health Care Association, some agreements were reached as to how to reconcile 2 of the CON bills, L.D.718 and L.D.939. However, there still remained many points of contention; and

the Federal government was working on new provisions for health planning. Therefore,the Health and Institutional Services Committee agreed to grant Leave to Withdraw to all bills affecting CON, and to study the issue.

II. STUDY PROCESS

This study was approved, with funding, by the Legislative Council in June, 1981. The legislative members were the two chairs of the Joint Standing Committee on Health and Institutional Services, Senator Barbara A. Gill (R-Cumberland) and Representative Sandra K. Prescott (D-Hampden), Senator Beverly M. Bustin (D-Kennebec), Representative Alfred L. Brodeur (D-Auburn) and Representative Mary H. MacBride (R-Presque Isle). After Representative Prescott resigned from the Legislature, her place was taken by the new House Chair of the Committee, Representative Merle Nelson (D-Portland). Dr. Edward David of Bangor representing the Maine Medical Association; Ted Hussey, Vice-President of the Maine Hospital Association, their representative; Stephen Mansfield, Executive Director of the Maine Health Systems Agency represented the planners and reviewers; Thomas Gorham, Director, Research Services, Maine Blue Cross and Blue Shield represented third-party payors; Ronald Thurston, Executive Director of the Maine Health Care Association represented the nursing home industry. Attorneys for each of the client groups and staff for the Committee also attended all meetings and provided technical support services.

From the first meeting in September, the Committee's task was to become thoroughly familiar with the provisions of the

Maine law, and the changes which were mandated by newly-promulgated Federal regulations, or the Omnibus Budget Reconciliation Act of 1981 and those changes which were permissive. This process of familiarization also involved a review of the previous history of the development of Maine's CON law, and its implementation in the succeeding 3 years. The practical experience of various members of the Committee was extremely helpful in this task. Examples of some of the material considered by the Committee in its deliberations, including the law, as amended to 1981 and various Federal announcements, are included as an appendix to this report.

Various changes at the Federal level have both permitted and required modifications of state Certificate of Need programs. The most recent changes were made through the 1981 Omnibus Budget Reconciliation Act, which increased the thresholds for review of projects. The prior thresholds for review by the state were $150,000 for new capital expenditures or for the purchase of major medical equipment, and $75,000 for the annual operating costs of a new institutional health service. The federal law now changes those thresholds to $600,000, $400,000 and $250,000 respectively.

Since states may adopt a CON program stricter than the Federal limits, one of the major tasks of the Committee was to decide which thresholds to adopt. After considerable discussion, compromises were arrived at in this area.

Once the Committee settled in to tackle the Federally-required and permissive modifications, there was a long period of

discussion over the appropriate levels of modification in the thresholds at which an expenditure would be reviewable. Debate concerned the relative merits of a lower threshold, which might capture more expenditures, versus the advisability of enacting into state law requirements which would be more stringent than those proposed by the Federal government. This discussion had both a practical and a theoretical, or ideological side. Examples were provided of the types of projects which would be subject to review, under current and proposed law and eventually bargains were struck. The eventually accepted thresholds for review were set lower (i.e., stricter) than those required by the Federal government, and higher than in present law. There was also considerable discussion about the circumstances under which new services would be reviewable. The "newness" of the service had to be determined, not only on the character of the service itself, but also on whether the service had been offered in the area - and then the area had to be defined. There was finally an agreement to accept the services as defined in the current State Health Plan (a document which is developed by the SHPDA, the SHCC, and finally approved by the Governor). A concern was expressed, and taken care of in the bill, to make sure that the Department would only be able to include in its regulations those services defined in the plan.

Considerable time was spent discussing the actual process of the review, and ways in which there can be roadblocks put in the way of an applicant by requests for additional information. From

the other side, frustration was expressed about the need to request further pieces of information, and delays caused by this. The Committee felt pleased that it had been able to work towards a compromise involving a limitation on the number of times the Department could request additional information, while also cautioning applicants that their non-compliance with requests might lead to non-approval.

In the review process, there are time limits specified during which the Health Systems Agency has a chance for review, and then must pass on the application to the Department. As part of this process, a public hearing takes place: it may be held by either the Department or the HSA, and it is possible for each to hold one or more hearings of its own. Several sessions were devoted to the need for a hearing, and the nature of the hearing. The degree of participation by those affected, how they might receive information used in determining the merits of the application, procedures for the conduct of the hearing, when the file of information would be considered closed, access to the file, communications after the close of the hearing between the Department and the applicant, whether or not that should include all those who had expressed an interest in the issue through participation in the hearing or the comment process - all were vigorously and thoroughly debated. It is probably superfluous to add that the resulting agreement was most definitely a compromise - with all its advantages and disadvantages.

Many other issues were discussed: the exact definition of various terms (e.g., "record", service, "ex parte", annual operating costs, etc.); the advisability of making only minor corrections

in Maine's law now, anticipating major changes as a result of declining Federal funding; the inter-relationship of the CON law with other current statutes, most notably the references to the HSA; and the Health Facilities Cost Review Board legislation.

After a total of 13 meetings (either the full Committee, or various subcommittees, including those which were charged with drafting particular sections and bringing them back for review and action by the full Committee) and provision of much material in written, tabular and anecdotal form the Committee at the end of January realized it could not meet its statutory deadline, and, therefore, requested an extension from the Legislative Council. This was granted, allowing the Committee four more meetings to complete its report and to prepare legislation which would, as much as possible, cover their responsibility of conformity to the Federal law, and also address some inequities, inaccuracies and inelegancies in the Maine statute.

III. CONCLUSION

At the meeting of February 11, 1982, the Committee agreed to adopt the text of the enclosed bill as encompassing the substance of their report. The bill's main features are the establishment of the criteria for review of new services, major medical equipment and capital expenditures including criteria therefor and definitions, where necessary, the procedures for initial review, and for subsequent review, where an action commenced without a certificate was later deemed to require one, the standards for conduct of the hearing, and for the decision and its publication by the commissioner.

The Committee acknowledged some areas of continued discussion which were to be addressed in other bills submitted during the current session. They, therefore, decided to leave an opportunity for further discussion and decision on such areas as the state health plan, the Health Systems Agency and the impact of dual funding on the HSA and the SHPDA until all the related bills could be appropriately dealt with in a comprehensive context of health planning and review.

IV. APPENDICES

SECOND REGULAR SESSION

ONE HUNDRED AND TENTH LEGISLATURE

Legislative Document No.

S.P. In Senate,

MAY M. ROSS, Secretary of the Senate

STATE OF MAINE

IN THE YEAR OF OUR LORD
NINETEEN HUNDRED AND EIGHTY-TWO

AN ACT to Amend the Maine Certificate of Need Law.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §303, sub-§§2-A and 2-B are enacted to read:

2-A. Annual operating costs. For purposes of section 304-A, subsection 4, paragraph B, "annual operating costs" means the total incremental costs to the institution which are directly attributable to the addition of a new health service.

2-B. Appropriately capitalized expenditures. "Appropriately capitalized expenditures" means those expenditures which would be capitalized if the project were implemented.

Sec. 2. 22 MRSA §303, sub-§3 is amended to read:

3. Capital expenditure. "Capital expenditure" means an expenditure, including a force account expenditure or

predevelopment activities, which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance and, for the purposes of this chapter, shall include capitalized interest on borrowed funds and the fair market value of any property or equipment which is acquired under lease or comparable arrangement or ~~through~~ by donation.

Sec. 3. 22 MRSA §303, sub-§§6-A and 6-B are enacted to read:

6-A. Expenditure minimum for annual operating costs. The "expenditure minimum for annual operating costs" is:

A. For services commenced between January 1 and December 31, 1983, $125,000 for the 3rd fiscal year, including a partial first year;

B. For services commenced between January 1 and December 31, 1984, $135,000 for the 3rd fiscal year, including a partial first year;

C. For services commenced between January 1 and December 31, 1985, $145,000 for the 3rd fiscal year, including a partial first year; and

D. For services commenced after December 31, 1985, $155,000 for the 3rd fiscal year, including a partial first year.

6-B. Generally accepted accounting principles. "Generally accepted accounting principles" means accounting principles approved by the American Institute of Certified Public Accountants.

Sec. 4. 22 MRSA §303, sub-§7, first sentence, as enacted by PL 1977, c. 687, §1, is amended to read:

"Health care facility" means any facility, whether public or private, proprietary or not for profit, required to obtain a certificate of need in accordance with federal laws and regulations under the National Health Planning and Resources Development Act of 1974, or any amendment, and shall include hospitals, psychiatric hospitals, tuberculosis hospitals, skilled nursing facilities, kidney disease treatment centers including free standing hemodialysis units, intermediate care facilities, rehabilitation facilities, ambulatory surgical facilities, home health care providers ~~certifiable under Title XVIII of the Federal Social Security Act of 1965, as amended,~~ and health maintenance organizations.

Sec. 5. 22 MRSA §303, sub-§§11-A and 11-B are enacted to read:

11-A. Home health care provider. "Home health care provider" means any business entity or subdivision thereof, whether public or private, proprietary or not for profit, which is engaged in providing acute, restorative, rehabilitative, maintenance, preventive or health promotion services through professional nursing and at least one other therapeutic service, such as physical therapy, occupational therapy, speech pathology, home health aides, nurse assistants, medical social work and nutritionist services, either directly or through contractual agreement, in a client's place of residence. This term does not apply to any sole practitioner providing private duty nursing services or other restorative, rehabilitative, maintenance, preventive or health promotion services in a client's place or residence.

11-B. Hospital. "Hospital" means an institution which primarily provides to inpatients by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment and care of injured, disabled or sick persons or rehabilitation services for the rehabilitation of injured, disabled or sick persons. This term also includes psychiatric and tuberculosis hospitals.

Sec. 6. 22 MRSA §303, sub-§12-A is enacted to read:

12-A. Major medical equipment. "Major medical equipment" means a single unit of medical equipment or a single system of components with related functions which is used to provide medical and other health services and which costs $300,000 or more. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services, if the clinical laboratory is independent of a physician's office and a hospital and has been determined under the United States Social Security Act, Title XVIII, to meet the requirements of Section 1861 (s), paragraphs 10 and 11 of that Act. In determining whether medical equipment costs more than $300,000, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to acquiring the equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

Sec. 7. 22 MRSA §303, sub-§13, as enacted by PL 1977, c. 687, §1, is amended to read:

13. Modification. "Modification" means the alteration, improvement, expansion, extension, renovation or replacement of a health care facility or health maintenance organization or portion thereof, including initial equipment thereof and the replacement of equipment ~~of~~ or existing buildings.

Sec. 8. 22 MRSA §303, sub-§13-A is enacted to read:

13-A. Obligation. An "obligation" for a capital expenditure is considered to be incurred by or on behalf of a health care facility:

1. When a contract, enforceable under Maine law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset;

2. When the governing board of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or

3. In the case of the donated property, on the date on which the gift is completed under applicable Maine law.

Sec. 9. 22 MRSA §303, sub-§15, as enacted by PL 1977, c. 687, §1, is amended to read:

15. Person. "Person" means an individual, trust or estate, partnership, corporation, including associations, joint stock companies and insurance companies, the State or a political subdivision or instrumentality, including a municipal corporation of the State, or any other legal entity recognized by state law.

Sec. 10. 22 MRSA §303, sub-§16, as enacted by PL 1977, c. 687, §1, is amended to read:

16. Predevelopment activities. "Predevelopment activities" means any appropriately capitalized expenditure by or on behalf of a health care facility made in preparation for the offering or development of a new health service for which a certificate of need would be required and arrangements or commitments made for financing the offering or development of the new health service; and shall include site acquisitions, surveys, studies, expenditures for architectural designs, plans, working drawings and specifications.

Sec. 11. 22 MRSA §303, sub-§17-A is enacted to read:

17-A. Rehabilitation facility. "Rehabilitation facility" means an inpatient facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent professional supervision.

Sec. 12. 22 MRSA §303, sub-§18, as enacted by PL 1977, c. 687, §1, is amended to read:

18. Secretary. "Secretary" means the United States Secretary of Health, ~~Education and Welfare~~ and Human Services and any other officer or employee of the United States Department of Health, ~~Education and Welfare~~ and Human Services to whom the authority involved may be delegated.

Sec. 13. 22 MRSA §303, sub-§22, as enacted by PL 1977, c.687, §1, is repealed.

Sec. 14. 22 MRSA §304, as amended by PL 1979, c. 375, is repealed.

Sec. 15. 22 MRSA §304-A is enacted to read:

§304-A. Certificate of need required

No person may enter into any commitment for financing a project which requires a certificate of need or incur an obligation for the project without having sought and received a certificate of need, except that this prohibition shall not apply to commitments for financing conditioned upon the receipt of a certificate of need or to obligations for predevelopment activities of less than $150,000.

A certificate of need from the department shall be required for:

1. Acquisition by lease, donation, transfer. Any acquisition by or on behalf of a health care facility under lease or comparable arrangement or through donation, which would have required review if the acquisition had been by purchase;

2. Acquisitions of major medical equipment. The following acquisitions:

A. The acquisition by any person of major medical equipment that will be owned by or located in a health care facility; or

B. The acquisition by any person of major medical equipment not owned by or located in a health care facility if:

(1) The equipment will not be used to provide services for inpatients of a hospital, but the person fails to file a written notice of intent to acquire the equipment at least 60 days prior to entering into a contract to acquire the equipment; or

(2) The department finds, within 30 business days after the date it receives a written notice of intent to acquire the equipment, that the equipment will be used to provide services for inpatients of a hospital.

There shall be a waiver for the use of major medical equipment on a temporary basis as provided in section 308, subsection 4.

3. Capital expenditures. The obligation by or on behalf of a health care facility of any capital expenditure of $350,000 or more;

4. New health services. The offering or development of any new health service. For purposes of this section, "new health services" shall include only the following:

A. The obligation of any capital expenditures by or on behalf of a health care facility which is associated with the addition of a health service which was not offered on a regular basis by or on behalf of the facility within the 12-month period prior to the time the services would be offered;

B. The addition of a health service which is to be offered by or on behalf of a health care facility which was not offered on a regular basis by or on behalf of the facility within the 12-month period prior to the time the services would be offered, and which, for the 3rd fiscal year of operation, including a partial first year, following addition of that service, absent any adjustment for inflation, is projected to entail annual operating costs of at least the expenditure minimum for annual operating costs; or

C. The addition of a health service which falls within a category of health services which are subject to review regardless of capital expenditure or operating

cost and which category the department has defined through regulations promulgated pursuant to section 312, based on recommendations from the State Health Coordinating Council;

5. Termination of a health service. The obligation of any capital expenditure by or on behalf of a health care facility which is associated with the termination of a health service which was previously offered by or on behalf of the health care facility;

6. Changes in bed complement. Any change in the existing bed complement of a health care facility, in any 2-year period, which:

A. Increases or decreases the licensed or certified bed capacity of the health care facility by more than 10% or more than 5 beds, whichever is less;

B. Increases or decreases the number of beds licensed or certified by the department to provide a particular level of care by more than 10% of that number or more than 5 beds, whichever is less; or

C. Relocates more than 10% of the health care facility's licensed or certified beds or more than 5 beds, whichever is less, from one physical plant to another;

7. Predevelopment activities. Any appropriately capitalized expenditure of $150,000 or more for predevelopment activities proposed to be undertaken in preparation for any project which would itself require a certificate of need;.

8. New health care facilities. The construction, development or other establishment of a new health care facility; and

9. Other circumstances. In the following circumstances:

A. Any proposed use of major medical equipment to serve inpatients of a hospital, if the equipment is not located in a health care facility and was acquired without a certificate of need, except acquisitions waived under section 308, subsection 4; or

B. If a person adds a health service not subject to review under subsection 4, paragraph A or C and which was not deemed subject to review under subsection 4,

paragraph B at the time it was established and which was not reviewed and approved prior to establishment at the request of the applicant, and its actual 3rd fiscal year operating cost, as adjusted with an appropriate inflation deflator promulgated by the Health Facilities Cost Review Board pursuant to sections 360 and 366, exceeds the expenditure minimum for annual operating cost in the 3rd fiscal year of operation following addition of these services.

Sec. 16. 22 MRSA §304-B is enacted to read:

§304-B. Subsequent review

Where a certificate of need has been issued, and changes occur as specified in this section, a subsequent review is required.

1. Criteria for subsequent review. The following activities require subsequent review and approval, if the department has previously issued a certificate of need and if within one year after the approved activity is undertaken:

A. There is a significant change in financing;

B. There is a change affecting the licensed or certified bed capacity as approved in the certificate of need;

C. There is a change involving the addition or termination of the health services proposed to be rendered by the facility;

D. There is a change in the site or the location of the proposed facility; or

E. There is a substantial change proposed in the design of the facility or the type of construction.

2. Procedures for subsequent review. Any person proposing to undertake any activity requiring subsequent review and approval shall file with the department, within 30 days of the time that person first has actual knowledge of the circumstances requiring subsequent review, a notice setting forth the following information:

A. The nature of the proposed change;

B. The rationale for the change including, where appropriate, an explanation of why the change was not set forth in the original application of letter of intent; and

C. Other pertinent detail subject to the procedures and criteria set forth in section 309.

The department shall, within 30 days of receipt of the information, advise that person in writing whether the proposed change is approved. If not approved, the application shall be treated as incomplete and reviewed in accordance with the application procedures in section 306-A, subsection 4. If approved, the department shall amend the certificate of need as appropriate. In either case, the department shall consult with the Health Systems Agency.

Sec. 17. 22 MRSA §306, as enacted by PL 1977, c. 687, §1, is repealed.

Sec. 18. 22 MRSA §306-A is enacted to read:

§306-A. Application process for a certificate of need

1. Letter of intent. Prior to filing an application for a certificate of need, an applicant shall file a letter of intent with the department no less than 30 days prior to the date on which the application is to be filed. The letter of intent shall form the basis for determining the applicability of this chapter to the proposed expenditure or action. A letter of intent shall be deemed withdrawn one year after receipt by the department, unless sooner superseded by an application; provided that the applicant shall not be precluded from resubmitting the same letter of intent.

2. Application filed. Upon a determination by the department, after consultation with the Health Systems Agency, that a certificate of need is required for a proposed expenditure or action, an application for a certificate of need shall be filed with the department if the applicant wishes to proceed with the project. Upon receipt of an application, the department shall immediately transmit a copy of the application to the Health Systems Agency.

3. Additional information required. Additional information may be required or requested as follows.

A. If, after receipt of an application, the department or the Health Systems Agency determines that additional

information is necessary before the application can be considered complete, the department may:

(1) Require the applicant to respond to 2 sets of requests for additional information from the department, the Health Systems Agency or both, provided that a 2nd request is directly related to the first information request or to the information provided in response to the first request; and

(2) Request, but not require, the applicant to respond to additional sets of requests for information, provided that each request is directly related to the last request or to the information provided in response to the last request.

B. The department shall immediately transmit the response to any request for information to the Health Systems Agency. The Health Systems Agency shall have 10 business days from the date on which the application or response to any information request is filed with the department in which to comment to the department upon the completeness of the application, indicating specifically and in writing any additional information which the Health Systems Agency requires before it can consider the application complete.

C. Within 15 business days after the filing of an application or response to any information request, whichever is applicable, with the department, the department shall, after considering the requirements of the Health Systems Agency, notify the applicant in writing that:

(1) The application contains all necessary information required and is complete; or

(2) Additional information is required by the department or by the Health Systems Agency. If, after receipt of the applicant's response to the 2nd or any subsequent request, the department determines that additional information is required, the notification shall also include a statement of the basis and rationale for that determination.

4. Review of incomplete application. Upon receipt of the 3rd or any subsequent notice described in subsection 3, paragraph C, subparagraph 2, the applicant must notify the department in writing that:

A. It will provide the additional information requested by the department. Following completion, it shall be entered into the next review cycle; or

B. That it is not able to or does not intend to provide the information requested and requests the application be entered into the next appropriate review cycle. In that case, the applicant shall be prohibited from submitting the information it had declined to provide into the record after the 25th day of the review cycle and the information shall not be considered in the determination to issue or to deny a certificate of need. If the applicant provides the information requested prior to the 25th day of the review cycle, the application may, at the discretion of the department, be returned to the beginning of the review cycle. Failure to submit additional information requested by the Health Systems Agency or the department may result in an unfavorable recommendation by the Health Systems Agency and may result in subsequent denial of the application by the department, as long as the denial is related to applicable criteria and standards.

5. Competitive reviews. In cases of competitive reviews, applicants shall submit additional information requested by the Health Systems Agency or the department within 30 business days or within a longer period of time, provided that the department and all competing applicants agree.

6. Automatic withdrawal. Any incomplete application shall be deemed withdrawn if the applicant fails to respond to a request for additional required information within one year of the date such request was forwarded by the department.

Sec. 19. 22 MRSA §307, sub-§1, first sentence, as enacted by PL 1977, c. 687, §1, is amended to read:

Upon determination that an application is complete, or upon receipt of a notice under section 306-A, subsection 4, paragraph B, or upon grouping of the application with other pending applications, the department shall provide for written notification of the beginning of a review.

Sec. 20. 22 MRSA §307, sub-§1, as enacted by PL 1977, c. 687, §1, is amended by adding after the 2nd sentence a new sentence to read:

The notice shall be provided to all persons who have requested notification by means of asking that their names be placed on a mailing list maintained by the department for this purpose.

Sec. 21. 22 MRSA §307, sub-§1, ¶¶C and D, as enacted by PL 1977, c. 687, §1, are amended to read;

C. A statement that a public hearing will be held during the course of a review if requested by persons directly affected by the review and the date by which the requests must be received by the department; ~~and~~

D. A description of the manner in which public notice will be given of a public hearing if one is to be held during the course of the review; and

Sec. 22. 22 MRSA §307, sub-§1, ¶E is enacted to read:

E. A statement of the manner and time in which persons may register as affected persons.

Sec. 23. 22 MRSA §307, sub-§2, as enacted by PL 1977, c. 687, §1, is repealed.

Sec. 24. 22 MRSA §307, sub-§2-A is enacted to read:

2-A. Public hearing. A public hearing shall be held during the course of a review by either the department or the Health Systems Agency, or both, if requested by persons directly affected by the review pursuant to subsection 1.

A. The department or agency shall provide notice of its hearing in accordance with the procedure described in subsection 1 .

B. Findings, recommendations, reports, analyses and related documents prepared by the staff of the agency shall be in final form and be made available to affected persons at least 5 business days prior to its hearing. The department shall make its preliminary staff report available to affected persons at least 5 business days prior to its hearing.

C. In a hearing, any person shall have the right to be represented by counsel or to present oral or written arguments and evidence relevant to the matter which is the subject of the hearing. Any person affected by the matter may conduct reasonable questioning of persons who make relevant factual allegations.

D. The department or agency shall record all hearings in a form susceptible to transcription. The department shall transcribe the recording when necessary for the prosecution of an appeal.

E. During the first 7 business days following the close of a public hearing conducted by the department, interested or affected persons may submit written comments concerning the review under consideration. The department shall provide copies of comments submitted in that manner to all persons registered as affected persons. In reviews where no hearing is held, interested or affected persons may submit comments up until the 80th day of a 90-day review cycle or the 140th day of a 150-day review cycle.

F. In the event that circumstances require the department to obtain further information from any source or to otherwise contact registered affected persons following the public hearing and submission of comments under paragraph E, or, when no hearing is held, following the 80th day of a 90-day review cycle or the 140th day of a 150-day review cycle, the department shall:

(1) Provide written notice to all registered affected persons who shall have at least 3 business days to respond; or

(2) Convene a public hearing with reasonable notice affording registered affected persons the opportunity to conduct reasonable questioning.

In either event, notwithstanding any other provision of this chapter, the time period in which decision is required shall be extended 20 days.

G. At the time the staff submits its final report to the commissioner, a copy of the report shall be sent to the applicant and a notification shall be sent to all registered affected persons. No further comments may be accepted.

Sec. 25. 22 MRSA §307, sub-§5, as enacted by PL 1977, c. 687, §1, is repealed.

Sec. 26. 22 MRSA §307, sub-§5-A is enacted to read:

5-A. Review by department. Review by the department shall consist of the following elements.

A. The department shall prepare its final staff report based solely on the record developed to date, as defined in paragraph C, subparagraphs (1) to (6).

B. After reviewing each application, the commissioner shall make a decision either to issue a certificate of need or to deny the application for a certificate of need. The decision of the commissioner shall be based on the informational record developed in the course of review as specified in paragraph C. Notice of the decision shall be sent to the applicant and to the Health Systems Agency. This notice shall incorporate written findings which state the basis of the decision, including the findings required by section 309, subsection 1. If the decision is not consistent with the recommendations of the Health Systems Agency, the department shall provide a detailed statement of the reasons for the inconsistency.

C. For purposes of this subsection, "informational record developed in the course of review" includes the following:

(1) All applications, filings, correspondence and documentary material submitted by applicants, interested or affected persons, or the Health Systems Agency prior to the termination of the public comment period under subsection 2-A, paragraph E or, if no hearing is held, prior to the 80th day of a 90-day review cycle and prior to the 140th day of a 150-day review cycle;

(2) All documentary material reflecting information generated by the department prior to termination of the public comment period or, if no hearing is held, prior to the 80th day of a 90-day review cycle and prior to the 140th day of a 150-day review cycle;

(3) Stenographic or electronic recording of any public hearing or meeting held during the course of review, whether or not transcribed;

(4) All material submitted or obtained in accordance with the procedures in subsection 2-A, paragraph F;

(5) The staff report of the agency and the preliminary staff report of the department;

(6) Officially noticed facts; and

(7) The final staff report of the department.

Documentary materials may be incorporated in the record by reference, provided that registered affected persons are afforded the opportunity to examine the materials.

Sec. 27. 22 MRSA §307, sub-§6, as enacted by PL 1977, c. 687, §1, is repealed.

Sec. 28. 22 MRSA §307, sub-§6-A is enacted to read:

6-A. Review cycles. The department shall establish review cycles for the review of applications. There shall be at least 6 review cycles for each calendar year, the dates for which shall be published at least 3 months in advance. An application shall be reviewed during the next scheduled review cycle following the date on which the application is either declared complete or submitted for review pursuant to section 306-A, subsection 4, paragraph B. The department may hold an application for up to 90 days following the commencement of the next scheduled review cycle if, on the basis of one or more letters of intent on file at the time the application is either declared complete or submitted for review pursuant to section 306-A, subsection 4, paragraph B, the department expects to receive within the addition 90 days one or more other applications pertaining to similar types of services, facilities or equipment affecting the same health service area. Pertinent health service areas shall be defined in regulations promulgated by the department pursuant to section 312, based on recommendations by the State Health Coordinating Council.

Sec. 29. 22 MRSA §308, sub-§4 is enacted to read:

4. Waiver of review of acquisitions of major medical equipment. The department may waive the review of an acquisition or proposed use of major medical equipment required pursuant to section 304-A if the equipment will be used to provide services to inpatients of a hospital only on a temporary basis in the case of:

A. A natural disaster;

B. A major accident; or

C. Equipment failure.

Sec. 30. 22 MRSA §309, sub-§1, ¶D, as enacted by PL 1977, c. 687, §1, is amended to read:

D. That the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State and are in accordance with standards, criteria or plans adopted and approved pursuant to the annual implementation plan, the health systems plan, and the state health plan ~~and the state medical facilities plan~~ developed by the Health Systems Agency and the department.

Sec. 31. 22 MRSA §309, sub-§2, ¶A, as enacted by PL 1977, c.687, §1, is amended to read:

A. The relationship of the health services being reviewed to the annual implementation plan, the health systems plan, and the state health plan ~~and the state medical facilities plan~~;

Sec. 32. 22 MRSA §309, sub-§§3, 4 and 5 are enacted to read:

3. Health maintenance organizations. Notwithstanding subsections 1 and 2, if a health maintenance organization or a health care facility which is controlled, directly or indirectly, by a health maintenance organization applies for a certificate of need, the department shall issue a certificate of need if it finds that:

A. Approval of the application is required to meet the needs of the members of the health maintenance organization and of the new members which the organization can reasonably be expected to enroll; and

B. The health maintenance organization is unable to provide, through services or facilities which can reasonably be expected to be available to the organization, its institutional health services in a reasonable and cost effective manner which is consistent with the basic method of operation of the organization and which makes the services available on a long-term basis through physicians and other health professionals associated with it. In assessing the availability of the proposed health services from other providers, the department shall consider only whether the services from these providers:

(1) Would be available under a contract of at least 5 years' duration;

(2) Would be available and conveniently accessible to physicians and other health professionals

associated with the health maintenance organizations;

(3) Would cost no more than if the services were provided by the health maintenance organization; and

(4) Would be available in a manner which is administratively feasible to the health maintenance organization.

4. Required approvals. Approval of proposed capital expenditures shall comply with the following:

A. Except as provided in paragraph B, the department shall issue a certificate of need for a proposed capital expenditure if:

(1) The capital expenditure is required to eliminate or prevent imminent safety hazards, as defined by applicable fire, building or life-safety codes and regulations; to comply with state licensure standards; or to comply with accreditation or certificate standards which must be met to receive reimbursement under the United States Social Security Act, Title XVIII, or payments under a state plan for medical assistance approved under Title XIX of that Act; and

(2) The department has determined that the facility or service for which capital expenditure is proposed is needed; the obligation of the capital expenditure is consistent with the state health plan; and the corrective action proposed by the applicant is the most cost effective alternative available under the circumstances.

B. Those portions of a proposed project which are not required to eliminate or prevent safety hazards or to comply with licensure, certification or accreditation standards are subject to review in accordance with the criteria established under section 312.

5. Standards applied in certificate of need. The commissioner shall, in issuing a certificate of need, make his decision, to the maximum extent practicable, directly related to criteria established under federal laws and standards or criteria prescribed in regulations promulgated by the department pursuant to subsections 1 to 4 and section 312.

The commissioner shall not deny issuance of a certificate of need, or make his decision subject to fulfillment of a condition on the part of the applicant, except where the denial or condition directly relates to criteria established under federal laws and standards or criteria prescribed in regulations promulgated by the department in accordance with subsections 1 to 4 and section 312, which are pertinent to the application.

Sec. 33. 22 MRSA §312, as enacted by PL 1977, c. 687, §1, is amended by adding after the first sentence a new sentence to read:

The department shall, to the extent applicable, take into consideration recommendations contained in the state health plan as approved by the Governor.

Sec. 34. 22 MRSA §316, as enacted by PL 1977, c. 687, §1, is repealed.

Sec. 35. 22 MRSA §316-A is enacted to read:

§316-A. Exemptions

Except as otherwise specifically provided, nothing in this Act shall be construed to preempt, replace or otherwise negate the requirements of any other laws or regulations governing health care facilities. The requirements of this Act shall not apply with respect to:

1. Health care facilities. Any health care facility:

A. Operated by religious groups relying solely on spiritual means through prayer for healing; or

B. For which any construction, modification or other change subject to this Act has been reviewed and has received approval pursuant to the United States Social Security Act, Section 1122, from appropriate agencies prior to the effective date of this Act.

2. Activities; acquisitions. Activities or acquisitions by or on behalf of a health maintenance organization or a health care facility controlled, directly or indirectly, by a health maintenance organization or combination of health maintenance organizations to the extent mandated by the National Health Planning and Resources Development Act of 1974, as amended and its accompanying regulations.

Sec. 36. 22 MRSA §317, as enacted by PL 1977, c. 687, §1, is repealed.

Sec. 37. 22 MRSA §317-A is enacted to read:

§317-A. Scope of certificate of need

1. Application determinative. A certificate of need shall be valid only for the defined scope, premises and facility or person named in the application and shall not be transferable or assignable.

2. Maximum expenditure. In issuing a certificate of need, the department shall specify the maximum capital expenditures which may be obligated under this certificate. The department shall, be regulation promulgated pursuant to section 312, prescribe the method to be used to determine capital expenditure maximums, establish procedures to monitor capital expenditures obligated under certificates and establish procedures to review projects for which the capital expenditure maximum is exceeded or expected to be exceeded.

3. Periodic review. After the issuance of a certificate of need, the department shall periodically review the progress of the holder of the certificate in meeting the timetable for making the service or equipment available or for completing the project specified in the approved application. A certificate of need shall expire if the project for which the certificate has been issued is not commenced within 12 months following the issuance of the certificate. The department may grant an extension of a certificate for an additional specified time not to exceed 12 months if good course is shown why the project has not commenced. The department may require evidence of the continuing feasibility and availability of financing for a project as a condition for extending the life of certificate. In addition if on the basis of its periodic review of progress under the certificate, the department determines that the holder of a certificate is not otherwise meeting the timetable and is not making a good faith effort to meet it, the department may, after considering any recommendation made by the Health Systems Agency, and after a hearing, withdraw the certificate of need. The department shall in accordance with section 312 promulgate the necessary procedures for withdrawal of certificates of need.

Sec. 38. 22 MRSA §323 is enacted to read:

§323. Relationship to the United States Social Security Act, Section 1122

1. Administration of Section 1122 reviews. The department shall, in reviewing those capital expenditures which require review under section 304-A and the United States Social Security Act, Section 1122, and regulations promulgated thereunder, allow the maximum flexibility permitted under the United States Social Security Act, Section 1122, consistent with this chapter.

2. Thresholds for review. The department shall waive review of proposed capital expenditures by health care facilities under the United States Social Security Act, Section 1122, and regulations promulgated thereunder, unless those expenditures are subject to review under section 304-A.

3. Procedures. The department shall, pursuant to section 312, modify its United States Social Security Act, Section 1122 Procedures Manual as required by this section, and shall promulgate the revised manual as a regulation on or before January 1, 1983.

Sec. 39. 22 MRSA §324 is enacted to read:

§324. Review

If the National Health Planning and Resources Development Act of 1974, Public Law 93-641, is repealed or significantly altered, but no later than December, 1986, the legislative joint standing committee having jurisdiction over health and institutional services shall review the continuing feasibility of this chapter and shall make a report to the Legislature and the Governor on its findings, together with any accompanying legislation.

The committee shall study all dollar amounts stated in this chapter as part of its review.

Sec. 40. Effective date. This Act shall take effect on January 1, 1983.

STATEMENT OF FACT

The purpose of this bill is to conform the Maine Certificate of Need Act to existing federal requirements, to provide for anticipated statutory and program funding changes at the federal level and to clarify the current Act in various areas, such as new services, subsequent review and establishment of thresholds for reviewable services.

Sections 1 to 14 add necessary new definitions or amend or repeal incorrect definitions.

Section 15 clarifies the circumstances under which a certificate of need is required. The establishment of a new health care facility, predevelopment activities and acquisition by lease, donation or transfer are retained from prior law. The addition of new health services, capital expenditures and changes in bed capacity are retained but new thresholds for their review are established. New categories of reviewable activities are added for acquisition of major medical equipment, except for certain waived acquisitions, and termination of a health service. Provisions are made for review of new health services not initially subject to review which are later expanded to exceed the threshold of review.

Section 16 establishes the criteria and procedures for subsequent review of a previously approved project if there are significant changes within one year after the project is undertaken.

Sections 17 and 18 repeal the provisions describing the application process for a certificate of need, and replaces them with a newly-organized section, including criteria for requesting and submitting additional information and review of incomplete applications.

Section 19 expands the notice requirement of the beginning of a review to include situations where commencement of review is based upon the request of the applicant, although the department does not consider the application complete, and commencement of review where the application has been grouped with other similar pending applications.

Sections 20 to 22 require the department to provide notice of the commencement of a review to all persons who have requested it, and expands the content of the notice to include a statement of the time and manner in which persons may register with the department as affected persons with respect to the application under review.

Sections 23 and 24 repeal and replace the provisions describing the public hearing to be held during the course of review.

Sections 25 and 26 repeal and replace the procedures for review and issuance of a decision on the application by the department.

Sections 27 and 28 repeal and replace the provisions pertaining to the establishment by the department of cycles for review of applications.

Section 29 provides for the waiver of review of major medical equipment which is to be used in temporary emergency situations.

Section 32 establishes criteria for review of health maintenance organizations and requires approval for certain proposed capital expenditures which are required to meet applicable safety, licensure and certification standards, and requires the commissioner to base his decision to grant or deny an application directly on criteria established in federal or state law.

Section 33 provides for the consideration of recommendations contained in the state health plan by the department in its promulgation of rules.

Sections 34 and 35 exempt certain activities from coverage by this act.

Sections 36 and 37 expand the content of the scope of certificate of need section. Provision is made for the department to specify, monitor and review the maximum capital expenditure for a project. Provision is also made for the establishment of timetables for completion of projects and for the withdrawal of the certificate when there is an unjustified failure to meet the specified timetables.

Section 38 requires the department to carry out review under this Act and under the United States Social Security Act, Section 1122, in a compatible manner.

Section 39 provides for review of this Act by the legislative joint standing committee having jurisdiction over health and institutional services by December, 1986, but in any case if the National Health Planning and Resources Development Act is altered or repealed.

Section 40 provides for an effective date for this Act.

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1. Committee.

   Health & Institutional Services Committee

2. Subject of Study.

   Certificate of Need

3. Priority number

   1

4. Completion date.

   February 1, 1982

5. Analysis of the problem.

   After extensive work on the proposed bills, the affected parties were able to come to some areas of agreement but still need to work out their differences. These differences include:

   1. The mechanism or approach to be used to provide for escalation of the minimum capital expenditure subject to review;

   2. The desirability and effect of establishing a minimum operating cost threshold for the review of new health services;

   3. The relationship between applicable federal statutes and regulations and the Maine Certificate of Need Act, specifically the desirability and effect of incorporating by reference all the applicable federal regulations into the Maine Certificate of Need Act.

   4. The extent to which the procedures to be employed by the Maine Health Systems Agency, Inc. and the Department of Human Services in conducting reviews of applications need or ought to be included in the Certificate of Need statute;

   5. The extent to which and the procedures by which an application may be reviewed and decided notwithstanding the failure of the applicant to provide all information considered necessary by the Department of Human Services or the Maine Health Systems Agency;

   6. The desirability and effect of designating the "criteria" presently contained in section 309-2 of the Maine Certificate of Need Act as "guidelines" or "considerations" rather than retaining the language previously adopted by the Maine Legislature; and

7. The feasibility and effect of modifying the Section 1122 agreement between the State of Maine and the federal government to make it consistent with the provisions of the Maine Certificate of Need Act; and

8. The extent to which health care facilities may acquire major medical equipment for emergency use without a certificate of need; and

9. The proper wording of a definition for the State health plan; and

10. The desirability of delineating in the Maine Certificate of Need Act all changes in a proposal subject to review; and

11. The desirability of delineating in the Maine Certificate of Need Act the method for determining expenditure maximums under a certificate; and

12. The extent to which certificate of need approval may be made subject to conditions; and

13. The extent to which specific provision for grouping of applications should be incorporated into the Maine Certificate of Need Act.

6. Reason for study.

3 bills were introduced this session dealing with Certificate of Need; one was withdrawn, because most of its provisions were contained within another, and the other two were worked on by the Committee and affected parties, including the Department of Human Services, Maine Hospital Association, Maine Blue Cross - Blue Shield, Maine Medical Association.

Legislation affecting Maine's Certificate of Need Act must be amended in certain areas, as a condition of receipt of federal funding, before January, 1983. Therefore, legislation must be prepared for and acted on, the 2nd session of the 110th Legislature.

7. Members of Subcommittee.

Three to five members of the Health & Institutional Services Committee, the Department of Human Services, Maine Health Care Association, the Maine Hospital Association, the Maine Health Systems Agency, Inc., the Maine Medical Association and Maine Blue Cross and Blue Shield.

APPROVED
MAR 30 '78
BY GOVERNOR

CHAPTER
687
PUBLIC LAW

STATE OF MAINE

IN THE YEAR OF OUR LORD NINETEEN HUNDRED SEVENTY-EIGHT

S. P. 652 — L. D. 2013

AN ACT Relating to Certificate of Need.

Emergency preamble. Whereas, Acts of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, the National Health Planning Act of 1974 and its accompanying regulations require the State to implement a certificate of need program by July 1, 1978, or be subject to the loss of federal funds for health planning as well as other purposes; and

Whereas, this bill may not become effective until after July 1, 1978, if it is not enacted as an emergency; and

Whereas, the loss of federal funds might severly restrict the state's efforts in health planning; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,

Be it enacted by the People of the State of Maine, as follows:

Sec. 1. 22 MRSA c. 103, is enacted to read:

CHAPTER 103

CERTIFICATE OF NEED

§ 301. Short title

This chapter may be cited as the "Maine Certificate of Need Act of 1978."

§ 302. Declaration of findings and purposes

1. Findings. The Legislature finds that unnecessary construction or modification of health care facilities and duplication of health services are substantial factors in the cost of health care and the ability of the public to obtain necessary medical services.

2. Purposes. The purposes of this chapter are to:

A. Promote effective health planning;

B. Assist in providing quality health care at the lowest possible cost;

C. Avoid unnecessary duplication in health facilities and health services and ensure that only those facilities that are needed will be built or modified;

D. Assure that state funds are not used to support unnecessary capital expenditures made by or on behalf of health care facilities;

E. Provide an orderly method of resolving questions concerning the need for health care facilities and health services which are proposed to be developed;

F. Permit consumers of health services to participate in the process of determining the distribution, quantity, quality and cost of these services; and

G. Provide for a certificate of need program which meets the requirements of the National Health Planning and Resources Development Act of 1974, Public Law 93-641 and its accompanying regulations.

§ 303. Definitions

As used in this chapter, unless the context otherwise indicates, the following words and phrases shall have the following meanings.

1. Ambulatory surgical facility. "Ambulatory surgical facility" means a facility, not part of a hospital, which provides surgical treatment to patients not requiring hospitalization. This term does not include the offices of private physicians or dentists, whether in individual or group practice.

2. Annual implementation plan. "Annual implementation plan" means the Health Systems Agency's annual statement describing the objectives which will achieve the goals identified in its health systems plan and setting the priorities for the objectives.

3. Capital expenditure. "Capital expenditure" means an expenditure, including a force account expenditure, which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance and, for the purposes of this chapter, shall include capitalized interest on borrowed funds and the fair market value of any property or equipment which is acquired under lease or comparable arrangement or through donation.

4. Construction. "Construction," when used in connection with "health care facility," means the establishment, erection, building, purchase or other acquisition of a health care facility.

5. Department. "Department" means the Department of Human Services.

6. Development. "Development," when used in connection with "health service," means the undertaking of those activities which on their completion will result in the offering of a new health service to the public.

7. Health care facility. "Health care facility" means any facility, whether public or private, proprietary or not for profit, required to obtain a certificate of need in accordance with federal laws and regulations under the National Health Planning and Resources Development Act of 1974, or any amendment, and shall include hospitals, psychiatric hospitals, tuberculosis hospitals, skilled nursing

facilities, kidney disease treatment centers including free standing hemodialysis units, intermediate care facilities, ambulatory surgical facilities, home health care providers certifiable under Title XVIII of the Federal Social Security Act of 1965, as amended, and health maintenance organizations. The term shall not apply to any facility operated by religious groups relying solely on spiritual means through prayer for healing.

8. Health maintenance organization. "Health maintenance organization" means a public or private organization which:

A. Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health services: Usual physician services, hospitalization, laboratory, x-ray, emergency and preventive health services and out-of-area coverage;

B. Is compensated, except for copayments, for the provision of the basic health services to enrolled participants on a predetermined periodic rate basis; and

C. Provides physicians' services primarily through physicians who are either employees or partners of the organization or through arrangements with individual physicians or one or more groups of physicians.

9. Health services. "Health services" means clinically related, that is, diagnostic, treatment or rehabilitative services, and includes alcohol, drug abuse and mental health services.

10. Health Systems Agency. "Health Systems Agency" means the not-for-profit corporation established in this State in accordance with the National Health Planning and Resources Development Act of 1974.

11. Health systems plan. "Health systems plan" means the Health Systems Agency's annual statement of the goals for the health care system of the State and the strategies for achieving these goals.

12. Intermediate care facility. "Intermediate care facility" means an institution which provides, on a regular basis, health-related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide, but who because of their mental or physical conditions require health related care and services above the level of room and board.

13. Modification. "Modification" means the alteration, improvement, expansion, extension, renovation or replacement of a health care facility or health maintenance organization or portion thereof, including initial equipment thereof and the replacement of equipment of existing buildings.

14. Offer. "Offer," when used in connection with "health services," means that the health care facility or health maintenance organization holds itself out as capable of providing or having the means to provide a health service.

15. Person. "Person" means an individual, trust or estate, partnership, corporation, including associations, joint stock companies and insurance companies, the State or a political subdivision or instrumentality, including a municipal corporation of the State.

16. Predevelopment activities. "Predevelopment activities" means any expenditure by or on behalf of a health care facility made in preparation for the offering or development of a new health service for which a certificate of need would be required and arrangements or commitments made for financing the offering or development of the new health service; and shall include site acquisitions, surveys, studies, expenditures for architectural designs, plans, working drawings and specifications.

17. Project. "Project" means any service, predevelopment activity or commitment for financing which requires a certificate of need under section 304.

18. Secretary. "Secretary" means the United States Secretary of Health, Education and Welfare and any other officer or employee of the United States Department of Health, Education and Welfare to whom the authority involved may be delegated.

19. Skilled nursing facility. "Skilled nursing facility" means an institution or a distinct part of an institution which is primarily engaged in providing to inpatients skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled or sick persons.

20. State Health Coordinating Council. "State Health Coordinating Council" means the entity established by the Governor in accordance with the provisions of section 1524 of the National Health Planning and Resources Development Act of 1974.

21. State health plan. "State health plan" means the plan prepared annually by the State Health Coordinating Council after consideration of the health systems plan and the preliminary state health plan prepared by the Bureau of Health Planning and Development.

22. State medical facilities plan. "State medical facilities plan" means the annual statement of the number, types and distribution of medical facilities needed to provide adequate health care services to the people of the State prepared by the Bureau of Health Planning and Development and approved by the State Health Coordinating Council.

§ 304. Certificate of need required

A certificate of need from the department shall be required for:

1. Health service. Any new health service proposed to be offered or developed within the State. For the purposes of this Act, "new health service" shall include only the following:

A. The construction, development or other establishment of a new health care facility;

B. Any expenditure by or on behalf of a health care facility in excess of $150,000 or more which, under generally accepted accounting principles consistently applied, is a capital expenditure. When a person makes an acquisition by or on behalf of a health care facility under lease or comparable arrangement or through donation, which would have required review if the acquisition had been by purchase, the acquisition shall be deemed a capital expenditure subject to review;

C. Any change in the existing bed complement of a health care facility which:

(1) Increases or decreases the licensed bed capacity of the health care facility by more than 10% or 5 beds, whichever is less;

(2) Redistributes the number of beds among various categories or types of care; or

(3) Relocates the number of beds from one physical facility or site to another; and

D. Health services which are offered in or through a health care facility or health maintenance organization and which were not offered on a regular basis in or through the health care facility within the 12-month period prior to the time the services would be offered; and

2. Predevelopment activities. Any expenditure of $150,000 or more for predevelopment activities proposed to be undertaken in preparation for any project which would itself require a certificate of need.

No person shall enter into any commitment for financing a project which requires a certificate of need or incur an obligation for the project without having sought and received a certificate of need, except that this prohibition shall not apply to commitments for financing conditioned upon the receipt of a certificate of need or to obligations for predevelopment activities of less than $150,000.

§ 305. Periodic reports

The department shall require health care facilities subject to the requirements of this chapter to maintain current health services and capital requirements' plans on file with the department. The department, in its rules and regulations, shall prescribe the form and contents of the health services and capital requirements' plans and shall require annual or other periodic reports updating the plans to be filed with the department. No application for a certificate of need made pursuant to this Act shall be accepted from any health care facility for which the current health services and capital requirements' plans are not on file.

§ 306. Application process

1. Letter of intent. Prior to filing an application for a certificate of need, an applicant shall file a letter of intent with the department no less than 60 days prior to the date on which the application is to be filed. The letter of intent shall form the basis for determining the applicability of this chapter to the proposed expenditure or action.

2. Application filed. Upon a determination by the department, after consultation with the Health Systems Agency, that a certificate of need is required for a proposed expenditure or action, an application for a certificate of need shall be filed with the department.

3. Applications. Upon receipt of an application, the department immediately shall transmit a copy of the application to the Health Systems Agency. The Health Systems Agency shall have 10 working days from the date on which the application is filed with the department in which to comment to the department upon the completeness of the application, indicating specifically and in writing, any

additional information which the Health Systems Agency requires before it can consider the application complete. Within 15 working days after the filing of an application with the department, the department, after considering the requirements of the Health Systems Agency, shall notify the applicant that:

A. The application contains all necessary information required and is complete; or

B. Additional information is required by the department or by the Health Systems Agency, or both.

4. Application completeness declared. The department, after consultation with the Health Systems Agency, shall declare an application complete when the department is satisfied that all necessary information has been submitted. If in the judgment of the department an application is complete, but the Health Systems Agency determines that it requires additional information, the department shall so notify the applicant and shall allow the applicant 15 working days from the date of that notice, or any additional amount of time which the applicant may request to submit the additional information prior to declaring the application complete. Failure to submit additional information so requested may result in an unfavorable recommendation by the Health Systems Agency and may result in subsequent denial of the application by the department.

§ 307. Review process

1. Notice. Upon determination that an application is complete, the department shall provide for written notification of the beginning of a review. Public notice shall be given by publication in the Kennebec Journal and in a newspaper of general circulation in the area in which the proposed expenditure or other action will occur. This notice shall include:

A. A brief description of the proposed expenditure or other action;

B. The proposed schedule for the review;

C. A statement that a public hearing will be held during the course of a review if requested by persons directly affected by the review and the date by which the requests must be received by the department; and

D. A description of the manner in which public notice will be given of a public hearing if one is to be held during the course of the review.

2. Public hearing. A public hearing shall be held during the course of a review by either the department or the Health Systems Agency if requested by persons directly affected by the review pursuant to subsection 1.

3. Reviews. To the extent practicable, a review shall be completed and the department shall make its decision within 90 days after the date of notification under subsection 1. The department, after consulting with the Health Systems Agency, shall establish criteria for determining when it is not practicable to complete a review within 90 days. Whenever it is not practicable to complete a review within 90 days, the department, after consultation with the Health Systems Agency, may extend the review period up to an additional 60 days. Any review period may be extended with the written consent of the applicant.

4. Review by Health Systems Agency. The Health Systems Agency shall be entitled to review all applications for a certificate of need and shall have at least 70 days or 2/3 of the allotted time for a review, whichever is greater, in which to submit its recommendations and comments to the department, unless it consents in writing to a shorter period of time.

5. Review by department. After reviewing each application and after considering the recommendations of the Health Systems Agency, the department shall make a decision either to issue a certificate of need or to deny the application for a certificate of need. Notice of the decision shall be sent to the applicant and to the Health Systems Agency. This notice shall state the basis of the decision. If the decision is not consistent with the recommendations of the Health Systems Agency, the department shall provide a detailed statement of the reasons for the inconsistency.

6. Review cycles. The department may establish review cycles for the review of applications. There shall be at least 6 review cycles scheduled for each calendar year, the dates for which shall be published at least 3 months in advance. If the department establishes review cycles, an application shall be reviewed during the next scheduled review cycle following the date on which the application is declared complete.

§ 308. Waiver of requirements; emergency certificate of need

1. Waiver of full review. The department may waive otherwise applicable requirements and establish a simplified review process for projects which do not warrant a full review. Procedures for conducting these reviews shall be established by the department in its rules and regulations. These procedures shall provide for a shortened review by the Health Systems Agency and for a public hearing to be held during the course of a review, if requested by any person directly affected by the review. In order to waive requirements for a full review, the department, after consulting with the Health Systems Agency, shall find that the proposed project:

A. Meets an already demonstrated need as established by applicable state health plans or by the rules and regulations of the department;

B. Is a part of a minor modernization or replacement program which is an integral part of an institutional health care facility's health services or capital expenditures' plans required by section 305; and

C. Is required to meet federal, state or local life safety codes or other applicable requirements.

2. Waiver of other requirements. The department, after consultation with the Health Systems Agency, may waive otherwise applicable provisions of this chapter and procedural requirements and criteria for review and issue an emergency certificate of need, subject to any limitations and restrictions in regard to duration, right of extension or renewal, subsequent review and other factors that may be imposed by the department. A review of any emergency certificate of need must begin within at least 90 days after its issuance. In order to issue an emergency certificate of need, the department shall find that an emergency situation exists and that the applicant has affirmatively demonstrated:

A. The necessity for immediate or temporary relief due to natural disaster, fire, unforeseen safety consideration or other circumstances;

B. The serious adverse effect of delay on the applicant and the community that would be occasioned by compliance with the regular requirements of this chapter and the rules and regulations promulgated pursuant to this chapter; and

C. The lack of substantial change in the facility or services which existed before the emergency situation.

§ 309. Principles governing the review of applications

1. Determinations for issue of certificate. A certificate of need shall be issued whenever the department, after considering the findings and recommendations of the Health Systems Agency, determines:

A. That the applicant is fit, willing and able to provide the proposed services at the proper standard of care;

B. That economic feasibility of the proposed services is demonstrated in terms of: Effect on the existing and projected operating budget of the applicant; the applicant's ability to establish and operate the facility or services in accordance with licensure regulations promulgated under pertinent state laws; and the projected impact on the facility's costs and rates and the total health care expenditures in the community and the State;

C. That there is a public need for the proposed services; and

D. That the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State and are in accordance with standards, criteria or plans adopted and approved pursuant to the annual implementation plan, the health systems plan, the state health plan and the state medical facilities plan developed by the Health Systems Agency and the department.

2. Criteria for certificate of need. In the determination to issue or deny a certificate of need under subsection 1, the department shall, among other criteria, consider the following:

A. The relationship of the health services being reviewed to the annual implementation plan, the health systems plan, the state health plan and the state medical facilities plan;

B. The relationship of the health services being reviewed to the health services and capital requirements' plans, if any, of the applicant;

C. The current and projected needs that the population served or to be served has for the proposed services;

D. The availability of less costly alternatives or more effective methods of providing the proposed services;

E. The relationship of the proposed services to the existing health care systems;

F. The availability of resources, including health personnel, management personnel and funds for capital and operating needs, for the provision of the proposed services and the availability of alternative uses of the resources for the provision of other health services;

G. The relationship, including the organizational relationship, of the proposed services to ancillary or support services;

H. The special needs and circumstances of health maintenance organizations;

I. The special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in health service areas in which the entities are located or in adjacent health service areas;

J. The importance of recognizing the public's choice of allopathic or osteopathic health services by considering the unique needs and circumstances of providers of allopathic and osteopathic health care;

K. The costs and methods of any proposed construction or modification of a facility, including the costs and methods of energy provisions;

L. The probable impact of the proposal being reviewed on the costs of providing health services;

M. The need for utilizing new technological developments on a limited experimental basis in the absence of sufficient data to establish the need for the services;

N. The gains that may be anticipated from innovative measures in the organization, financing and delivery of health care and the development of comprehensive services for the community to be served; and

O. The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

§ 310. Reconsideration

Any person directly affected by a review may, for good cause shown, request in writing a hearing for the purposes of reconsideration of the decision of the department to issue or to deny a certificate of need. The department, if it determines that good cause has been demonstrated, shall hold a hearing to reconsider its decision. To be effective, a request for the hearing shall be received within 30 days of the department's decision. If the Department of Human Services determines that good cause for a hearing has been demonstrated, the hearing shall commence within 30 days of receipt of the request. For purposes of this section, a request for a hearing shall be deemed to have shown good cause if it:

1. New information. Presents significant, relevant information not previously considered by the department;

2. Changes in circumstances. Demonstrates that there have been significant changes in factors or circumstances relied upon by the department in reaching its decision;

3. Failure to follow procedures. Demonstrates that the department has materially failed to follow its adopted procedures in reaching its decision; or

4. Other bases. Provides other bases for a hearing that the department has determined constitutes good cause.

§ 311. Remedy

Any person aggrieved by a final decision of the department made under the provisions of this Act shall be entitled to review in accordance with Title 5, chapter 375, subchapter VII, of the Administrative Procedure Act. A decision of the department to issue a certificate of need or to deny an application for a certificate of need shall not be considered final until the department has taken final action on a request for reconsideration under section 310.

§ 312. Rules and regulations

The department shall adopt any rules, regulations, standards, criteria or plans that may be necessary to carry out the provisions and purposes of this Act. The department shall provide for public notice and hearing on all proposed rules, regulations, standards, criteria, plans or schedules pursuant to Title 5, chapter 375. The department is authorized to accept any federal funds to be used for the purposes of carrying out this chapter.

§ 313. Public information

The general public shall have reasonable access to all applications reviewed by the department and to all other written material pertinent to its review of these applications. The department shall prepare and publish at least annually a report on its activities conducted pursuant to this Act.

§ 314. Conflict of interest

Any member or employee of the Department of Human Services or Health Systems Agency who has a substantial economic or fiduciary interest which would be affected by a recommendation or decision to issue or deny a certificate of need, or who has a close relative or economic associate whose interest would be so affected shall be ineligible to participate in the review, recommendation or decision making process with respect to any application for which the conflict of interest exists.

§ 315. Division of project to evade cost limitation prohibited

No health care facility or other party required to obtain a certificate of need shall separate portions of a single project into components, including, but not limited to, site facility and equipment, to evade the cost limitations or other requirements of section 304.

§ 316. Exemptions

Except as otherwise specifically provided, nothing in this Act shall be construed to preempt, replace or otherwise negate the requirements of any other laws or regulations governing health care facilities. The requirements of this Act shall not apply with respect to any health care facility:

1. Operated by religious groups. Operated by religious groups relying solely on spiritual means through prayer for healing; or

2. Other approval. For which any construction, modification or other change subject to this Act has been reviewed and has received approval pursuant to section 1122 of the Federal Social Security Act from appropriate agencies prior to the effective date of this Act.

§ 317. Scope of certificate of need

A certificate of need shall be valid only for the defined scope, premises and facility or person named in the application and shall not be transferable or assignable. A certificate of need shall expire if the project for which the certificate has been issued is not commenced within 12 months following the issuance of the certificate. The department may grant an extension of a certificate for an additional specified time not to exceed 12 months if good cause is shown why the project has not commenced. The department may require evidence of the continuing feasibility and availability of financing for a project as a condition for extending the life of a certificate.

§ 318. Withholding of license

No new health care facility, as defined in section 303, shall be eligible to obtain a license under the applicable state law, if the facility has not obtained a certificate of need as required by this chapter. The license of any facility shall not extend to include or otherwise be deemed to allow the delivery of any services, the use of any equipment which has been acquired, the use of any portion of a facility or any other change for which a certificate of need as required by this Act has not been obtained. Any unauthorized delivery of services, use of equipment or portion of a facility, or other change shall be deemed to be in violation of the respective chapter under which the facility is licensed.

§ 319. Withholding of funds

No health care facility or other provider shall be eligible to apply for or recieve any reimbursement, payment or other financial assistance from any state agency, either directly or indirectly, for any capital expenditure or operating costs attributable to any project for which a certificate of need as required by this Act has not been obtained. For the purposes of this section, the department shall determine the manner of computing the eligibility of a facility to receive public funds, using generally accepted accounting principles.

§ 320. Injunction

The Attorney General, upon the request of the department, shall seek to enjoin any project for which a certificate of need as required by this Act has not been obtained, and shall take any other action as may be appropriate to enforce this Act.

§ 321. Penalty

Whoever violates any provision of this chapter or any rate, rule or regulation established hereunder shall be subject to a civil penalty payable to the State of not more than $5,000 to be recovered in a civil action.

§ 322. Implementation reports

The holder of a certificate of need shall make a written report at the end of each 6-month period following its issuance regarding implementation activities, obligations incurred and expenditures made and any other matters as the department may require. A final report shall be made when the service or services for which the certificate of need was issued becomes operational. The department, in its rules and regulations, shall prescribe the form and contents of the reports. Any holder of a certificate of need which has been issued for the construction or modification of a facility or portion thereof shall file final plans and specifications therefor with the department within 6 months, or any other time that the department may allow, following the issuance of the certificate for review by the department to determine that the plans and specifications are in compliance with the certificate of need which has been issued therefor and are in compliance with applicable licensure, life safety code and accreditation standards. The department may revoke any certificate of need it has issued when the person to whom it has been issued fails to file reports or plans and specifications required by this section on a timely basis.

Sec. 2. Appropriation. The following funds shall be appropriated from the General Fund to carry out the purposes of this Act:

	1978-79
HUMAN SERVICES, DEPARTMENT OF	
All Other	$60,000

Emergency clause. In view of the emergency cited in the preamble, this Act shall take effect when approved.

IN HOUSE OF REPRESENTATIVES, ... 1978

Read twice and passed to be enacted.

.....Speaker

IN SENATE, ...1978

Read twice and passed to be enacted.

..... President

Approved..... 1978

.....Governor

CHAPTER 374

Emergency preamble. Whereas, Acts of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas certain amendments must be made to the statute before pending railroad acquisitions can be completed; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,

Be it enacted by the People of the State of Maine, as follows:

23 MRSA § 4207, sub-§ 3, as amended by PL 1975, c. 629, is further amended by adding at the end a new paragraph to read:

Whenever the department acquires railroad lines, to hold and to manage for future railroad uses, those lines shall not be considered abandoned for railroad purposes. The commissioner shall periodically review the need to hold such lines for future railroad uses.

Emergency clause. In view of the emergency cited in the preamble, this Act shall take effect when approved.

Effective June 8, 1979.

P.L. 1979
CHAPTER 375

S. P. 283 — L. D. 857

AN ACT to Amend the Maine Certificate of Need Act of 1978.

Be it enacted by the People of the State of Maine, as follows:

22 MRSA § 304, sub-§ 1, ¶C, as enacted by PL 1977, c. 687, § 1, is repealed and the following enacted in its place:

C. Any change in the existing bed complement of a health care facility which:

(1) Increases or decreases the licensed bed capacity of the health care facility by more than 10% or more than 5 beds, whichever is less;

(2) Increases or decreases the number of beds licensed by the department to provide a particular level of care by more than 10% of that number or more than 5 beds, whichever is less; or

(3) Relocates more than 10% of the health care facility's licensed beds or more than 5 beds, whichever is less, from one physical plant to another; and

CHAPTER 376

H. P. 700 — L. D. 890

AN ACT Concerning Reimbursement for Health Care Services in Certified Rural Health Clinics.

Be it enacted by the People of the State of Maine, as follows:

24 MRSA § 2324 is enacted to read:

§ 2324. Certified ambulatory health care center outpatient coverage

1. Contract coverage. Every nonprofit hospital and medical service organization which issues group and individual health care contracts providing coverage for inpatients and outpatient hospital care to residents of the State shall make available coverage for outpatient health care to subscribers with health care facilities certified by the Department of Human Services for purposes of reimbursement under the United States Rural Health Clinic Services Act, Public Law 95-210, or its successor, and with incorporated nonprofit health centers engaged in the delivery of comprehensive primary care provided the health care facility or nonprofit health center providing the care has contracted with the organization on terms and conditions which the organization deem its membership.

2. Services required. Services provided under such contract t health clinics shall include, but need not be limited to, services pr for under group and individual health care contracts to hospit hospitals presently licensed under Title 22, chapter 405, or its succ shall services provided under such contracts to these health clini to require a nonprofit hospital or medical services organiza contract coverage for a service in a particular rural health clinic meet state qualifications or criteria.

CHAPTER 377

H. P. 806 — L. D. 1009

AN ACT Relating to the Powers of Hospital and Medical Service

Be it enacted by the People of the State of Maine, as follows:

24 MRSA § 2301, sub-§ 7 as last repealed and replaced by PL amended to read:

7. Administrative services. With the prior approval of the s such corporation shall have the right to utilize its organization either directly or through another legal entity owned by it corporations located in other states, to perform services for the U the State of Maine Government or the units or agencies of e charitable or nonprofit organization involved in health care

CHAPTER 378

H. P. 1067 — L. D. 1348

AN ACT to Establish Standard Assessment Procedures for the

Be it enacted by the People of the State of Maine, as follows:

Sec. 1. 36 MRSA c. 5, as amended by PL 1975, c. 771, § 398, is

Sec. 2. 36 MRSA c. 7, § 111 is enacted to read

§ 111. Definitions

As used in this title, unless the context otherwise indicates, the foll shall have the following meanings.

1. Assessor. "Assessor" means the State Tax Assessor, except 2, Property Taxes, it means the State Tax Assessor with res unorganized territory and the respective municipal assessors or chief primary assessing areas with respect to the organized areas.

2. Notice. "Notice" means notification served personally or certified or registered mail to the last known address of the person fo notification is intended.

If the State Tax Assessor attempts to give notice by certified or regi and the mailing is returned by the United States Postal Service with "unclaimed" or "refused", he may then give notice, for purposes of t sending the notification by first-class mail to the person for whom the is intended at the address used on the returned certified or registered r given in this manner shall be deemed to be received 3 days after th mailing.

In the case of a joint income tax return, notice may be a single joint no that, if the State Tax Assessor is notified by either spouse that separate have been established, he shall mail a joint notice to each spouse.

If the person for whom notification is intended is deceased or un

P.L. 1979

CHAPTER 601

S. P. 697 — L. D. 1833

AN ACT to Amend the Provisions of the Maine Certificate of Need Act Governing the Issuance of an Emergency Certificate of Need.

Be it enacted by the People of the State of Maine, as follows:

Sec. 1. 22 MRSA § 308, sub-§ 2, as enacted by PL 1977, c. 687, § 1, is repealed and the following enacted in its place:

2. Waiver of other requirements. In order to expedite the review of an application submitted in response to an emergency situation, the department, after consultation with the Health Systems Agency, may:

A. Waive the requirement that an applicant shall file a letter of intent with the department no less than 60 days prior to the date on which an application is to be filed;

B. Limit the period within which the Health Systems Agency may comment on the completeness of an application to less than 10 working days from the date on which it was filed with the department; and

C. Establish a schedule for the review of an application which commences on a day other than the first day of an established review cycle and requires the Health Systems Agency to submit its recommendations and comments to the department in less than 70 days from the day on which the review period commenced, provided that the Health Systems Agency shall be afforded no less than 2/3 of the time the department has allotted for the completion of its review.

Sec. 2. 22 MRSA § 308, sub-§ 3 is enacted to read:

3. Emergency defined. The department shall determine that an emergency situation exists whenever it finds that an applicant has demonstrated:

A. The necessity for immediate or temporary relief due to natural disaster, fire, unforeseen safety consideration or other circumstances;

B. The serious adverse effect of delay on the applicant and the community that would be occasioned by compliance with the regular requirements of this chapter and the rules and regulations promulgated by the department; and

C. The lack of substantial change in the facility or services which existed before the emergency situation.

CHAPTER 602

H. P. 1788 — L. D. 1907

AN ACT Relating to the Vocational-Technical Institutes.

Emergency preamble. Whereas, Acts of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, this Act makes significant changes in the laws relating to the vocational-technical institutes; and

Whereas, these changes should be carried out prior to the end of the current fiscal year in preparation for the beginning of the 1980-81 school year in order to ensure a smooth transition; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,

Be it enacted by the People of the State of Maine, as follows:

Sec. 1. 5 MRSA § 1507, first ¶, 2nd sentence, as repealed and replaced by PL 1975, c. 771, § 67, is amended to read:

The Governor may allocate from such account amounts not to exceed in total the sum of $300,000 in any fiscal year in accordance with the purposes specified in subsections 1, 2, 3 ~~and~~ ,4 and 4-A.

Sec. 2. 5 MRSA § 1507, sub-§ 4-A is enacted to read:

4-A. Vocational-technical institutes. The Governor may allocate funds from such account in amounts not to exceed in total the sum of $100,000 in any fiscal year to provide funds for any unusual and unforeseen needs as may arise in the operation of the vocational-technical institutes. Allocations may be made from this fund by the Governor only upon the written request of the State Board of Education and after consultation with the State Budget Officer.

Sec. 3. 20 MRSA c. 303-A is enacted to read:

CHAPTER 303-A

VOCATIONAL-TECHNICAL INSTITUTES

§ 2261. Purpose

The purpose of this chapter is to create vocational-technical institutes in Maine which will be able to respond to the needs of the people of the State for vocational, technical and occupational training and to provide for responsive administration of the vocational-technical institutes.

§ 2261-A. Intent

It is the intent of the Legislature that the vocational-technical institutes shall:

1. Vocational, technical and occupational education. Provide vocational, technical and occupational education for those who demonstrate aptitude and need and who require training designed for service in a trade, industry or commerce;

2. Job skills. Provide each graduate with job skills;

3. General education. Provide the general education necessary to complement the requirements of specific vocational and technical skills;

4. Supplementary programs. Provide supplementary educational programs to upgrade those persons already employed or retrain persons for new employment opportunities; and

5. Special programs. Provide special programs for disadvantaged and handicapped persons to permit them to take maximum advantage of their aptitudes and interests.

§ 2262. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Commissioner. "Commissioner" means the Commissioner of Educational and Cultural Services.

2. Department. "Department" means the Department of Educational and Cultural Services.

3. Institute. "Institute" means a vocational-technical institute as established in section 2263.

§ 2263. Establishment of institutes; general duties and authority of State Board of Education.

1. Establishment. The following vocational-technical institutes are established:

A. Central Maine Vocational-Technical Institute in the City of Auburn;

B. Eastern Maine Vocational-Technical Institute in the City of Bangor;

C. Kennebec Valley Vocational-Technical Institute in the City of Waterville;

D. Northern Maine Vocational-Technical Institute in the City of Presque Isle;

E. Southern Maine Vocational-Technical Institute in the City of South Portland; and

F. Washington County Vocational-Technical Institute in the City of Calais.

2. General duties and authority. The State Board of Education shall maintain

HEALTH PLANNING AND RESOURCES DEVELOPMENT AMENDMENTS OF 1979

For Legislative History of Act, see p. 2880

An Act to amend titles XV and XVI of the Public Health Service Act to revise and extend the authorities and requirements under those titles for health planning and health resources development, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Health Planning and Resources Development Amendments of 1979.

SHORT TITLE; REFERENCES TO PUBLIC HEALTH SERVICE ACT; AND TABLE OF CONTENTS

42 USC 201 note.

SECTION 1. (a) This Act may be cited as the "Health Planning and Resources Development Amendments of 1979".

Post, pp. 607, 629.

(b) Whenever in this Act (other than in subsections (j) and (k) of section 115 and in section 128) an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

42 USC 201 note.

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42 USC 300m-4.
42 USC 300m.
42 USC 300*l*-2.

section 1525 to the State Agency designated for such State under section 1521(b)(3).".

(h) Section 1513(c)(2) is amended (1) by striking out "may" and inserting in lieu thereof "shall", and (2) by inserting "in obtaining and filling out the necessary forms and may provide other technical assistance" after "technical assistance".

Ante, p. 604, 607-609.

(i)(1)(A) The first sentence of section 1513(b)(2) is amended by striking out "annually" and inserting in lieu thereof "at least triennially".

(B) The second sentence of section 1513(b)(2) is amended by striking out "Before establishing an HSP" and inserting in lieu thereof "Before establishing or amending an HSP and in its review of an HSP".

42 USC 300m-2.
Ante, p. 608.

(2) The first sentence of section 1523(a)(2) and the first sentence of section 1524(c)(2)(A) are each amended by striking out "and review and revise as necessary (but at least annually)" and inserting in lieu thereof ", review at least triennially, and revise as necessary".

42 USC 300m-3.
Ante, p. 607.

(3) Section 1524(c)(1) (as amended by subsection (a)) is amended by striking out "review annually and coordinate the HSP and AIP" and inserting in lieu thereof "review and coordinate at least triennially the HSP and review at least annually the AIP".

Ante, p. 608.

(4) The third sentence of section 1524(c)(2)(A) is amended by striking out "for each year".

(j)(1) Section 303(a) of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 is amended by adding after and below paragraph (16) the following: "Such plan shall be consistent with the State health plan in effect for such State under section 1524(c) of the Public Health Service Act.".

42 USC 4573.

21 USC 1176.

(2) Section 409(e) of the Drug Abuse Office and Treatment Act of 1972 is amended by adding after and below paragraph (13) the following: "Such plan shall be consistent with the State health plan in effect for such State under section 1524(c) of the Public Health Service Act.".

42 USC 2689t.

(k)(1) Section 237(a) of the Community Mental Health Centers Act is amended in the matter preceding paragraph (1) by inserting "shall be consistent with the State health plan in effect for such State under section 1524(c) of the Public Health Service Act and" before "shall be".

Supra.

(2) Paragraph (2)(D)(iv) of subsection (g) of section 314 of the Public Health Service Act is amended by striking out "a plan" and inserting in lieu thereof "a plan which is consistent with the State health plan in effect for the State under section 1524(c) and".

42 USC 246.

Supra.

CRITERIA AND PROCEDURES FOR REVIEWS

42 USC 300n-1.
Post, p. 611, 612.

SEC. 116. (a)(1) The first sentence of section 1532(a) is amended (A) by striking out "; and in performing" and inserting in lieu thereof "; in performing", and (B) by inserting before the period a semicolon and the following: "and in performing its review functions a Statewide Health Coordinating Council shall (except to the extent approved by the Secretary) follow procedures and apply criteria developed and published by the Council in accordance with regulations of the Secretary".

(2) The second sentence of such section is amended by striking out "and States Agencies" and inserting in lieu thereof ", State Agencies, and Statewide Health Coordinating Councils".

Ante, p. 595.

(b)(1) Subsections (b) and (c) of section 1532 are each amended—

(A) by striking out "agency and State Agency" each place it occurs (other than in paragraph (11) of subsection (b)) and

inserting in lieu thereof "agency, State Agency, and Statewide Health Coordinating Council", and

(B) by striking out "agency or State Agency" each place it occurs and inserting in lieu thereof "agency, State Agency, or Statewide Health Coordinating Council".

(2) Subsection (b)(4) of such section is amended by striking out "agency or a State Agency" and inserting in lieu thereof "agency, State Agency, or Statewide Health Coordinating Council".

(3) Section 1532(c)(1) is amended by striking out "HSP and AIP" and inserting in lieu thereof "HSP, AIP, and State health plan". 42 USC 300n-1.

(c) Section 1532(a) is amended by adding at the end the following: "Health systems agencies, the State Agency, and, if appropriate, the Statewide Health Coordinating Council within each State shall cooperate in the development of procedures and criteria under this subsection to the extent appropriate to the achievement of efficiency in their reviews and consistency in criteria for such reviews.".

(d)(1)(A) Section 1532(b)(1) is amended (i) by striking out "Written" and inserting in lieu thereof "Timely written", and (ii) by inserting before the period "and, if a person has asked the entity conducting the review to place the person's name on a mailing list maintained by the entity, such notification shall be sent to such person".

(B) Section 1532(b)(7) is amended by striking out "Notification" and inserting in lieu thereof "Timely notification".

(2) Section 1532(b)(2) is amended by adding at the end the following: "If, after a review has begun, a State Agency, health systems agency, or Statewide Health Coordinating Council requires, in accordance with paragraph (3), the person subject to the review to submit information respecting the subject of the review, such person shall be provided at least fifteen days to submit the information.".

(3) Section 1532(b) is amended by adding after paragraph (11) the following new paragraph:

"(12) The following procedural requirements with respect to proceedings under a certificate of need program:

"(A) Hearings under a certificate of need program shall be held before a State Agency or a health systems agency to which the State Agency has delegated the authority to hold such a hearing. In a hearing under the program, any person shall have the right to be represented by counsel and to present oral or written arguments and evidence relevant to the matter which is the subject of the hearing, any person directly affected by the matter which is the subject of the hearing may conduct reasonable questioning of persons who make factual allegations relevant to such matter, and a record of the hearing shall be maintained. The requirements of this subparagraph do not apply to hearings held by a health systems agency in the performance of a review under section 1513(f). 42 USC 300l-2.

"(B) Any decision of a State Agency to issue or to not issue a certificate of need or to withdraw a certificate of need shall be based solely (i) on the review of the State Agency conducted in accordance with procedures and criteria it has adopted in accordance with this section and regulations promulgated under this section, and (ii) on the record established in administrative proceedings held with respect to the application for such certificate or the Agency's proposal to withdraw the certificate, as the case may be. Any decision of a State Agency to approve or disapprove an application for an exemption under section 1527(b) shall be based solely on Post, p. 614.

the record established in the administrative proceedings held with respect to the application.

"(C)(i) The State Agency shall establish the period within which approval or disapproval by the State Agency of applications for certificates of need and for exemptions under section 1527(b) shall be made. If, after a review has begun by the State Agency, the State Agency or health systems agency requires, in accordance with section 1532(b)(3), an applicant to submit information respecting the subject of the review, the period prescribed pursuant to the preceding sentence shall, at the request of the applicant, be extended fifteen days.

Post, p. 614.

42 USC 300n-1.

"(ii) If the State Agency fails to approve or disapprove an application within the applicable period under clause (i), the applicant may, within a reasonable period of time following the expiration of such period, bring an action in an appropriate State court to require the State Agency to approve or disapprove the application.

"(D) The program shall provide that each decision of the State Agency to issue, not to issue, or to withdraw a certificate of need or to approve or disapprove an application for an exemption under section 1527(b) shall, upon request of any person directly affected by such decision, be administratively reviewed under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies or, if there is no such State law, by an entity (other than the State Agency) designated by the Governor.

"(E) Any person adversely affected by a final decision of a State Agency with respect to a certificate of need or an application for an exemption under section 1527(b) and a health systems agency if the decision respecting the certificate of need is inconsistent with a recommendation made by the agency to the State Agency with respect to the certificate of need may, within a reasonable period of time after such decision is made (and any administrative review of it completed), obtain judicial review of it in an appropriate State court. The decision of the State Agency shall be affirmed upon such judicial review unless it is found to be arbitrary or capricious or not made in compliance with applicable law.

"(F) There shall be no ex parte contacts—

"(i) in the case of an application for a certificate of need, between the applicant for the certificate of need, any person acting on behalf of the applicant, or any person opposed to the issuance of a certificate for the applicant and any person in the State Agency who exercises any responsibility respecting the application after the commencement of a hearing on the applicant's application and before a decision is made with respect for it; and

"(ii) in the case of a proposed withdrawal of a certificate of need, between the holder of the certificate of need, any person acting on behalf of the holder, or any person in favor of the withdrawal and any person in the State Agency who exercises responsibility respecting withdrawal of the certificate after commencement of a hearing on the Agency's proposal to withdraw the certificate of need and before a decision is made on withdrawal.

The requirements of this paragraph are in addition to the requirements of the other paragraphs of this subsection and may, as appropriate, apply to other review programs.".

(e) Section 1532(b) is amended by adding after paragraph (12) (added by subsection (d)) the following new paragraph: *Ante*, p. 611.

"(13)(A) In the case of reviews by health systems agencies under section 1513(f) and by State Agencies under paragraphs (4) and (5) of section 1523(a)— 42 USC 300*l*-2. 42 USC 300m-2.

"(i) provision for applications to be submitted in accordance with a timetable established by the reviewing agency,

"(ii) provision for such reviews to be undertaken in a timely fashion, and

"(iii) provision for all completed applications pertaining to similar types of services, facilities, or equipment affecting the same health service area to be considered in relation to each other (but no less often than twice a year).

"(B) In the case of reviews by health systems agencies under section 1513(g) and by State Agencies under paragraph (6) of section 1523(a), provision for reviews of similar types of institutional health services affecting the same health service area to be considered in relation to each other.".

(f) Section 1532(c)(6) is amended to read as follows: 42 USC 300n-1.

"(6) In the case of health services proposed to be provided—

"(A) the availability of resources (including health manpower, management personnel, and funds for capital and operating needs) for the provision of such services,

"(B) the effect of the means proposed for the delivery of such services on the clinical needs of health professional training programs in the area in which such services are to be provided,

"(C) if such services are to be available in a limited number of facilities, the extent to which the health professions schools in the area will have access to the services for training purposes,

"(D) the availability of alternative uses of such resources for the provision of other health services, and

"(E) the extent to which such proposed services will be accessible to all the residents of the area to be served by such services.".

(g)(1) Section 1532(c)(9)(B) is amended by inserting "and on the costs and charges to the public of providing health services by other persons" after "construction project" the second time it occurs.

(2) Section 1532(c) (as amended by section 103(d)) is amended by adding at the end the following: *Ante*, p. 594.

"(13) In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those proposed.

"(14) In the case of existing services or facilities, the quality of care provided by such services or facilities in the past.".

(h) Section 1532(a) is amended by adding after the sentence added by subsection (c) the following: "The Secretary shall review at least annually regulations promulgated under this section and provide opportunity for the submission of comments by health systems agencies, State Agencies, and Statewide Health Coordinating Councils on the need for the revision of such regulations. At least forty-five days before the initial publication of a regulation proposing a revision in a regulation of the Secretary under this section, the Secretary shall, with respect to such proposed revision, consult with and solicit *Ante*, p. 611.

the recommendations from health systems agencies, State Agencies, and Statewide Health Coordinating Councils.".

42 USC 300n-1. (i)(1) Section 1532(b)(3) is amended by adding at the end the following: "Each health systems agency, State Agency, and Statewide Health Coordinating Council shall develop procedures to assure that requests for information in connection with a review under this title are limited to only that information which is necessary for the agency, State Agency, or Statewide Health Coordinating Council to perform the review.".

(2) Section 1532(b)(10) is amended by striking out "pertinent" and inserting in lieu thereof "essential".

CERTIFICATE OF NEED PROGRAMS

SEC. 117. (a) Part C of title XV is amended by adding at the end the following:

"CERTIFICATE OF NEED PROGRAM

42 USC 300m-6. 42 USC 300m-2. "SEC. 1527. (a) The certificate of need program required by section 1523(a)(4)(B) shall, in accordance with this section, provide for the following:

"(1) Review and determination of need under such program for—

"(A) major medical equipment and institutional health services, and

"(B) capital expenditures,

shall be made before the time such equipment is acquired, such services are offered, substantial expenditures are undertaken in preparation for such offering, or capital expenditures are obligated.

"(2) The acquisition and offering of only such equipment and services as may be found by the State Agency to be needed; and the obligation of only those capital expenditures found to be needed by the State Agency. Except as otherwise authorized by this section, review under the program of an application for a certificate of need may not be made subject to any criterion and the issuance of a certificate of need may not be made subject to any condition unless the criterion or condition directly relates to—

42 USC 300n-1. "(A) criteria prescribed by section 1532(c),

"(B) criteria prescribed by regulations of the Secretary promulgated under section 1532(a) before the date of the enactment of the Health Planning and Resources Development Amendments of 1979, or

"(C) criteria prescribed by regulation by the State Agency in accordance with an authorization prescribed by State law.

The Secretary may not require a State to include in its program any criterion in addition to criteria described in subparagraphs (A) and (B).

"(3) An application for a certificate of need for an institutional health service, medical equipment, or a capital expenditure shall specify the time the applicant will require to make such service or equipment available or to obligate such expenditure and a timetable for making such service or equipment available or obligating such expenditure. After the issuance of a certificate of need, the State Agency shall periodically review the progress of the holder of the certificate in meeting the timetable specified in the approved application for the certificate. If on the basis of

such a review the State Agency determines that the holder of a certificate is not meeting such timetable and is not making a good faith effort to meet it, the State Agency may, after considering any recommendation made by the health systems agency which received a report from the State Agency on such review, withdraw the certificate.

"(4) In issuing a certificate of need, the State shall specify in the certificate the maximum amount of capital expenditures which may be obligated under such certificate. The program shall, in accordance with regulations promulgated by the Secretary, prescribe the extent to which a project authorized by a certificate of need shall be subject to further review if the amount of capital expenditures obligated or expected to be obligated for the project exceed the maximum specified in the certificate of need.

"(5) The program shall provide that (A) the requirements of section 1532 shall apply to proceedings under the program, and (B) each decision to issue a certificate of need (i) may only be issued by the State Agency, and (ii) shall, except in emergency circumstances that pose a threat to public health, be consistent with the State health plan in effect for such State under section 1524(c). 42 USC 300m-1 42 USC 300m-2

"(b)(1) Under the program a State shall not require a certificate of need for the offering of an inpatient institutional health service or the acquisition of major medical equipment for the provision of an inpatient institutional health service or the obligation of a capital expenditure for the provision of an inpatient institutional health service by—

"(A) a health maintenance organization or a combination of health maintenance organizations if (i) the organization or combination of organizations has, in the service area of the organization or the service areas of the organizations in the combination, an enrollment of at least 50,000 individuals, (ii) the facility in which the service will be provided is or will be geographically located so that the service will be reasonably accessible to such enrolled individuals, and (iii) at least 75 percent of the patients who can reasonably be expected to receive the institutional health service will be individuals enrolled with such organization or organizations in the combination;

"(B) a health care facility if (i) the facility primarily provides or will provide inpatient health services, (ii) the facility is or will be controlled, directly or indirectly, by a health maintenance organization or a combination of health maintenance organizations which has, in the service area of the organization or service areas of the organizations in the combination, an enrollment of at least 50,000 individuals, (iii) the facility is or will be geographically located so that the service will be reasonably accessible to such enrolled individuals, and (iv) at least 75 percent of the patients who can reasonably be expected to receive the institutional health service will be individuals enrolled with such organization or organizations in the combination, or

"(C) a health care facility (or portion thereof) if (i) the facility is or will be leased by a health maintenance organization or combination of health maintenance organizations which has, in the service area of the organization or the service areas of the organizations in the combination, an enrollment of at least 50,000 individuals and on the date the application is submitted under paragraph (2) at least fifteen years remain in the term of the lease, (ii) the facility is or will be geographically located so

that the service will be reasonably accessible to such enrolled individuals, and (iii) at least 75 percent of the patients who can reasonably be expected to receive the institutional health service will be individuals enrolled with such organization,

if, with respect to such offering, acquisition, or obligation, the State Agency has, upon application under paragraph (2), granted an exemption from such requirement to the organization, combination of organizations, or facility.

"(2) A health maintenance organization, combination of health maintenance organizations, or health care facility shall not be exempt under paragraph (1) from obtaining a certificate of need before offering an institutional health service, acquiring major medical equipment, or obligating capital expenditures unless—

"(A) it has submitted, at such time and in such form and manner as the State Agency shall prescribe, an application for such exemption,

"(B) the application contains such information respecting the organization, combination, or facility and the proposed offering, acquisition, or obligation as the State Agency may require to determine if the organization or combination meets the requirements of paragraph (1) or the facility meets or will meet such requirements, and

"(C) the State Agency approves such application.

In the case of a proposed health care facility (or portion thereof) which has not begun to provide institutional health services on the date an application is submitted under this paragraph with respect to such facility (or portion), the facility (or portion) shall meet the applicable requirements of paragraph (1) when the facility first provides such services. The State Agency shall approve an application submitted under this paragraph if it determines that the applicable requirements of paragraph (1) are met.

"(3) Notwithstanding subsection (d), a health care facility (or any part thereof) or medical equipment with respect to which an exemption was granted under paragraph (1) may not be sold or leased and a controlling interest in such facility or equipment or in a lease of such facility or equipment may not be acquired and a health care facility described in subparagraph (C) of paragraph (1) which was granted an exemption under paragraph (1) may not be used by any person other than the lessee described in such subparagraph unless—

"(A) the State Agency issues a certificate of need approving the sale, lease, acquisition, or use, or

"(B) the State Agency determines, upon application, that (i) the entity to which the facility or equipment is proposed to be sold or leased, which intends to acquire the controlling interest, or which intends to use the facility is a health maintenance organization or a combination of health maintenance organizations which meets the requirements of clause (i) of subparagraph (A) of paragraph (1) and (ii) with respect to such facility or equipment, the entity meets the requirements of clauses (ii) and (iii) of such subparagraph (A) or the requirements of clauses (i) and (ii) of subparagraph (B) of paragraph (1).

"(4) In the case of a health maintenance organization or an ambulatory care facility or health care facility which ambulatory or health care facility is controlled, directly or indirectly, by a health maintenance organization or a combination of health maintenance organizations, a State may under the program apply its certificate of need requirements only to the offering of inpatient institutional health services, the acquisition of major medical equipment, and the obligation of capital expenditures for the offering of inpatient institu-

tional health services and then only to the extent that such offering, acquisition, or obligation is not exempt under paragraph (1).

"(5) Notwithstanding section 1532(c), if a health maintenance organization or a health care facility which is controlled, directly or indirectly, by a health maintenance organization apply for a certificate of need, such application shall be approved by the State Agency if the State Agency finds (in accordance with criteria prescribed by the Secretary by regulation) that— State Agency approval. 42 USC 300n-1.

"(A) approval of such application is required to meet the needs of the members of the health maintenance organization and of the new members which such organization can reasonably be expected to enroll, and

"(B) the health maintenance organization is unable to provide, through services or facilities which can reasonably be expected to be available to the organization, its institutional health services in a reasonable and cost-effective manner which is consistent with the basic method of operation of the organization and which makes such services available on a long-term basis through physicians and other health professionals associated with it.

Except as provided in paragraph (1) and notwithstanding subsection (d), a health care facility (or any part thereof) or medical equipment with respect to which a certificate of need was issued under this subsection may not be sold or leased and a controlling interest in such facility or equipment or in a lease of such facility or equipment may not be acquired unless the State Agency issues a certificate of need approving the sale, acquisition, or lease.".

"(c) Notwithstanding section 1532(c), an application for a certificate of need for a capital expenditure which is required—

"(1) to eliminate or prevent imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations,

"(2) to comply with State licensure standards, or

"(3) to comply with accreditation standards compliance with which is required to receive reimbursements under title XVIII of the Social Security Act or payments under a State plan for medical assistance approved under title XIX of such Act, 42 USC 1395. 42 USC 1396.

shall be approved unless the State Agency finds that the facility or service with respect to which such capital expenditure is proposed to be made is not needed or that the obligation of such capital expenditure is not consistent with the State health plan in effect under section 1524. An application for a certificate of need approved under this subsection shall be approved only to the extent that the capital expenditure is required to eliminate or prevent the hazards described in paragraph (1) or to comply with the standards described in paragraph (2) or (3). 42 USC 300m-4.

"(d)(1) Under the program a certificate of need shall, except as provided in subsection (b), be required for the obligation of a capital expenditure to acquire (either by purchase or under lease or comparable arrangement) an existing health care facility if—

"(A) the notice required by paragraph (2) is not filed in accordance with that paragraph with respect to such acquisition, or

"(B) the State Agency finds, within thirty days after the date it receives a notice in accordance with paragraph (2) with respect to such acquisition, that the services or bed capacity of the facility will be changed in being acquired.

"(2) Before any person enters into a contractual arrangement to acquire an existing health care facility which arrangement will require the obligation of a capital expenditure, such person shall

notify the State Agency of the State in which such facility is located of such person's intent to acquire such facility and of the services to be offered in the facility and its bed capacity. Such notice shall be made in writing and shall be made at least thirty days before contractual arrangements are entered into to acquire the facility with respect to which the notice is given.

"(e)(1)(A) Except as provided in subsection (b) and subparagraph (B), under the program a certificate of need shall not be required for the acquisition of major medical equipment which will not be owned by or located in a health care facility unless—

"(i) the notice required by paragraph (2) is not filed in accordance with that paragraph with respect to such acquisition, or

"(ii) the State Agency finds, within thirty days after the date it receives a notice in accordance with paragraph (2) with respect to such acquisition, that the equipment will be used to provide services for inpatients of a hospital.

"(B) The certificate of need program of a State may include a requirement for a certificate of need for an acquisition of major medical equipment which requirement is in addition to the requirement for a certificate of need established by subparagraph (A), except that after September 30, 1982, the certificate of need program of a State may not be changed to include any such additional requirement.

"(2) Before any person enters into a contractual arrangement to acquire major medical equipment which will not be owned by or located in a health care facility, such person shall notify the State Agency of the State in which such equipment will be located of such person's intent to acquire such equipment and of the use that will be made of the equipment. Such notice shall be made in writing and shall be made at least thirty days before contractual arrangements are entered into to acquire the equipment with respect to which the notice is given.

Major medical equipment, donations and leases.

"(3) For purposes of this subsection, donations and leases of major medical equipment shall be considered acquisitions of such equipment, and an acqusition of medical equipment through a transfer of it for less than fair market value shall be considered an acquisition of major medical equipment if its fair market value is at least $150,000.

Osteopathic or allopathic facility.
42 USC 300n-1.

"(f) Notwithstanding section 1532(c), when an application is made by an osteopathic or allopathic facility for a certificate of need to construct, expand, or modernize a health care facility, acquire major medical equipment, or add services, the need for that construction, expansion, modernization, acquisition of equipment, or addition of services shall be considered on the basis of the need for and the availability in the community of services and facilities for osteopathic and allopathic physicians and their patients. The State Agency shall consider the application in terms of its impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

"(g) In approving or disapproving applications for certificates of need or in withdrawing certificates of need under such a program, a State Agency shall take into account recommendations made by health systems agencies within the State under section 1513(f).".

42 USC 300*l*-2.
42 USC 300m-2.

(b)(1) Section 1523(a)(4)(B) is amended (A) by striking out "new institutional health services proposed to be offered or developed within the State" and inserting in lieu thereof "the obligation of capital expenditures within the State and the offering within the State of new institutional health services and the acquisition of major medical equipment", and (B) by striking out "which is satisfactory to

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the Secretary" and inserting in lieu thereof "which is consistent with standards established by the Secretary by regulation".

(2) The second sentence of section 1523(a)(4) is amended to read as follows: "A certificate of need program shall provide for procedures and penalties to enforce the requirements of the program.". 42 USC 300m-2.

(3) Section 1531 is amended (i) by striking out "For purposes of this title" and inserting in lieu thereof "Except as otherwise provided, for purposes of this title", and (ii) by adding after paragraph (5) the following new paragraphs: 42 USC 300n.

"(6) For purposes of sections 1523 and 1527, the term 'capital expenditure' means an expenditure— "Capital expenditure." 42 USC 300m-2. *Ante*, p. 614.

"(A) made by or on behalf of a health care facility (as such a facility is defined in regulations prescribed under paragraph (5)); and

"(B)(i) which (I) under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance, or (II) is made to obtain by lease or comparable arrangement any facility or part thereof or any equipment for a facility or part; and

"(ii) which (I) exceeds the expenditure minimum, (II) substantially changes the bed capacity of the facility with respect to which the expenditure is made, or (III) substantially changes the services of such facility.

For purposes of subparagraph (B)(ii)(I), the cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure described in subparagraph (B)(i) is made shall be included in determining if such expenditure exceeds the expenditure minimum. Donations of equipment or facilities to a health care facility which if acquired directly by such facility would be subject to review under section 1527 shall be considered capital expenditures for purposes of sections 1523 and 1527, and a transfer of equipment or facilities for less than fair market value shall be considered a capital expenditure for purposes of such sections if a transfer of the equipment or facilities at fair market value would be subject to review under section 1527. For purposes of this paragraph, the term 'expenditure minimum' means $150,000 for the twelve-month period beginning with the month in which this paragraph is enacted and for each twelve-month period thereafter, $150,000 or, at the discretion of the State, the figure in effect for the preceding twelve-month period, adjusted to reflect the change in the preceding twelve-month period in an index maintained or developed by the Department of Commerce and designated by the Secretary by regulation for purposes of making such adjustment.

"(7) For purposes of sections 1523 and 1527, the term 'major medical equipment' means medical equipment which is used for the provision of medical and other health services and which costs in excess of $150,000, except that such term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services if the clinical laboratory is independent of a physician's office and a hospital and it has been determined under title XVIII of the Social Security Act to meet the requirements of paragraphs (10) and (11) of section 1861(s) of such Act. In determining whether medical equipment has a value in excess of $150,000, the value of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of such equipment shall be included. "Major medical equipment." 42 USC 1395. 42 USC 1395x.

"Health maintenance organization." 42 USC 300e-9.

"(8) The term 'health maintenance organization' means a public or private organization, organized under the laws of any State, which—

"(A) is a qualified health maintenance organization under section 1310(d); or

"(B)(i) provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physician services, hospitalization, laboratory, X-ray, emergency and preventive services, and out of area coverage; (ii) is compensated (except for copayments) for the provision of the basic health care services listed in clause (i) to enrolled participants by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided; and (iii) provides physicians' services primarily (I) directly through physicians who are either employees or partners of such organization, or (II) through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).".

42 USC 300m-1. (4)(A) Section 1522(b)(13) is amended (i) by striking out "(3),", (ii) by inserting "in a timely manner" after "reviewed" in subparagraph (A), and (iii) by inserting after "agencies," in subparagraph (A) the following: "or, if there is no such State law,".

(B) Section 1522(b)(13)(B) is amended by inserting "under subparagraph (A)" after "the reviewing agency".

42 USC 300n-1. (5) Section 1532(c)(8) is amended by striking out "for which assistance may be provided under title XIII".

42 USC 300m-6 note. (c) The Comptroller General shall conduct an evaluation of the exemption authority provided by section 1527(b) of the Public Health Service Act. In conducting the evaluation, the Comptroller General shall determine—

(1) the health maintenance organizations, combinations of health maintenance organizations, and health care facilities which have applied to receive an exemption under that section,

(2) the services, facilities, and equipment with respect to which applications have been submitted under that section,

(3) the impact of the exemption on existing contractual arrangements between health maintenance organizations and health care facilities and on plans of such organizations respecting such arrangements, and

(4) the impact of the exemption on health care delivery systems, including its impact on the cost, availability, accessibility, and quality of health care.

Report to congressional committees. The Comptroller General shall report the results of the evaluation to the Committee on Labor and Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives not later than February 1, 1982.

Regulations. 42 USC 300m-6 note. (d) Within one hundred and eighty days of the date of the enactment of this Act, the Secretary of Health, Education, and Welfare shall promulgate such regulations as may be necessary to enable the States to establish certificate of need programs which meet the requirements of section 1527 of the Public Health Service Act.

Ante, p. 614.

APPROPRIATENESS REVIEW

42 USC 300*l*-2. SEC. 118. (a)(1) Section 1513(g)(1) is amended by striking out "all institutional health services offered in the health service area of the agency" and inserting in lieu thereof "at least those institutional and home health services which are offered in the health service area of

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the laws of any State, (1) which is a qualified health maintenance organization under section 1310(d) of the Act, or (2) which:

(i) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physician services, hospitalization, laboratory, x-ray, emergency and preventive services, and out of area coverage; and

(ii) Is compensated (except for copayments) for the provision of the basic health care services listed in paragraph (2)(i) of this definition to enrolled participants by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided; and

(iii) Provides physicians' services primarily (A) directly through physicians who are either employees or partners of the organization, or (B) through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

The term "health services" means clinically related (i.e., diagnostic, treatment, or rehabilitative) services, and includes alcohol, drug abuse, and mental health services.

The term "major medical equipment" means a single unit of medical equipment or a single system of components with related functions which is used to provide medical and other health services and which costs more than $150,000. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services, if the clinical laboratory is independent of a physician's office and a hospital and has been determined under title XVIII of the Social Security Act to meet the requirements of paragraphs (10) and (11) of section 1861(s) of that Act. In determining whether medical equipment costs more than $150,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to acquiring the equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

Note.—The acquisition of equipment which does not meet the definition of major medical equipment and thus is not subject to review under § 123.404(a)(4), will be subject to review if it meets any other requirement under § 123.404(a).

The term "person" means an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies, and insurance companies), a State, a political subdivision or an instrumentality (including a municipal corporation) of a State, or any legal entity recognized by the State.

The term "physician" means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by a State.

§ 123.402 Purpose and applicability.

(a) Section 1523(a)(4)(B) of the Act requires each State health planning and development agency (State Agency) to administer a State certificate of need program which (1) applies to the obligation of capital expenditures within the State, the offering within the State of new institutional health services, and the acquisition of major medical equipment, and (2) is consistent with regulations of the Secretary. This subpart sets forth the requirements and standards that a State certificate of need program must meet. A State certificate of need program may include additional provisions not inconsistent with the requirements of this subpart.

(b) Section 1532(a) of the Act requires that in performing its review functions under section 1523(a)(4)(B) of the Act, each State Agency shall (except to the extent approved by the Secretary) follow procedures, and apply criteria, developed and published by the State Agency in accordance with regulations of the Secretary. This subpart sets forth requirements respecting these procedures and criteria.

§ 123.403 General.

(a) Each State Agency shall administer within the State a certificate of need program meeting the requirements of this subpart.

(b) Only the State Agency (or the appropriate administrative or judicial review body) may issue, deny or withdraw certificates of need, grant exemptions from certificate of need reviews, or determine that certificate of need reviews are not required.

(c) In issuing or denying certificates of need or in withdrawing certificates of need, the State Agency shall take into account recommendations made by health systems agencies under Subpart D of Part 122 of this title.

(d) Each decision of the State Agency (or the appropriate administrative or judicial review body) to issue a certificate of need must be consistent with the State health plan, except in emergency circumstances that pose an imminent threat to public health.

(e) Each decision of a State Agency to issue, deny, or withdraw a certificate of need must be based (1) on the review by the State Agency conducted in accordance with procedures and criteria it has adopted under this subpart, and (2) on the record of the administrative proceedings held on the application for the certificate or the State Agency's proposal to withdraw the certificate. Each decision of a State Agency to grant or deny an exemption under § 123.405 (HMOs) must be made in accordance with the State Agency's procedures for reviewing applications for exemptions and must be based solely on the record of the administrative proceedings held on the application.

§ 123.404 Scope of certificate of need review programs.

(a) *Required coverage.* The State certificate of need program must apply to the obligation of capital expenditures, the offering of new institutional health services, and the acquisition of major medical equipment. For purposes of this subpart, "the obligation of capital expenditures, offering of new institutional health services, and acquisition of major medical equipment" means the following:

(1) *Capital expenditures that exceed the expenditure minimum.* The obligation by or on behalf of a health care facility of any capital expenditure (other than to acquire an existing health care facility) that exceeds the expenditure minimum for capital expenditures (or any lesser amount the State may specify). The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities (including staff effort and consulting and other services) essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds the expenditure minimum. As to the obligation of a capital expenditure to acquire an existing health care facility, see paragraph (a)(5) of this section.

Explanatory note.—Expenditures by a component of a larger institution, such as a university, which is distinct from a separate health care facility component, such as the university's hospital, need not be viewed as being "by a health care facility" for purposes of this section. Thus, a capital expenditure by a university medical school that is a distinct component of the university need not be considered to be "by" the hospital of the university. In finding that the medical school is distinct, the State Agency should find at least that the revenues derived from patient charges at the hospital of the university are not used for operating expenses of the medical school. If a capital expenditure

exceeds the expenditure minimum, for it to be required to be subject to review, the State Agency must find that it is "on behalf of" a health care facility. Such an expenditure is also required to be subject to review if it is for the acquisition of major medical equipment and meets the conditions set forth in § 123.404(a)(4) of this subpart. The same analysis would apply to a distinct research component of a legal entity, the primary activity of which is operating a hospital.

(2) *Bed capacity.* The obligation of any capital expenditure by or on behalf of a health care facility which—(i) increases or decreases the total number of beds, (ii) redistributes beds among various categories, or (iii) relocates beds from one physical facility or site to another—by ten beds or ten percent, whichever is less, in any two-year period.

(3) *Health services.* (i) The obligation of any capital expenditure by or on behalf of a health care facility which is associated with (A) the addition of a health service which was not offered by or on behalf of the facility within the previous twelve months, or (B) the termination of a health service which was offered in or through the facility; or

(ii) The addition of a health service which is offered by or on behalf of the health care facility which was not offered by or on behalf of the facility within the twelve-month period before the month in which the service would be offered, and which entails annual operating costs of at least the expenditure minimum for annual operating costs.

(4) *Major medical equipment.* (i) The acquisition by any person of major medical equipment that will be owned by or located in a health care facility; or

(ii) The acquisition by any person of major medical equipment not owned by or located in a health care facility, if (A) the notice of intent required by § 123.406(a) is not filed in accordance with that paragraph, or (B) the State Agency finds, within 30 days after the date it receives a notice in accordance with § 123.406(a), that the equipment will be used to provide services for inpatients of a hospital.

(iii) An acquisition of major medical equipment need not be reviewed if it will be used to provide services to inpatients of a hospital only on a temporary basis in the case of (A) a natural disaster, (B) a major accident, or (C) equipment failure.

(iv) A State program may cover major medical equipment not owned by or located in a health care facility beyond the minimum coverage required by this subparagraph; however, after September 30, 1982, the certificate of need program of a State may not be changed to include additional requirements for coverage of this equipment.

(5) *Acquisitions of health care facilities.* (i) Except as provided in § 123.405(b) (HMOs), the obligation of a capital expenditure by any person to acquire an existing health care facility (A) if the notice of intent required at § 123.406(b) is not filed in accordance with that paragraph, or (B) if the State Agency finds, within 30 days after the date it receives a notice in accordance with § 123.406(b), that the services or bed capacity of the facility will be changed in being acquired.

(ii) Each State Agency shall specify, for purposes of the preceding sentence, what activities result in a change in the services or bed capacity of a health care facility; however, these activities must include at least (A) a change in bed capacity as described in paragraph (a)(2) of this section, (B) the addition of a health service which was not offered by or on behalf of the facility within the previous twelve months, and (C) the termination of a health service which was offered by or on behalf of the facility.

(b) *Leases, donations, and transfers.* An acquisition by donation, lease, transfer, or comparable arrangement must be reviewed if the acquisition would be subject to review under paragraph (a) of this section if made by purchase. An acquisition for less than fair market value must be reviewed if the acquisition at fair market value would be subject to review under paragraph (a) of this section.

(c) *Incurring an obligation.* No person may incur an obligation for a capital expenditure that is subject to review under paragraphs (a)(1), (a)(2), (a)(3)(i), or (a)(5) of this section without obtaining a certificate of need for the capital expenditure. An obligation for a capital expenditure is considered to be incurred by or on behalf of a health care facility: (1) When a contract, enforceable under State law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease or financing of a capital asset; or (2) When the governing board of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or (3) In the case of donated property, on the date on which the gift is completed under applicable State law.

Note.—A State may consider an obligation for a capital expenditure which is contingent upon issuance of a certificate of need not to be incurred until the certificate of need is issued.

(d) *Subsequent reviews.*—(1) *Capital expenditures.* The State program must provide as follows: A proposed change in a project associated with a capital expenditure for which the State Agency has previously issued a certificate of need will require review if the change is proposed within one year (or any longer period established under the State Program) after the date the activity for which the expenditure was approved is undertaken. (As an illustration, where a hospital receives approval to construct a new wing for its facility, the hospital will "undertake the activity" when it begins to provide services in the wing.) This subparagraph applies to changes associated with capital expenditures that were subject to review under paragraph (a)(1), (a)(2) or (a)(3)(i) of this section. A review is required under this subparagraph whether or not a capital expenditure is associated with the proposed change. A "change in a project" shall include, at a minimum, any change in the bed capacity of a facility as described in paragraph (a)(2) of this section, and the addition or termination of a health service.

Explanatory note.—Examples that illustrate coverage required by this paragraph are as follows: (1) A certificate of need is obtained for the obligation of a capital expenditure which results in the addition of ten psychiatric beds. Within one year, those beds are proposed to be converted to pediatric beds. Certificate of need review is required for the conversion, regardless of whether this later activity is associated with a capital expenditure. (2) A certificate of need is obtained for the obligation of a capital expenditure which results in the addition of a new psychiatric service. Within one year, this service is proposed to be converted to a new pediatric service. Certificate of need review is required, regardless of whether a capital expenditure associated with the new service will be incurred or annual operating costs of at least the expenditure minimum will result.

(2) *Major medical equipment.* If a person acquires major medical equipment not located in a health care facility without a certificate of need and proposes at any time to use that equipment to serve inpatients of a hospital the proposed new use must be reviewed unless the use is one described in paragraph (a)(4)(iii) of this section.

(3) *Existing facilities.* If a person acquires an existing health care facility without a certificate of need and proposes to change within one year after the acquisition (or any longer period of time established under the State program) the services or bed capacity of the facility, the proposed change must be reviewed if it would have required review under paragraph (a)(5) of this section originally.

Status of State Conformance
With Federal Certificate of Need Laws
(As Of August, 1981)

	with PL93-641	with PL96-79	non-conforming
1. Alabama	X		
2. Alaska	X		
3. Arizona			X
4. Arkansas		X	
5. California			X
6. Colorado	X		
7. Connecticut	X		
8. Delaware	X		
9. District of Columbia		X	
10. Florida		X	
11. Georgia			X
12. Hawaii		X	
13. Idaho			X
14. Illinois	X		
15. Indiana			X
16. Iowa	X		
17. Kansas		X	
18. Kentucky		X	
19. Louisiana			X(no law)
20. Maine	X		
21. Maryland	X		
22. Massachusetts	X		
23. Michigan	X		
24. Minnesota	X		
25. Mississippi		X	
26. Missouri			X
27. Montana	X		
28. Nebraska	X		
29. Nevada*	X		
30. New Hampshire	X		
31. New Jersey		X	
32. New Mexico		X	
33. New York	X		
34. North Carolina	X		
35. North Dakota	X		
36. Ohio			X
37. Oklahoma		X	
38. Oregon			X
39. Pennsylvania			X
40. Rhode Island		X	
41. South Carolina*	X		
42. South Dakota	X		
43. Tennessee*	X		
44. Texas*	X		
45. Utah		X	
46. Vermont	X		
47. Virginia	X		
48. Washington		X	
49. West Virginia		X	
50. Wisconsin	X		
51. Wyoming	X		

*Have enacted CON amendments which may make them conforming to 96-76.

Status of Certificate of Need
and Section 1122 Programs in the States
(As Of August, 1981)

State	Year Certificate of Need First Enacted	Effective Date of Section 1122 Agreement	Both Programs
Alabama*	1977**	(terminated 6/30/80)	
Alaska*	1976**	04/01/74 (terminated 6/30/81)	
Arizona	1971	---	
Arkansas*	1975**	07/01/73 (renewed thru 6/30/82)	X
California	1969	---	
Colorado*	1973**	03/01/74 (terminated 6/30/79)	
Connecticut*	1969**	---	
Delaware*	1978**	07/01/73 (renewed thru 6/30/82)	X
Florida*	1972**	01/01/73 (terminated 6/30/78)	
Georgia	1974	02/27/74 (renewed thru 6/30/82)	X
Hawaii*	1974**	08/16/73 (terminated 2/08/77)	
Idaho	1980	02/01/74 (terminated 9/30/80)	
Illinois*	1974**	---	
Indiana	1980	07/01/73 (renewed thru 1/1/82)	X
Iowa*	1977**	03/07/73 (renewed thru 6/30/82)	X
Kansas*	1972**	---	
Kentucky*	1972**	03/15/74 (renewed thru 6/30/82)	X
Louisiana	----	05/16/73 (renewed thru 9/30/81)	
Maine*	1978**	03/01/73 (renewed thru 6/30/82)	X
Maryland*	1968**	02/15/74 (terminated 6/30/78)	
Massachusetts*	1971**	---	
Michigan*	1972**	12/14/73 (renewed thru 1/1/82)	X
Minnesota*	1971**	02/25/74 (renewed thru 1/1/82)	X
Missouri	1979	08/20/79 (terminated 7/30/81)	
Mississippi*	1979**	11/01/76 (terminated 6/30/81)	
Montana*	1975**	02/26/74 (terminated 2/8/80)	
Nebraska*	1979**	02/26/73 (renewed thru 6/31/81)	X
Nevada*	1971**	03/15/74 (terminated 3/19/80)	
New Hampshire*	1979**	04/01/73 (terminated 7/01/79)	

* Fully designated SHPDA
** "Satisfactory" programs

State	Year Certificate of Need First Enacted	Effective Date of Section 1122 Agreement	Both Programs
New Jersey*	1971**	02/28/74 (renewed thru 6/30/82)	X
New Mexico*	1978**	07/01/73 (renewed thru 6/30/82)	X
New York*	1964**	02/28/74 (terminated 6/30/79)	
North Carolina*	1978**	04/02/73 (renewed thru 6/30/82)	X
North Dakota*	1971**	02/28/74 (terminated 6/30/81)	
Ohio	1975	06/28/74 (terminated 6/01/78)	
Oklahoma*	1971**	02/27/74 (renewed thru 6/30/82)	X
Oregon	1971	03/01/74 (terminated 6/30/79)	
Pennsylvania	1979	03/01/73 (terminated 6/30/81)	
Rhode Island*	1968**	-------	
South Carolina*	1971**	03/15/74 (terminated 6/30/81)	
South Dakota*	1972**	-------	
Tennessee*	1973**	-------	
Texas*	1975**	-------	
Utah*	1979**	01/02/75 (terminated 7/01/79)	
Vermont*	1979**	01/02/75 (terminated 7/01/79)	
Virginia*	1973**	07/01/73 (terminated 7/01/78)	
Washington*	1971**	02/01/74 (terminated 6/30/80)	
West Virginia*	1977**	02/28/74 (renewed thru 6/30/82)	X
Wisconsin*	1977**	09/01/73 (terminated 7/01/78)	
Wyoming*	1977**	02/28/74 (terminated 6/30/79)	

* Fully designated SHPDA
** "Satisfactory" programs

SPECIAL ARTICLE

DUPLICATED HOSPITAL FACILITIES

How Much Can We Save by Consolidating Them?

WILLIAM B. SCHWARTZ, M.D., AND PAUL L. JOSKOW, PH.D.

Abstract One strategy for controlling the costs of health care is to eliminate duplicative hospital facilities so that the current volume of services can be delivered more efficiently. We evaluated the potential saving from consolidating hospital facilities according to the guidelines recently established by the Department of Health and Human Services (HHS). Eliminating duplication in four categories (computerized axial-tomographic scanners, open-heart surgery and cardiac-catheterization units, megavoltage-radiation units, and general hospital beds) would yield a potential theoretical saving of about $1 billion a year. However, the resulting indirect costs, such as those incurred by certificate-of-need programs and by moving patients from one facility to another, would reduce or possibly eradicate this gain. Overall, the expected saving falls far short of HHS goals. We conclude that only by reducing the demand for services will substantial savings be realized. (N Engl J Med. 1980; 303:1449-57.)

OVER the past decade, a massive state and federal regulatory apparatus has been created to carry out health planning and to determine the need for hospital facilities. This regulatory effort has been undertaken on the assumption that consolidating certain types of facilities can yield a large saving without reducing the quality of care. To this end, federal guidelines were promulgated in 1978, yet there has been no systematic evaluation of the saving that could indeed be achieved by implementing them fully. We shall focus on the four kinds of facility that have been singled out most often as costly and redundant. The four — computed axial-tomographic (CAT) scanners, facilities for open-heart surgery and cardiac catheterization, radiation-therapy units, and the supply of general hospital beds — have been designated by the Department of Health and Human Services (HHS) as major targets for cost reduction.

Taking the present demand for care as fixed, we ask whether a reorganized hospital sector could deliver the current level of services more economically. We determined the saving that could theoretically be achieved under the guidelines established by the Health Resources Administration (HRA), and we examined the offsetting costs that implementing the regulations would incur — both as dollars spent directly and as the price of inconvenience to patients and their families.

Throughout the paper we made calculations on the assumption that any facilities identified as redundant could be closed immediately. We recognize, however, that most state certificate-of-need laws primarily affect the rate at which new facilities are added to the system. The estimates that we provide can therefore be interpreted in one of two ways. They reflect the saving that would have been achieved by now if the utilization standards had been in effect for many years. Equivalently, they predict the cost saving that could be achieved in the future by forcing the system to grow into the existing capacity until the levels of use defined by the guidelines are achieved.

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METHODS

For each type of service, we needed to know how much is currently being spent to provide care and how much could be saved by consolidating facilities, provided that aggregate levels of care are held constant. We began by establishing how many facilities of each type exist, how heavily they are used, and how much they cost each year. Secondly, we compared current patterns of use with the HRA guidelines to see whether excess capacity is detectable. Then, if excess capacity appeared to exist, we calculated how much could be saved by eliminating it.

The direct theoretical saving from closing underused facilities is the number of patients currently using the facilities multiplied by the average cost per patient. To find the net theoretical saving, we must subtract the additional (marginal) cost of adding these same patients to the load carried by the remaining active units. In general, the larger the marginal cost, the smaller the net theoretical saving that can be achieved by consolidation.

This approach, based on assumptions expressed in Figure 1, reflects the way unit costs change as the use of an individual facility increases. Presumably, the average cost per patient treated (AC) diminishes until it reaches some minimum level at which all economies of scale are exhausted. At low levels of use, the cost of adding one more patient to a facility's existing load is lower than the average cost for a patient already using the facility; that is, the marginal cost (MC) is lower than the average cost. This statement remains true until unit costs are minimized — the condition described by point B in the figure. Increasing use beyond this level effects no further saving within the facility itself. Meanwhile, other costs, such as travel to the facility, will offset some of this purely internal economy of scale. Such considerations shift the optimal level to the left, such as to point A.

We can imagine that each existing facility lies at a point somewhere along the curve of average cost. The location of this point depends on the facility's rate of use. Those facilities in which use falls short of point A are targets for consolidation. For the sake of argument, we assumed that point A is correctly specified by the HRA's 1978 guidelines, unless the guideline assumes implicitly or

explicitly that the demand for care is also to be reduced, in that case, we made appropriate adjustments to keep our calculations based on fixed demand. This issue was important only with regard to the supply of general hospital beds.

Quality of Data

When we began this project, the federal government had already issued detailed guidelines in each area that we intended to examine.[1] We assumed that the requisite data on numbers of facilities, use levels, and total expenditures associated with each aspect of care, for example, would be readily available. We soon discovered that the state of knowledge in government agencies about the most obvious matters of cost and use was often abysmal. As a result, we had to assemble and analyze published information and to seek unpublished data from numerous government agencies, third-party payers, and independent research projects. The sources were not always ideal. However, taken together, our data are unique in that they are far more extensive than any of which we are aware. In cases in which we were uncertain of a number, we tested our estimates against the reasonable maximum and minimum values, carrying out a so-called sensitivity analysis.

In every instance we sought the latest information on the actual cost of operating the type of facility under examination: expenditures on labor, capital, and materials as well as the number of facilities operating and their levels of use. The data that we compiled on both costs and use are based on observations for the period 1976 to 1978. When it was necessary, we adjusted some values for inflation so that estimates can be expressed in 1978 dollars. In 1978, total expenditures in short-term general hospitals amounted to $58 billion, excluding physicians' fees.[2]

Estimation of Theoretical Savings for Individual Types of Facilities

CAT Scanners

Number of Units and Costs of Equipment

At the beginning of 1979, there were 1254 CAT scanners operating in the United States.[3] Among these, about one third were head scanners and two thirds body scanners. Approximately 1000 were operating in hospitals. Purchase price for CAT scanners varied considerably; in 1978 they ranged from about $150,000 for a head scanner to about $700,000 for a state-of-the-art body scanner.[4] The average annual cost to operate a head scanner for 30 patients a week was $369,000,[5] and to run a body scanner for 30 patients a week cost about $354,000.[6] From these figures we estimate that the total cost of CAT scanning in hospitals amounted to about $400 million in 1978.

In 1978, over 70 per cent of a sample of head scanners in operation for more than 2½ years met the HRA criterion of at least 30 patient procedures per week, or more than 2500 per year.[5] The remainder had a mean case load of 37 per week, or about 1900 per year. At the same time, a sample of body scanners in operation for at least 18 months were used at a substantially lower rate.[6] About 80 per cent of these units failed to meet HRA guidelines, and about 70 per cent performed fewer than 2000 procedures per year.

Potential Saving from Consolidation

We estimated the potential yield from consolidating scanner services, by first estimating how unit cost

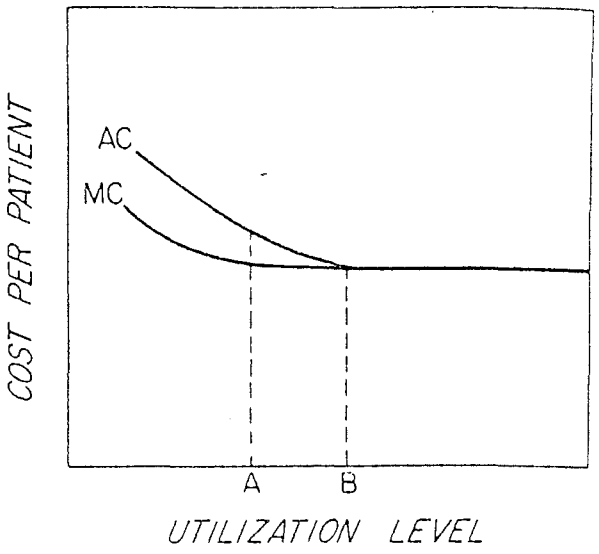

Figure 1. Theoretical Relation between Cost per Patient and Rate of Use of a Given Type of Hospital Facility

As the rate of use increases, the average cost per patient (AC) declines until all economies of scale have been achieved (point B). Average cost falls as long as any additional patient can be treated at a marginal cost (MC) lower than AC. Point B reflects only the minimized cost of operating the facility itself. When other relevant costs (such as for travel and inconvenience) are taken into account, the total social expenditure will be minimized at a lower rate of use than point B; for example, at a level such as point A.

varies with rate of use and then extrapolating utilization data from a sample of head and body scanners[5,6] to all such instruments in hospitals. The Massachusetts Department of Public Health (MDPH) estimates that for both head and body scanners, the unit cost of a scan is approximately 30 per cent lower at 4000 hours of operation than at 1800 hours of operation.[4] Most of this saving is achieved below 3000 hours. Above that level, the need to hire more personnel or make overtime payments substantially reduces the opportunity for additional reductions in unit costs.

Head scans can be performed at an average rate of one every 45 minutes, and body scans at a rate of one every 75 minutes.[4,6] It seems reasonable to assume that the typical scanning facility, treating a variety of patients, can handle about one patient per hour.

From the MDPH cost data and the assumption that personnel costs are fixed at usage levels below 2000 patients per year, we estimate that meeting the HRA guideline of 2500 procedures per year would save about $85 million, almost entirely through consolidation of the use of body scanners. Detailed data are available in an appendix filed with the National Auxiliary Publications Service (NAPS).* Requiring

*For more detailed information order NAPS Document 03740 from ASIS/NAPS c/o Microfiche Publications, P.O. Box 3513, Grand Central Station, New York, NY 10017. Remit, in advance, $3 for each microfiche copy reproduction or $5 for each photocopy. Outside the United States and Canada, postage is $3 for a photocopy or $1 for a microfiche. Make checks payable to Microfiche Publications.

greater use of head scanners — 4500 procedures a year — would save another $10 million.

Open-Heart Surgery and Cardiac Catheterization

Current Number and Cost

Data from the National Center for Health Statistics indicate that approximately 130,000 open-heart operations were performed in 1978[7]; Stoney et al. estimated the number at 70,000 to 100,000 in 1976.[8] Thus, it appears that the number of open-heart procedures continues to increase at a rapid rate. We estimate that the average cost of each operation was $10,500 in 1978. This figure is derived from two studies conducted in 1976; the first was based on analysis of itemized bills from 45 hospitals,[9] and the second on an evaluation of average bills for 700 patients treated in a single facility,[8] adjusted for changes in the average cost per patient day between 1976 and 1978. The figure of $10,500, which excludes physicians' fees, implies that in 1978 total hospital expenditures on open-heart surgery were approximately $1.4 billion.

Changes in Unit Costs as Volume Increases

Hospital bills indicate that only 20 to 25 per cent of the cost of open-heart surgery is incurred in the operating room.[8,9] The remainder is composed of expenses — intensive care, ancillary services, and ordinary ward care[8,9] — that any patient undergoing serious surgery requires.

If the unit cost of such general services is not markedly affected by the volume of open-heart cases (experts whom we have consulted indicate that this is the situation at volumes below 200 cases per year), and if hospital bills roughly reflect actual costs, the saving from performing more procedures in each unit could not possibly exceed 25 per cent of the total. Indeed, the saving must be much lower because average operating-room costs could not be driven to zero no matter how heavily a unit was used. Even at a low volume of open-heart procedures, basic operating-room facilities continue to be used for other kinds of surgery. Thus, potential economies of scale in open-heart surgery depend on heavier use of equipment and personnel devoted exclusively to that purpose.

The potential saving from reducing the number of open-heart facilities and using them more heavily would be small. According to McGregor and Pelletier,[10] at a usage level of 25 cases per year a facility has fixed costs of about $750 per operation, and these costs diminish to about $350 when the number of cases is doubled. Fixed costs in this calculation chiefly involve the payroll for specialized personnel employed exclusively for open-heart surgery. This $400 saving, though not trivial, represents a small fraction of the total hospital bill of a patient who undergoes open-heart surgery. A further fourfold increase to the HRA minimum of 200 a year would save only $265 more per patient.

We independently estimated that the fixed costs required to bring open-heart surgery into a typical community hospital that already has standard operating-room and intensive-care facilities would be about $75,000 a year in 1978 dollars, excluding physicians' fees and cardiac catheterization. (The detailed data have been filed with NAPS [Document 03740].) At 50 procedures per year, the average fixed cost would be $1,500 a case; at 200 per year the cost would be $375. This $1,100 saving represents only about 10 per cent of the total hospital bill of a patient undergoing cardiac surgery.

This difference is so small that it is difficult to detect any systematic relation between the caseload of an open-heart facility and the patient's bill. Over a range of caseloads from 60 to more than 600 per year, the average bill for open-heart surgery from hospital to hospital is about the same.[9]

Potential Saving from Consolidation

We took an annual caseload of 200 as a minimum because it is the figure in the HRA guidelines and because many experts say it is the minimum needed to maintain medical proficiency.[11] Next, we wished to know the number of open-heart procedures performed in each facility in the United States. Although information is limited, detailed data are available for California, where in 1978 about 12 per cent of the nation's open-heart procedures were carried out[12] in 80 facilities representing about 15 per cent of the national total. In addition, we know that on the average each open-heart surgical facility in the United States performed about 220 procedures in 1978, whereas the average in California was about 200. It appears that the facilities in California are somewhat underutilized in relation to those in the rest of the country.

To calculate the national saving, we first estimated the saving that would be achieved in California if all facilities performed at least 200 procedures a year. We then assumed that the distribution of use in California is representative of the entire country. Any bias, we believe, would overestimate the potential saving because the level of use per facility in California is a bit below the national average. We estimate that the total saving for California would be $1.6 million per year, and for the United States as a whole about $15 million per year — less than 2 per cent of the total cost of hospitalization for open-heart surgery. (Detailed data are available in NAPS Document 03740.) Using the data of McGregor and Pelletier, we calculate that the aggregate saving would amount to less than $10 million per year.

As a rough check, we also used 1975 data on open-heart surgery performed in 93 hospitals with training programs in thoracic surgery. These hospitals performed 40 per cent of the nation's open-heart surgery in 1975, and all but 5 per cent of them handled more than 200 cases per year. (Cleveland R. Unpublished data). We made two extreme assumptions in performing the sensitivity analysis: that all increases in volumes of open-heart surgery since 1975 are attributable to facilities other than those in the sample and

that all the remaining facilities perform fewer than 200 cases per year, with loads uniformly distributed between 50 and 200 cases per year. These assumptions yield estimated savings of between $12 million and $35 million per year for the country as a whole. The lower figure is based on McGregor and Pelletier's cost estimates, and the higher value on our own.

The only report to conclude that a substantial saving could be achieved by consolidation is that of Finkler[13] (cited by Enthoven[14]), who studied a single California hospital in detail. He estimated a potential $400 million saving for the United States as a whole. We believe that unrealistic assumptions led Finkler to overestimate the figure; for example, that adding open-heart surgery at small volumes to an existing hospital requires an entirely new operating room, intensive-care unit, and inhalation-therapy unit, all exclusively for patients undergoing open-heart surgery. This belief and similar assumptions about staffing patterns are not consistent with real hospital practices. The result is an order-of-magnitude overestimate in the fixed costs of open-heart surgery.

Cardiac Catheterization

In 1978, about 305,000 cardiac catheterizations were performed[7]; the average estimated cost was $589 in 1976[8] and $625 in 1977.[15] We took the average total cost of a cardiac catheterization to be $750 in 1978. Accordingly, expenditures for cardiac catheterization in the United States, exclusive of other inpatient charges, were probably less than $250 million.

From a study of two Canadian hospitals, McGregor and Pelletier[10] report that the average fixed cost declines rapidly as use of a facility increases from 100 to 400 cases a year; in 1976, this cost decreased from $700 to $300.

Detailed information on the number of catheterizations per hospital is available for California, where about 15 per cent of the catheterizations in the United States were performed in 1978.[7,12] If we assume that the distribution of catheterizations for California is representative of the entire United States, we can use McGregor and Pelletier's data on cost, adjusted for inflation, to estimate that $15 million a year would be saved by consolidating cardiac catheterizations into facilities that perform no fewer than 300 a year, as specified by the HRA guidelines. (Detailed data are available in NAPS Document 03740.) In sum, the theoretical saving that could be achieved by consolidating open-heart surgery and cardiac catheterization to meet the guidelines of the Department of Health and Human Services appears to be less than $50 million per year.

Therapeutic Radiology

According to the HRA guidelines, the annual caseload of a megavoltage-radiation-therapy unit should be at least 300 cases, although some flexibility is allowed for units in rural areas, where travel time becomes an important factor.[1] In 1977, according to a questionnaire survey of all centers, treatment was initiated in 353,000 patients, with a typical course of 20 sessions.[16] There were 1186 facilities with at least one megavoltage unit and about 1600 megavoltage units in the country, all told.[16] Thus, each facility treated 300 new patients on the average, and each unit treated 220. Over 70 per cent of the patients were treated in facilities that met the HRA guidelines, each unit handling at least 300 new patients a year, and over 85 per cent of the patients were treated by units in facilities with caseloads of 200 or more new patients a year. Given the distribution of patient volumes across all facilities in the United States,[16] we estimated that some 30 per cent of megavoltage units would have to be closed to bring all remaining units to the HRA's recommended level of at least 300 new cases annually. The inpatient load at the affected hospitals (less than 20 per cent of the national pool of patients undergoing therapy) would, in the process, have to be treated elsewhere.

The total cost of radiation therapy in the United States in 1976 was estimated by the Radiation Oncology Group to be $505 million.[16] Allowing for inflation and a 10 per cent increase in use between 1976 and 1978 yields a figure of $700 million in expenditures on megavoltage-radiation therapy in 1978. We found no information on how unit costs decline with the volume of cases handled by a unit. Our discussions with experts indicated that therapeutic-radiology units have many of the same cost characteristics of CAT-scan facilities. The equipment itself is expensive, but in addition substantial personnel costs are incurred. With more intensive use, additional personnel must be hired to operate the facility beyond the normal eight-hour day and on weekends. Accordingly, we assumed that unit costs for therapeutic radiology (as for CAT scans) are fixed at levels below [illegible] cases per year and fall by about 30 per cent as the volume increases from 150 to 300 patients per year, for an annual saving of $115 million. (Detailed data appear in NAPS Document 03740.) If unit cost falls by 40 per cent instead, the estimated saving is $150 million; if it falls by 20 per cent, the saving is only $90 million.

Bed Capacity

Definition of "Excess" Beds

An excess of hospital beds has been repeatedly cited as a major source of escalating hospital costs in the United States.[17-19] Roughly 5 to 10 per cent (60,000 to 100,000) of the beds in short-term general hospitals have been estimated to be unnecessary. This conclusion has two bases: analyses suggesting that there is some desirable maximum ratio of beds to population, such as four per 1000,[17,20] and the application of ideal criteria for occupancy, typically 80 to 85 per cent.[1,17,18] The HRA guidelines include both.

However, the precise meaning of "excess" as applied to hospital beds has always been characterized by considerable ambiguity. Some commentators sug-

gest that 80,000 beds are always empty, that is, that about 10 per cent are never used. A more sophisticated view considers the major problem to be not simply that of unused beds, but rather that a single large hospital can serve a population just as well as do several smaller ones in terms of turnaway probabilities and admission delays, with fewer total beds and at lower cost per bed.

Alternatively, beds may be underused in the sense that too high a reserve capacity is maintained for meeting peak demands on the hospital. In other words, the cost of holding the present reserve capacity could be seen as exceeding the benefit. By lengthening waiting lists slightly and increasing the probability that some patients will have to be turned away, hospitals can reduce expenditures.

Finally, the term "excess beds" is sometimes used to refer to beds that are misused, in that patients occupying them could be cared for equally well, with less expense, as outpatients or with shorter hospital stays. This perspective is based on the assumption that the demand for hospital services is too large.

As a result of this confusion, statements about excess beds do not necessarily refer to the same thing. McClure, for example, clearly indicates that he is referring to both underused and misused beds.[18] The HRA guidelines appear to aggregate the various types of excess beds.[1] Others are ambiguous on the point[17] or give the impression that they are contemplating only unused beds[19] while presenting estimates that are based on more than this category.

Definitions are not the only problem. Typical studies of bed use entirely neglect the realities of fluctuating patient demand and instead apply such criteria as an ideal occupancy rate or an optimal ratio of beds to population. Although more sophisticated models have been constituted, the analyses have typically suffered from a lack of crucial data,[18,21] notably the daily census data for individual hospital services (medical, surgical, and others). Unfortunately, only average rates of use for entire hospitals have usually been available.

Even if definitions were clear and data on underused beds were available, certain value judgments are still critical to policy decisions. How does one establish an optimal probability for turning away admissions? What is the optimal delay in admissions? What is the proper length of stay? When should the patient be cared for as an outpatient rather than as an inpatient? What surgery should be considered excessive? How are misused beds to be identified? These questions are all the harder to answer because physicians disagree in their assessments of appropriate patterns of care and because almost no comprehensive information is available on the costs of alternative methods of treatment.

For this analysis we sought an estimate of beds that are unused. Existing studies, often by implicitly assuming that all "excess" beds are truly unused, overestimate the theoretical saving and ignore the social cost of reducing hospitals' reserve capacity. They also neglect the offsetting cost of closing misused beds, since an alternative (if cheaper) form of care must be provided.

We have seen only one estimate that even comes close to making the appropriate distinction. McClure attempts to distinguish between underused beds (presumably both unused beds and others maintained at excessive cost to meet peak demand) and misused beds (which he calls "excessively utilized").[18] He gives two numbers for underused beds in the United States: 83,000, based on Hill-Burton formulas adjusted for areas with a shortage of beds, and 69,000, based on a queuing model. On the one hand, these numbers probably overestimate the number of unused beds because increases in turnaway probabilities and associated admissions delays are not analyzed. On the other hand, this bias should be at least partially eliminated by the failure to incorporate the saving that might be achieved by changing the size distribution of hospitals in favor of larger institutions. Assuming that the effects approximately cancel out, we take 75,000 to be the number of beds that could be eliminated without markedly affecting usage patterns or demand. This figure is well within the range of excess-bed estimates that have appeared elsewhere.

Options for Consolidation

Unused beds could be reduced in one of three ways, each with a different implication for the amount to be saved.

First of all, rooms, wards, or wings of a hospital can be closed, almost certainly with a trivial saving. Some staff could be consolidated, but the cost of materials, supplies, food, administration, and other necessities would not be affected, nor would expenditures on laboratories, radiology, and other ancillary facilities (some 30 per cent of hospital costs), which are staffed in proportion to the patient load rather than the number of beds. The saving from reduced housekeeping and maintenance would be small, because these items amount to only 5 per cent of total hospital expenditures.[22]

Secondly, whole services — obstetric, pediatric, or special-care units — could be closed, and the patients currently using them could be shifted to other hospitals. Once again, the potential saving depends on the extent to which economies of scale are possible, but it is likely to be a small gain. For example, obstetric services, which consume only about 5 per cent of expenditures,[22] have already been largely consolidated. The marginal cost of admitting a patient to a large obstetric unit has been estimated at 80 to 90 per cent of the average cost,[23,24] and the average cost of care in large units is higher than that in smaller ones.[23] As a result, closing even 25 per cent of the existing obstetric units would save no more than about $60 million a year.

Finally, closing entire hospitals appears to offer the greatest opportunity for reducing costs with no change in levels and patterns of care.[18] As before, the

cost of serving patients in another facility must be paid. For any immediate saving, hospitals would actually have to be closed, but a long-term equivalent would be the passive tactic of limiting construction of new hospitals and permitting the population to grow into the existing capacity. The eventual saving would be the same, although the regulatory and political consequences would be markedly different.

Potential Saving from Closing Hospitals

We needed four facts: the number of beds to be eliminated, the number of patients to be treated elsewhere, the current cost of treating patients in the hospitals to be closed, and the marginal cost of treating patients elsewhere. We chose 75,000 as the number of beds to be closed. For a measure of gross savings per bed closed, we use the average total cost per bed for community hospitals, $52,000 per bed per year,[2] as is commonly used in these computations. Estimating the marginal cost, however, is more complex.

From an extensive econometric literature on hospital-cost functions (Lipscomb et al.[25] have summarized the key studies), we can derive a mean estimate of the ratio of marginal cost to average cost.[26-31a] The mean estimate is 0.70, and nine of the 11 estimates[25] fall between 0.65 and 0.90. Studies taking the average occupancy rate as the independent variable (a method that appears to be most appropriate for our purposes) yield a ratio of about 0.80, which we considered our best guess: for every dollar saved in closing a hospital, 80 cents must be spent to treat the patients in another hospital. This figure, however, could easily be as little as 60 cents or as much as 90 cents.

The total saving would thus fall between $400 million a year and $1.6 billion, depending on the ratio of marginal cost to average cost. If the estimate of unused beds is off by 10,000, the saving changes by less than 15 per cent. Our best estimate of the potential saving is about $800 million a year (detailed data appear in NAPS Document 03740).

These figures may seem surprisingly small. How can closing 7 per cent of all hospital beds save little more than 1 per cent of total hospital expenditures? The answer is fairly simple: these calculations assume that the same number of patients is being treated whether the hospital sector is reorganized or not. As facilities are closed, patients must seek care elsewhere, and resources must still be expended to provide that care.

Substantially larger estimates of the potential saving seem to be based on the assumption (often implicit) that reducing the supply of hospital beds will reduce the demand for hospital services and redirect it to more cost-efficient types of care. In essence, this reasoning is based on the thesis that supply creates demand.[32,33] It is far from clear that this theory is correct,[34] but even if it were, it seems far more sensible to approach the problem of inappropriate demand directly than to influence demand indirectly by curtailing the supply of beds. The indirect approach, which relies on reduced bed supplies as a policy instrument, offers no assurance that the available bed stock will be used for the proper patients or that the problems of misuse will be satisfactorily resolved.

Total Saving from Consolidation

Total Theoretical Saving

Our best estimate is that a theoretical saving of approximately $1 billion in hospital expenditures (less than 2 per cent of total hospital expenditures) would have been achieved in 1978 if the HRA guidelines had been followed (Table 1). Under extreme but plausible assumptions, the figure might rise to as much as $2 billion or fall to $650 million.

Table 1. Potential Theoretical Savings from Eliminating Duplicated Facilities.

Service to be Consolidated	Potential Net Savings
Computed tomographic scanners	$85 million
Open-heart surgery & cardiac catheterization	50 million
Therapeutic radiology	115 million
Excess beds	800 million
Total savings	1,050 million
Total general hospital expenditures, 1978	58 billion

The uncertainty in our overall estimate is dominated by the value for excess beds. This result is hardly surprising. Eliminating beds by closing hospitals exploits economies of scale across the entire range of services offered, whereas consolidating specific services such as CAT scanners, open-heart surgery, and therapeutic radiology can have only a smaller effect. In aggregate, these three specific services accounted for less than $3 billion of the $58 billion spent in 1978.

Much of whatever gain may be anticipated from consolidating facilities consists of "one-shot" savings. For example, to eliminate excess beds — either by closing hospitals or preventing new construction — reduces the base level of expenditures, but it does not do so year after year. Indeed, the effect on rate of increase, the area of greatest public concern, is likely to be much smaller than the single reduction in base expenditures.

Offsetting Costs

These estimates of the theoretical saving from consolidating facilities do not account for important offsetting costs. In particular, they do not account for the administrative costs of government regulation, nor for the additional inconvenience imposed on patients and their families.

Costs of Regulation

Under current institutional arrangements, consolidations are to be achieved through a complex federal, state, and local apparatus for planning and regulation, as established by the National Health Plan

and Resources Development Act of 1974 (P.L. 93-641) and by state certificate-of-need laws. These regulatory agencies incur costs of their own. In 1978 the federal government, through the HRA, spent $160 million on planning activities,[34a] much of it in the form of grants to local, regional, and state agencies. Additional funding comes from the individual states. It is reasonable to assume that to sustain the required level of regulatory effort the states could well spend at least 50 cents for every dollar spent by the federal government.[35] Accordingly, we can anticipate that altogether about $250 million per year would be spent by the government on planning and certificate-of-need activities.

The regulations also impose an expense on providers. To file a certificate-of-need application, a provider must collect extensive data, prepare the application, and then defend it in detail. To our knowledge, no detailed data are available for an assessment of these costs, but we think it is safe to assume that providers spend at least as much as the agencies do in compiling data and reviewing applications, and probably more.

Lawsuits brought by dissatisfied communities or providers add additional costs; perhaps more importantly, such litigation restricts the ability of agencies to implement the guidelines. As of May 1978, P.L. 93-641 itself had occasioned some 23 lawsuits[36,37]; in Massachusetts, the state legislature has voted to overturn numerous certificate-of-need decisions.[38] Many such legislative moves have been vetoed, but some have been signed into law.[38-40] In many states, efforts to close facilities have been met with public opposition and court challenges.[41-44] In short, accounting only for the administrative costs and frictions associated with governmental regulation, it is clear that the actual saving would fall far short of the theoretical saving from economies of scale.

Costs to Patients and Their Families

If fewer facilities are to serve the same patient population, some patients will inevitably have to seek treatment further from home. Additional travel costs will be incurred, and the quality of care that some patients receive will be reduced.

In the case of the CAT scanner, some outpatients would have to travel further than they did before, and some inpatients would require transportation to and from the facility. For patients with trauma and patients with severe illness, increased travel time reduces the quality of care. A similar case can be made for radiation-therapy units: because patients with cancer must return many times for treatment, travel time is of economic importance. Reducing the number of general-hospital beds not only increases travel distance but can also lead to longer delays in treatment, which impose real costs.

These kinds of cost are obviously hard to measure. Among other things, they depend on patients' preferences and on the precise ways the regulations are put into effect. Of special concern is the distinct possibility that large urban medical centers are more likely to fare well under any regulation scheme than are smaller, less sophisticated hospitals located in rural, suburban, and ghetto areas.

To the extent that areas of low population density bear the brunt of the regulations, offsetting costs will be higher. In addition, if patients are forced from low-cost hospitals into relatively expensive urban medical centers, the net result may be to increase costs. Our calculations assumed that consolidations would be encouraged only if the unit cost of care could be reduced; unfortunately, there is no guarantee that the processes will work this way. Finally, if minority groups in low-income areas find that their hospitals cannot survive the regulatory contests, as appears to have been the case in New York, we may end up harming precisely those groups that many advocates of hospital regulation hope to help.[45]

In the face of all these offsetting costs, how much can be saved through a regulatory system that accommodates current levels and patterns of care in fewer, larger facilities? Perhaps a few hundred million dollars a year, but possibly nothing. We suspect that consolidation is better justified by an improvement in the quality of care than by the expectation that economies of scale will yield a large monetary saving.[46]

Discussion

The Carter Administration's cost-containment program envisions cumulative savings of $40 billion in 1978 dollars ($55 billion in nominal dollars) from fiscal years 1980 to 1984.[47] These savings are to be achieved by virtually freezing the population-adjusted growth in real hospital expenditures. Clearly, even if the four consolidations we examined could be accomplished instantly, they would make only a small contribution to this goal. The relatively small effect should surprise no one; even now, few facilities are operating below the minimum caseloads indicated by the HRA guidelines. The costs of regulation and of travel are rising. Thus, although the saving from consolidation is probably worth the effort, it can hardly be expected to solve the problem. Relying on state certificate-of-need programs and federally mandated planning programs to control hospital costs has yielded, and will continue to yield, disappointing results.

There is no doubt that additional small savings could be achieved by consolidating specific services or facilities that we have not analyzed — say, laundries and certain specialized laboratories — yet estimates of potential saving in these areas can easily be inflated by "double counting." For example, obstetric beds to be closed with entire hospitals must not be counted again when the saving from consolidating obstetric facilities is estimated. Moreover, the saving that might be achieved from specific consolidations is likely to be relatively small, as we have demonstrated in our sample calculation for obstetric beds. Trying to slice up

hospital operations into smaller and smaller pieces for consolidation is unrealistic. To formulate general usage criteria of any practical value for laundry services or a laboratory service, for example, is unlikely to prove either feasible or profitable.

In short, although we have not provided an exhaustive list of ways to save money by eliminating duplicated facilities, we believe that we have accounted for those areas that are most amenable to regulation and offer the largest potential yield. This saving is disappointingly small.

What Does Account for the Rise in Costs?

If the underused facilities identified by HRA account for such a small fraction of hospital costs, what is responsible for the escalation of hospital expenditures? First of all, general inflation in the economy has had a substantial effect on the cost of delivering hospital care. Secondly, hospital use has increased from year to year as the population has grown and aged and as insurance coverage has expanded. Admissions have increased over the past decade by an average of 2 per cent per year, and outpatient visits have increased over the same period by about 6 per cent.[2] Thirdly, the services provided by hospitals have increased both in number and in complexity. Finally, organizational slack, resulting from inadequate incentives for hospitals to operate efficiently, probably leads to further waste. We conclude that only by altering the quantity, quality, or patterns of care that we offer and by providing general incentives for hospitals to eliminate organizational slack can we hope to achieve a worthwhile saving.

Excessive use of laboratories, x-ray procedures, and surgery might be reduced. More outpatient care, preadmission screening, shorter stays, more intensive use of hospital facilities during off-peak periods, and other improvements in hospital management may also save resources without affecting the quality of care. We consider this set of demand-side factors to be the best target for efforts at cost containment. Whether all the suggested changes can in fact be achieved without impairing the quality of care, and whether they can yield the savings that have sometimes been predicted, must be investigated further.

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MEDICAL INTELLIGENCE

INTRAOPERATIVE MEASUREMENTS OF URINARY CYCLIC AMP TO GUIDE SURGERY FOR PRIMARY HYPERPARATHYROIDISM

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SURGERY is the main form of therapy for primary hyperparathyroidism. The goal of therapy is to restore normal parathyroid function and avoid either persistent hyperfunction or permanent hypofunction. To achieve this goal the surgeon must remove an appropriate amount of hyperfunctioning tissue without injuring residual normal glands. At present the surgeon relies on gross and microscopical morphologic criteria in deciding which and how much parathyroid tissue to resect. Theoretically, intraoperative assessment of parathyroid function should help the surgeon to decide how much tissue to resect. We have previously shown[1] that urinary cyclic AMP excretion, an accurate index of parathyroid function,[2] falls promptly after successful parathyroidectomy. The availability of a technique to measure urinary cyclic AMP rapidly (in less than seven minutes)[3] prompted us to evaluate prospectively the utility of intraoperative urinary cyclic AMP measurement in guiding surgery for primary hyperparathyroidism. Our experience, reported here, shows that such measurement is useful in determining how much parathyroid tissue needs to be removed.

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METHODS

We studied 20 consecutive patients undergoing surgery for primary hyperparathyroidism between October 1979 and April 1980. Eighteen patients were referred to the National Institutes of Health (NIH) because of unsuccessful previous neck surgery and were undergoing repeat exploration; two patients with multiple endocrine neoplasia Type I had not had surgery previously. The diagnosis of primary hyperparathyroidism was based on elevated serum concentrations of calcium and parathyroid hormone (PTH) or elevated urinary cyclic AMP or both, and was confirmed surgically in 19 of 20 patients; in one patient no normal or abnormal parathyroid tissue was found. Patients with a single enlarged gland and at least one normal biopsied gland were considered to have an adenoma; biopsy-proved enlargement of two or more glands was considered evidence of hyperplasia. All five patients with Type I multiple endocrine neoplasia were diagnosed as having parathyroid hyperplasia by the above criteria. Preoperative parathyroid localization studies, including arteriography and venous sampling,[4] were performed in all 18 patients undergoing repeat neck exploration.

After induction of anesthesia, the bladder was catheterized and urine was collected every half hour. Informed consent was obtained for bladder catheterization. Urine collections continued until two hours after the patient had arrived at the surgical recovery room, at which time the bladder catheter was removed.

All operations were performed by the same two surgeons, who kept a detailed record of the operation on a standard chart that showed the site of exploration in half-hour intervals, as well as the times of identification and removal of tissue specimens. The surgeons also recorded the histologic diagnoses for frozen tissue sections examined during surgery. Results of urinary cyclic AMP determinations were sent to the operating room as soon as available, generally within 15 minutes of sample collection. A fall in urinary cyclic AMP excretion to below 3 nmol per deciliter of glomerular filtrate was considered evidence of successful parathyroidectomy. A doubling in urinary cyclic AMP excretion above the base line was designated as a "peak."

Creatinine was measured with a Beckman creatinine analyzer-2 with use of a Jaffe rate method.[5] Cyclic AMP was measured by radioimmunoassay[6] and the Gammaflo (Squibb) system.[3] Urine samples were generally diluted 1:10 in 0.05 M sodium acetate buffer at a pH of 4.7. Goat antiserum to cyclic AMP (No. 122K, kindly provided by Dr. G. Brooker) was used at a final dilution of 1:40,000. [^{125}I]-Succinyl cyclic AMP tyrosine methylester (20,000 to 30,000 counts per minute per sample) (Meloy Laboratories) was used as a tracer. Twenty per cent of total tracer was bound in the absence of unlabeled cyclic AMP. The minimum detectable cyclic AMP concentration under the conditions used was 310 pmol per milliliter. Aliquots from a pooled urine sample and a solution with a known cyclic AMP concentration (determined by optical density) were analyzed as external standards in each assay. The interassay coefficient of variation was 6 per cent, and the intraassay coefficient of variation was 4 per cent. Urinary cyclic AMP is expressed as nanomoles per deciliter of glomerular filtrate (ob-

Bureau of Health Planning
Program Information Letter

81-39

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • Public Health Service • Health Resources Administration

April 21, 1981

TO: State Health Planning and Development Agencies
Statewide Health Coordinating Councils
Health Systems Agencies
Centers for Health Planning

SUBJECT: Certificate of Need Technical Amendments

On December 17, 1980, the Health Programs Extension Act of 1980 (Public Law 96-538) was signed into law. This Act contains a number of amendments affecting State certificate of need (CON) programs, and they are as follows:

1. A new subparagraph (h) has been added to section 1527. This addition amends the CON program's scope of coverage to permit, but not require, a State to exclude from CON review a health care facility's acquisition of major medical equipment, offering of a new institutional health service, or obligation of a capital expenditure, if these are solely for research and if two conditions are met. First, the acquisition offering or obligation may not: (1) affect the charges of the facility for the provision of medical or other patient care services, other than the services which are included in the research, (2) substantially change the bed capacity of the facility, or (3) substantially change the medical or other patient care services of the facility which were offered before the acquisition, offering, or obligation. Second, the health care facility must notify the SHPDA in writing of the facility's intent to acquire, offer or obligate and the purpose of the facility's action.

   Note: The Act specifies that "the term 'solely for research' includes patient care provided on an occasional and irregular basis and not as part of a research program."

   In States that change their certificate of need programs by adopting this provision, their programs must provide that if the notice is not filed or the State agency determines within 60 days after receipt of

the notice that one of the other conditions mentioned above is not met, then the health care facility will be required to obtain a certificate of need. Moreover, any subsequent change to the excluded acquisition, offering or obligation which (1) affects the charges of the facility for the provision of medical or other patient care services, other than the services which are included in the research, (2) substantially changes the bed capacity of the facility, or (3) substantially changes the medical or other patient care services of the facility, will require a CON before that change can be made. This amendment is permissive; therefore, a State that covers research medical equipment as provided in the existing certificate of need regulations will also have a conforming program.

Note: The appendix to (and several explanatory notes in) the October 21, 1980, certificate of need regulations (45 FR 69740-73) contains a discussion of the reviewability of research activities as the matter stood prior to the enactment of the new Act. In States that amend their certificate of need laws to provide for the research exemptions now allowed, the October 21 discussion is no longer relevant. Because the activities discussed in that document would not be subject to certificate of need review, it is no longer necessary to determine whether the expenditures are "by or on behalf of" a health care facility or constitute the acquisition of "major medical equipment." States that do not amend their certificate of need laws to provide for the new research exemptions may continue to determine whether research activities are subject to review in the manner suggested in the October 21 regulations.

2. The definition of institutional health services (in section 1531(5) of the PHS Act) was amended by striking the words "maintained or developed by the Department of Commerce, and." Under the statute before this amendment, the Department had designated the Department of Commerce Composite Construction Cost Index as the index for adjusting the operating cost expenditure minimum, which sets the threshold for reviews of institutional health services. This change allows the Department to designate a more appropriate index for States to use in adjusting the operating cost "expenditure minimum" under the CON program.

Note: This amendment did not itself change the index specified to adjust the capital "expenditure minimum" threshold. The Department will consider the appropriateness of other suitable indexes, and if a decision is made to use a different index, the Department will undertake appropriate rulemaking procedures. In the interim the Department will continue to use the Department of Commerce Composite Construction Cost Index.

3. Also amended was the provision of Section 1532(a)(12)(D) of the PHS Act which required a State to provide an opportunity for administrative review of a certificate of need decision by a SHPDA. This requirement

also appears in regulation at 42 CFR 123.410(a)(13). Section 1532 (a)(12)(D) has been amended by deleting the word "administratively." A State's review process is now required to provide for review of the SHPDA's decision "under an appeals mechanism consistent with State law governing the practices and procedures of administrative agencies or, if there is no such State law, by an entity (other than the State Agency) designated by the Governor." Because the word "administratively" has been deleted, a State is now required to have an administrative review as its appeals mechanism only if an administrative agency is the appeals mechanism under the State's law governing the practices and procedures of administrative agencies. If under that State law a State provides only for judicial review as its appeals mechanism, it need not have a second judicial appeal as required by section 1532(b)(12)(E) of the PHS Act and 42 CFR 123.410 (a)(14):

4. Finally the requirements related to the sale or lease of an HMO-related health care facility or medical equipment, the acquisition or construction of which was initially exempted from review, have been revised. The amendments to this provision (section 1527(b)(3)(B) of the PHS Act) appear to have been made to correct a drafting error in the original legislation. This provision now provides that such a sale or lease will be exempt from review if the requirements that provided for the initial exemption are met.

The amendments also extended the dates by which States are to have conforming CON programs, and the dates by which they are to have fully designated SHPDAs. For most States, the extension is for one year but not later than 1982. States which have questions about their dates should write to the Bureau.

These amendments were effective upon enactment. A copy of Title III of the Act, Health Planning Amendments, is enclosed.

Colin C. Rorrie, Jr., Ph.D.
Director

Enclosure for addressees only

Public Law 96-538
96th Congress

An Act

To amend the Public Health Service Act to revise and extend the authorities under that Act relating to national research institutes, and for other purposes.

Dec. 17, 1980
[S. 988]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) this Act may be cited as the "Health Programs Extension Act of 1980".

Health Programs Extension Act of 1980.
42 USC 201 note.

(b) Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

* * *

TITLE III—HEALTH PLANNING AMENDMENTS

SEC. 301. The second sentence of section 1501(b)(1) (42 U.S.C. 300k-1(b)(1)) is amended by striking out "in" and inserting in lieu thereof "including those in".

SEC. 302. Effective with respect to fiscal years beginning after September 30, 1981, section 1516(d)(3) (42 U.S.C. 3001-5(d)(3)) is amended to read as follows:

"(3) Notwithstanding subsection (c)(1), if the total of the amounts appropriated under paragraph (1) for any fiscal year (reduced by the amount to be retained by the Secretary for use under paragraph (2)) is less than the amount required to make grants to each health systems agency designated under section 1515(c) in the amount prescribed for such agency by subsection (c)(1), the Secretary shall make a pro rata reduction in the amount of the grant to each such agency as follows:

42 USC 300*l*-4.

Grant, pro-rata reduction.

"(A) The Secretary shall compute the amount of the grant each such agency would be entitled to receive under such subsection if the dollar limit prescribed by subparagraph (A)(ii) of such subsection did not apply.

"(B) The Secretary shall reduce on a pro rata basis the amount of the grant to each such agency computed under subparagraph (A) of this paragraph so that the total amount of such grants equals the total of the amounts appropriated for such fiscal year (as so reduced), except that—

"(i) the amount of the grant to any such agency may not exceed $3,750,000,

"(ii) to the extent of available appropriations, no such agency shall receive a grant in an amount less than the amount prescribed by subparagraph (C) of subsection (c)(1) for such fiscal year, and

"(iii) if the total of the appropriations for the fiscal year ending September 30, 1982, for such grants—

"(I) is equal to or greater than the total of the appropriations for such grants for the preceding fiscal year, no such agency shall receive a grant in an amount less than the amount of the grant it received in such preceding fiscal year unless the population of the area for which it is designated has decreased, unless the level of non-Federal funds on which its grant is computed had decreased, or unless the amount available for its grant is decreased because of an increase in the minimum grant prescribed by subsection (c)(1)(C), or

"(II) is less than the total of the appropriations for such grants for the preceding fiscal year, no such agency shall receive a grant in an amount greater than the amount of the grant it received in such preceding fiscal year unless the population of the area for which it is designated has increased, unless the level of non-Federal funds on which its grant is computed has increased, or unless the amount of its grant is increased under subsection (c)(1)(C).".

42 USC 300m-6 note.

SEC. 303. (a) Section 129(b)(2)(A) of Public Law 96-79 (93 Stat. 630) is amended by striking out "Health Planning and Resources Development Amendments of 1979" and inserting in lieu thereof "Health Programs Extension Act of 1980".

Ante, p. 3183.

(b) Section 1521(d)(1)(B)(i) (42 U.S.C. 300m(d)(1)(B)(i)) is amended by striking out "Health Planning and Resources Development Amendments of 1979" and inserting in lieu thereof "Health Programs Extension Act of 1980".

Ante, p. 3183.

(c) Section 117(c) of the Health Planning and Resources Development Amendments of 1979 (93 Stat. 620) is amended by striking out "February 1, 1982" and inserting in lieu thereof "February 1, 1983".

42 USC 300m-6 note.

42 USC 300m-3.

SEC. 304. Section 124(c) of Public Law 96-79 (93 Stat. 627) is amended to read as follows:

42 USC 300m-3.

"(c)(1) Section 1524(b)(1)(C) is amended by striking out 'one-third' and inserting in lieu thereof 'one-half'.

"(2) Section 1524(b)(1)(D) is amended (A) by striking out 'two' and inserting in lieu thereof 'one', and (B) by striking out 'an ex officio' and inserting in lieu thereof 'a nonvoting, ex officio'.".

SEC. 305. The first sentence of section 1524(c)(6) (42 U.S.C. 300m-3(c)(6)) is amended by striking out "section 409" and inserting in lieu thereof "section 409 or 410".

Certificate of need program.

SEC. 306. Section 1527(b)(3)(B) (42 U.S.C. 300m-6(b)(3)(B)) is amended (1) by striking out "that (i)" and inserting in lieu thereof "that", (2) by striking out ", which intends to acquire the controlling interest or which intends to use the facility is" and inserting in lieu thereof "which intends to acquire the controlling interest in or use the facility is (i)", (3) by striking out "and (ii)" and inserting in lieu thereof "and", and (4) by striking out "or the requirements of clauses (i) and (ii) of subparagraph (B) of paragraph (1)" and inserting in lieu thereof ", or (ii) a health care facility which meets the requirements of clauses (i), (ii), and (iii) of subparagraph (B) of paragraph (1) and with respect to its patients meets the requirements of clause (iv) of such subparagraph".

SEC. 307. Section 1527 (42 U.S.C. 300m-6) is amended by adding at the end the following new subsection:

Major medical equipment; acquisition, conditions.

"(h)(1) Subsection (a) does not require a certificate of need program to require a health care facility to obtain a certificate of need for the acquisition of major medical equipment to be used solely for research, institutional health services to be offered solely for research, or the obligation of a capital expenditure to be made solely for research if the acquisition, offering, or obligation does not—

"(A) affect the charges of the facility for the provision of medical or other patient care services other than the services which are included in the research;

"(B) substantially change the bed capacity of the facility; or

"(C) substantially change the medical or other patient care services of the facility which were offered before the acquisition, offering, or obligation.

State Agency of the State, notification.

"(2)(A) Before a health care facility acquires major medical equipment to be used solely for research, offers an institutional health service solely for research, or obligates a capital expenditure solely for research, such health care facility shall notify in writing the State Agency of the State in which such facility is located of such facility's intent and the use to be made of such medical equipment, institutional health service, or capital expenditure.

"(B) Paragraph (1) does not apply with respect to the acquisition of major medical equipment, the offering of institutional health services, or the obligation of a capital expenditure if—

"(i) the notice required by subparagraph (A) is not filed with the State Agency with respect to such acquisition, offering, or obligation, or

"(ii) the State Agency finds, within 60 days after the date it receives a notice in accordance with subparagraph (A) respecting the acquisition, offering, or obligation, that the acquisition, offering, or obligation will have the effect or make a change described in subparagraph (A), (B), or (C) of paragraph (1).

"(3) If major medical equipment is acquired, an institutional health service is offered, or a capital expenditure is obligated and a certificate of need is not required for such acquisition, offering, or obligation as provided in paragraph (1), such equipment or service or equipment or facilities acquired through the obligation of such capital expenditure may not be used in such a manner as to have the effect or to make a change described in subparagraph (A), (B), or (C) of paragraph (1) unless the State Agency issues a certificate of need approving such use.

"Solely for research."

"(4) For purposes of this subsection, the term 'solely for research' includes patient care provided on an occasional and irregular basis and not as part of a research program.".

SEC. 308. The last sentence of section 1531(3) (42 U.S.C. 300n(3)) is amended (1) by striking out "An individual" and inserting in lieu thereof "Notwithstanding subparagraph (B), an individual", and (2) by striking out "an entity" and inserting in lieu thereof "one or more entities".

SEC. 309. Section 1531(5) (42 U.S.C. 300n(5)) is amended by striking out "maintained or developed by the Department of Commerce and".

SEC. 310. Section 1532(b)(12)(D) (42 U.S.C. 300n-l(b)(12)(D)) is amended by striking out "administratively".

. . .

Approved December 17, 1980.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 96-997 accompanying H.R. 7036 (Comm. on Interstate and Foreign Commerce) and No. 96-1478 (Comm. of Conference).
SENATE REPORT No. 96-714 (Comm. on Labor and Human Resources).
CONGRESSIONAL RECORD, Vol. 126 (1980):
June 19, considered and passed Senate.
Aug. 28, H.R. 7036 considered and passed House; passage vacated and S. 988, amended, passed in lieu.
Dec. 1, Senate agreed to conference report.
Dec. 4, House agreed to conference report.

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Administrator

Director

Certificate of Need Briefing Memo

BACKGROUND

One of the requirements for having a fully designated State Agency is for that State to have a complying certificate of need program. The recently published certificate of need regulations put into effect the applicable portions of Title XV of the Public Health Services Act (the Act) as amended by Public Law 96-79.

Currently, all States except Louisiana have enacted certificate of need legislation; the District of Columbia administers a program on the basis of administrative regulations, and all Territories, except the Virgin Islands, have enacted a certificate of need program. However, most States have not made the changes required by the amended statute and the final regulations to have a complying program. To be compliant, under Section 1523(a)(4)(B) of the Act, State Agencies are required to administer certificate of need programs which (1) apply to the obligation of capital expenditures, the offering of new institutional health services, and the acquisition of major medical equipment, (2) are consistent with standards established by the Secretary by regulations, and (3) have procedures and penalties which will enforce the requirements of the program. Under Section 1513(f) of the Act, health systems agencies are to review and make recommendations to the State Agency concerning the need for a proposed project subject to certificate of need review.

Specific Requirements

The regulations do not address every aspect of a State's certificate of need program; they represent minimum requirements (with certain exceptions, i.e., Health Maintenance Organizations (HMOs) provisions, and coverage of major medical equipment acquisitions which has a time deadline for States to exceed statutory coverage requirements) and, as such, do not preclude States from administering more comprehensive or stringent programs.

In order to comply with the minimum Federal requirements, State certificate of need programs must:

1. Cover the obligation of capital expenditures, the offering of new institutional health services and the acquisition of major medical equipment. Specifically:

a. The obligation by or on behalf of a non-Federal health care facility (hospital, skilled nursing facility, kidney disease treatment center (including freestanding hemodialysis units), intermediate care facility, rehabilitation facility, and ambulatory surgical facility) of any capital expenditure of $150,000 or more (which figure may be adjusted by the State), except to acquire another health care facility.

b. The obligation of any capital expenditure by or on behalf of any non-Federal health care facility which by 10 beds or 10 percent over a 2-year period,

(1) increases or decreases total number of beds,

(2) redistributes beds among various categories, or

(3) relocates beds from one physical facility or site to another.

c. The obligation of any capital expenditure of any amount by or on behalf of a non-Federal health care facility associated with either the addition of a new health service or the termination of a new health service.

d. Addition of a new health service by or on behalf of a non-Federal health care facility which entails an annual operating cost of at least $75,000 (a State may adjust this figure).

e. Acquisition by any person of major medical equipment to be owned by or located in a non-Federal health care facility.

f. Acquisition by any person of major medical equipment not owned by or located in a health care facility if:

(1) a notice of intent is not filed with the State Agency, or

(2) the equipment will serve inpatients of a hospital.

g. The obligation of a capital expenditure to acquire an existing halth care facility if:

(1) a notice of intent is not filed with the State Agency, or

(2) the State Agency determines that services or bed capacity of the facility will be changed (see Federal regulations at 42 CFR 123.404).

2. Cover projects proposed by a HMO by or on behalf of its inpatient health care facility as described above unless exempted. Cover acquisitions of major medical equipment by an ambulatory care facility of an HMO unless exempted. Not extend coverage of HMOs beyond this scope (see 42 CFR 123.405). Use only specific HMO related criteria when reviewing those projects not exempted (see 42 CFR 123.412(a)(13)).

3. A Certificate of need must be issued (1) if the proposed capital expenditure is to eliminate imminent safety hazards or to comply with State licensure or accreditation standards for reimbursement under Medicaid or Medicare and (2) if the facility is needed and the obligation of the capital expenditure is consistent with the State health plan.

4. Provide that (a) only a State Agency may issue a certificate of need and that only needed projects receive one, (b) persons may perform the actions covered above only after they receive a certificate and (c) sanctions are established which are sufficient to ensure that an activity covered under the certificate of need scope is not done if the certificate is not issued or is withdrawn (see 42 CFR 123.408).

5. Develop and follow review procedures which, among other things, provide for

a. applications to be batched,
b. written notification at the beginning of a review be made to all affected persons
c. information required of applicants be known before the review starts,
d. a public hearing during the review,
e. written findings stating the basis for a decision be made,
f. administrative and judicial appeals be avaiable,
g. recourse to a court for an applicant to force the State Agency to make a decision (see 42 CFR 123.410).

6. Develop and apply review criteria which take into account applicable State and local conditions on, among others, the relationship of the project to the State health plan, financial feasibility of the project, need of the population, access, special needs and circumstances of HMOs, and competition (see 42 CFR 123.412).

7. Provide that for each approved project the State Agency must make a written finding on the extent to which the project will meet the need and the access criteria established. Three exceptions to this required written finding have been made:

a. The project will either eliminate or prevent imminent safety hazards or is being proposed to comply with certain licensure or accreditation standards,

b. The project is not directly related to the provision of beds, health services or major medical equipment,

c. The project is proposed by or on behalf of a qualified HMO (see 42 CFR 123.413).

Copy of Reconciliation Act (Budget), see also section 979 on HMO changes. (3)

Subtitle E--Health Planning

Authorizations

Sec. 933. (a)(1) Section 1516(d)(1) of the Public Health Service Act (42 U.S.C. 300l-5(d)(1)) is amended by inserting ''and'' after ''1980,'' and by inserting a period after ''1981'' and striking out the remainder of such section.

(2) Section 1525(c) of such Act (42 U.S.C. 300m-4(c)) is amended by inserting ''and'' after ''1980,'' and by inserting a period after ''1981'' and striking out the remainder of such section.

(3) Section 1534(d) of such Act (42 U.S.C. 300n-3(d)) is amended by inserting ''and'' after ''1980,'' and by inserting a period after ''1981'' and striking out the remainder of such section.

(b) Part D of the Public Health Service Act is amended by adding at the end the following:

''Authorizations for Fiscal Year 1982

''Sec. 1537. For grants and contracts under sections 1516(a), 1525(a), and 1534(a) there is authorized to be appropriated $102,000,000 for fiscal year 1982. Of the amount appropriated under this section, not more than $65,000,000 may be used for grants under section 1516(a).''.

Minimum Grant; Waiver of Requirements

Sec. 934. (a). Section 1516(c)(1)(C)(iv) of the Public Health Service Act is amended by striking out ''$250,000''

and inserting in lieu thereof ``$100,000''.

(b) The Secretary of Health and Human Services may--

(1) upon application waive the application of the requirements of subsection (e), (g), or (h) of section 1513 of the Public Health Service Act, or any combination of such subsections, to a health systems agency if the Secretary determines that the Federal funds made available to the agency are not sufficient to enable it to meet such requirements or

(2) by regulation waive the application of the requirements of subsection (e), (g), or (h) of section 1513 of the Public Health Service Act, or any combination of such subsections, to all health systems agencies if the Secretary determines that the Federal funds made available to all the agencies are not sufficient to enable them to meet such requirements.

States Without Health Systems Agencies

Sec. 935. (a)(1) Section 1536 of the Public Health Service Act (42 U.S.C. 300n-5) is amended--

(1) by striking out subsection (a),

(2) by amending the matter in subsection (b) preceding paragraph (1) to read as follows: ``Upon application of the chief executive officer of a State or the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, the Northern

Mariana Islands, or American Samoa, it shall, upon approval of the application, be considered to be a State for purposes of this title and'',

(3) by striking out ''sections 1516 and 1640'' and inserting in lieu thereof ''section 1640'', and

(4) by adding after and below paragraph (4) the following:

''An application made under this section for a fiscal year shall be made not later than November 1 in that fiscal year and shall contain the certification of the chief executive officer that the State is willing and able to meet the purposes of this title in such fiscal year without any health systems agency in the State.''.

(b) A State which--

(1) because of section 1536(b) of the Public Health Service Act (as in effect on September 30, 1981) received a grant under section 1516 of such Act for fiscal year 1981, and

(2) had an application under section 1536 of such Act (as amended by subsection (a)) approved,

shall be eligible to receive a grant under section 1516 of such Act for fiscal year 1982.

(c) If a State which on the date of the enactment of this Act has a population of less than 600,000 and has only one health service area has an application approved under this

D.C. R.I. Haw.

section, such State shall be eligible to receive a grant under section 1516 of the Public Health Service Act for fiscal year 1982.

(d) The last sentence of section 1512(b)(5) of the Public Health Service Act (42 U.S.C. 300l-1(b)(5)) is amended by inserting before the period the following: ''or health insurance''.

Certificate of Need Review

Sec. 936. (a) Section 1531 of the Public Health Service Act (42 U.S.C. 300n) is amended--

(1) by striking out ''$75,000'' each place it occurs in paragraph (5) and inserting in lieu thereof ''$250,000'';

(2) by striking out ''$150,000'' each place it occurs in paragraph (6) and inserting in lieu thereof ''$600,000''; and

(3) by striking out ''$150,000'' each place it occurs in paragraph (7) and inserting in lieu thereof ''$400,000''.

(b)(1) Section 1521(c)(1)(B) of the Public Health Service Act (42 U.S.C. 300m(d)(1)(B)(ii)) is amended--

(A) by striking out ''twelve months'' the second time it appears in clause (i) and inserting in lieu thereof ''twenty-four months'', and

(B) by striking out ''twelve months'' the second time

it appears in clause (ii) and inserting in lieu thereof ''twenty-four months''.

(2) The first sentence of section 1521(b)(2)(B) of such Act is amended to read as follows: ''The period of an agreement described in subparagraph (A) shall not extend beyond the period set forth in subsection (d)(1)(B).''.

Effective Date

Sec. 937. The amendments made by this subtitle shall take effect October 1, 1981.

The Conference agreement provides for criminal penalties for false statements made with regard to services or items funded with the block grant funds.

The application and certification process under this block grant has been greatly streamlined. The Secretary is prohibited from prescribing the manner of compliance with the certification process. This prohibition is intended to avoid complex pre-award review by the Secretary. The Conferees do not, however, intend that this prohibition preclude the Secretary from carrying out his duties to ensure that the allotments are spent in conformity with the law.

The Conference agreement requires States to prepare annual reports on its activities under the block grant. These reports would be in such form and contain such information as the Secretary determines to be necessary (A) to determine whether funds were expended as required by the block grants and consistent with the needs of the State; (B) to secure a description of the activities of the State; and (C) to secure a record of the purposes for which funds were spent, of the recipients of funds and the progress made toward achieving the purposes for which the block grant was awarded to the States. However, in determining the information which must be included in this report, the Secretary may not establish reporting requirements that are burdensome.

Subtitle G—Health Planning

The House bill reduced the authorizations for Health Systems Agencies (HSAs) for fiscal year 1982 to $90 million and made a number of revisions in the statutory authority for the health planning program. The Senate amendment did not include specific authorizations or any revisions to current authority, but provided for an overall authorization for programs managed by the Health Resources Administration which assumed that expenditures for HSAs would not exceed $7 million in fiscal year 1982.

The conference agreement authorizes $102 million for HSAs, State agencies and planning centers in fiscal year 1982 of which not more than $65 million is to be expended for HSAs. A number of amendments to the statutory authority are included in the agreement.

AUTHORIZATIONS

The conference agreement reduces authorizations for HSAs, state agencies and centers for health planning for Fiscal Year 1982 to $102 million and provides that not more than $65 million of this amount may be expended for HSAs.

With an appropriation of $65 million or less it is clear that the Federal government will no longer financially sustain all the statutory obligations placed upon local planning agencies. If any health service area in which funding is not adequate to support an effective HSA, the committee expects that the Secretary will not renew the designation of the HSA. In such cases, the Governor may propose to the Secretary, under the provisions of Section 1511, a consolidation of the affected area with one or more other areas.

Consistent with the reduced authorization levels, the conference [illegible] grant for HSAs from $245,000 to

$100,000 and allows HSAs to accept contributions from health insurance companies. The term "health insurance" is meant to include all forms of third party payment for health care; *e.g.*, service prepayment plans as well as indemnity plans. This provision complements the existing provision allowing major employers, whether self insured or otherwise, to contribute to HSAs.

The agreement also allows the Secretary to waive by regulation or on a case by case basis for any or all HSAs, the current requirements for conducting appropriateness review, proposed use of federal funds review, and the collection and publication of data on hospital costs.

STATE HEALTH PLANNING

The proposed amendment to Section 1536 would allow any Governor of a State to request that the Secretary eliminate the Federal designation and funding of HSAs located within that State. The Governor must apply to the Secretary by November 1 of the fiscal year in which the change is to take place. Such application must certify that the State is willing and able to carry out the purposes of the planning program without HSAs in the State. It is expected that, when a Governor makes such a certification by November 1, the State Health Planning and Development Agency in that State, in its next grant year, will begin to handle its health planning activities with the advice of a Statewide Health Coordinating Council (SHCC) constituted according to current regulations for SHCCs in 1536 States. The conferees have selected November 1 as the deadline for application for 1536 designation in order to allow HSAs to receive their FY 82 grants without disruption of their established funding cycle.

The conference agreement provides for the states which currently have 1536 designations—Rhode Island and Hawaii—and states with less than 600,000 population and only one HSA—Vermont, Delaware and Wyoming—to share in funds appropriated under section 1516 for HSAs.

CERTIFICATE OF NEED REQUIREMENTS

The conference agreement extends for 12 months the time for imposition of any penalties on States not in compliance with the CON and other Federal requirements. Given the current status of the program, it is not resonable to retain the current deadline for the exercise of sanctions on non-complying states.

The agreement also changes the Federal minimum requirements for CON programs by eliminating the need to review many projects now being reviewed by the planning agencies. Currently the law requires review of any new capital expenditure of $150,000 or more, or the purchase of any major medical equipment of $150,000 or more, or the start of any new institutional health service whose annual operating costs equal $75,000 or more. The agreement would change those thresholds to $600,000, $400,000, and $250,000 respectively. These changes will promote focusing the resources available for CON reviews on the most expensive and future cost-generating new investments in medical care.

A Summary of the Data on the Impact of Health Planning on the Cost of and Access to Health Care

May 1981

Prepared by:

asim
american society of internal medicine
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A Summary of the Data on the Impact of Health Planning on the Cost of and Access to Health Care

American Society of Internal Medicine

May 1981

INTRODUCTION

The Health Planning and Resource Development Act of 1974 (PL 93-641) and its subsequent amendments, as well as the state Certificate-of-Need (CON) programs mandated by the Act, resulted from a desire to bring order, economy and efficiency to the allocation of health care resources in the United States. The specific problems which the legislation attempts to address are the rise in the cost of medical care, the wasteful presence of excess capacity within the system, and the related problems of access and efficient resource allocation.

Health planning and CON have been the subject of many studies, several of which present persuasive evidence that mandatory health planning not only falls far short of its goals, but is in many cases actually counter-productive to its own stated objectives.

COST

1. Cost Containment

The primary issue which must be addressed when evaluating federal health planning is the question of the effects of health planning, and CON in particular, on controlling costs in health care.

One of the more comprehensive studies of CON was published by David S. Salkever of Johns Hopkins University and Thomas N. Bice of Washington University, St. Louis, under contract with DHHS in 1976. Their report, "Impact of State Certificate-of-Need Laws on Health Care costs and Utilization," concluded:

> "The results of this analysis indicate that Certificate of Need (CON) controls reduced expansion in beds, but increased expansion in plant assets per bed, and had no discernible negative effect on total investment (change in total plant assets). In other words, CON controls altered the composition of investment but not its magnitude, discouraging new beds, but encouraging investment in new equipment and services.
>
> "In summary, our analysis points to the (perhaps) surprising conclusion that CON controls have contributed to cost inflation; thus, they have tended to produce the very result which they were designed to prevent. This conclusion must, of course, be treated cautiously due to the limitations of the analyses on which it was based... At a minimum, our findings signal the need for a much more thorough and detailed study of

the effectiveness of CON regulation as a cost control device. The presumption of its effectiveness is clearly not warranted by the available evidence."[1] (emphasis added)

More recently, a study conducted by Policy Analysis, Inc. (PAI) under contract to the Health Resources Administration, also raised questions about CON's cost-effectiveness.

The summary below is quoted from the Bureau of Health Planning's Program Information Letter which accompanied the study.

"PAI attempted to test a number of general hypotheses regarding interstate CON program variation and the programs' effects on capital accumulation, the rate of cost inflation, geographic distribution and the structure of the hospital industry.

"The study found some differences among states with regard to holding applicants to stated or intended criteria. These were associated with program strength. However, it found no evidence that CON programs have significantly reduced the rate of growth of hospital capital stock, nor did 'strong' programs succeed in holding hospital cost increases below those of states with no or 'weak' CON programs. Distribution-oriented programs--mostly located outside the Northeast--do seem to give preference to undeserved areas, as measured by mean county income. Based upon these findings, PAI recommends that the federal government should limit its reliance on CON as a cost containment mechanism because of its lack of impact."[2] (emphasis added)

In November 1978, the Department of Health and Human Services, as part of its Health Planning Bibliography series, published a study entitled "Certificate of Need Programs: A Review, Analysis, and Annotated Bibliography of the Research Literature."

In summarizing its findings, the study concluded that:

> "The pessimism of this discussion is a reflection of the pessimism in the literature on regulation in general and CON in particular. The most enthusiastic program advocates in the literature argue that CON is effective on theoretical grounds (stemming from the public interest theory of regulation). The reality of the evidence, however, only suggests that in some settings and under some circumstances, the program may yield results consistent with its goals. While the final verdict is not yet in, the preliminary hearing has not been encouraging."[3]

The same study pointed out that:

> "Prices may rise under CON both because higher prices will be needed to finance the subsidies and inefficiencies created by regulation and because supply restrictions may cause a disequilibrium between supply and demand."[4]

2. Compliance Costs

The cost and effort of complying with government regulations has long been a burden on the health care industry. Below is a review of studies which examine the costs to hospitals in various states of compliance with government

regulations in general, a sizable portion of which is specifically attributable to health planning and CON laws.

A. Hospital Association of New York State Cost Study - 1978:

-- 25% of hospital costs attributable to meeting goverment regulation

-- annual cost of regulation exceeds $1.1 billion per year

-- time required for reporting, 115 million person-hours, is equivalent to 56,000 full-time hospital employees

-- 56,000 employees could staff 75 hospitals, each with an average of 250 beds

-- regulatory matters occupy 24% of all person-hours

-- completion of forms and reports costs New York hospitals $128 million annually

-- estimated cost $40.00 per hospital/per day

B. California Hospital Medical Center reivew - 1976:

Direct compliance costs estimated to be $70 per admission ($10.75 per patient day). Estimates did not take into account engineering, maintenance, and remodeling costs required by regulatory action.

C. Health Controls Out of Control - Warnings to the Nation from Massachusetts - Regulatory Actions - 1977, David Kinzer:

Direct Compliance costs estimated to be 3 1/2% to 4% of operating expenses. No estimates of indirect costs.

D. Michigan Hospital Association - Hospital Costs Attributable to Government Regulation, December 1977:

Direct costs estimated to represent 1.5% of the annual operating budgets of the surveyed hospitals, which equals $3.00 per hospital/per day.

E. South Carolina Hospital Association - Hospital Costs and Changes in the Financial Position Attributable to Selected Government Regulations, Arthur Young & Co., March, 1978:

Six hospitals of varying sizes, bed capacities, occupancy rates, and other representative characteristics were surveyed. The following costs for fiscal year 1976 were attibutable to four areas of government regulation:

	Utilization Review & PSRO	Personnel Management	Capital Planning/ Certificate of Need	Reimbursement Mechanisms	Total
Hospital A	$16,571 or .83/patient day	$21,542 or 1.06 patient day	$ 163	$13,536; 2364 person-hours expended	$ 51,812
Hospital B	$17,547 or .47/patient day	$21,204 or .57/patient	---	$3,738; 643 person-hours expended	$ 42,489
Hospital C	N.A.	$53,462 or 1.38/patient day	$13,326	$11,134; 2645 person-hours expended	$ 77,922
Hospital D	$45,795 or .59/patient day	$60,539 or .78/patient day	$22,610	$43,885; 8067 person-hours expended	$172,829
Hospital E	$12,741 or .17/patient day	$109,216 or 1.42/patient day	$ 2,377	$14,412; 3842 person-hours expended	$138,746
Hospital F	$47,617 or .30/patient day	$117,543 or .73/patient day	$17,265	$42,669; 7523 person-hours expended	$224,594

3. Indirect Costs

Thus far, it has been suggested that health planning and CON laws, which hold cost containment in health care as a primary objective, have the following effects:

-- They cost the federal and state governments hundreds of millions of dollars to administer.

-- Hospitals and health care providers spend "at least as much as the agencies"[5] in complying with the regulations.

-- Their actual effectiveness in holding down health care costs is, at best, highly questionable.

In addition, many studies have pointed out that health planning also produced "indirect costs." These include:

A. Travel Costs

The New England Journal of Medicine has pointed out that efforts to reduce duplication of facilities through government regulation can lead to high travel costs and costly delays in treatment:

"If fewer facilities are to serve the same patient population, some patients will inevitably have to seek treatment further from home. Additional travel costs will be incurred, and the quality of care that some patients receive will be reduced.

"In the case of the CAT scanner, some outpatients would have to travel further than they did before, and some inpatients would require transportation to and from the facility. For patients with trauma and patients with severe illness, increased travel time reduces the quality of care. A similar case can be made for radiation-therapy units: because patients with cancer must return many times for treatment, travel time is of economic importance. Reducing the number of general-hospital beds not only increases travel distance but can also lead to longer delays in treatment, which impose real costs."[6]

B. Legal Costs

Law suits brought by communities and providers dissatisfied with the actions of their local HSAs have imposed a considerable cost on all parties involved.[7]

C. Costs of Delay

While it is clear that careful study is necessary before constructing or adding to a hospital or other health care facility, the CON bureaucracy causes unnecessary delays of months and often years, and then usually ends up granting approval, sometimes with minor modifications.[8] When this occurs, the final cost of construction (or cost of purchase, in the case of equipment) is often considerably higher than it would have been without CON-imposed delays--as much as 30-40 percent higher.[9]

All in all, there is a great deal of evidence to support the conclusion that health planning costs a great deal, directly and indirectly, and yet "relying on state certificate-of-need programs and federally mandated planning programs to control hospital costs has yielded, and will continue to yield, disappointing results.[10]

ACCESS

1. Effects of Health Planning on Access

The second major aim of PL 93-641 is "equal access to quality health care." Whether this is actually being realized under health planning is in as much doubt as the cost-effectiveness of health planning.

An article in The New England Journal of Medicine pointed out several of the problems health planning causes with regard to access.

"Of special concern is the distinct possibility that large urban medical centers are more likely to fare well under any regulation scheme than are smaller, less sophisticated hospitals located in rural, suburban, and ghetto areas.

"To the extent that areas of low popultion density bear the brunt of the regulations, offsetting costs will be higher. In addition, if patients are forced from low-cost hospitals into relatively expensive urban medical centers, the net result may be to increase costs. Our calculations assumed that consolidations would be encouraged only if the unit cost of care could be reduced; unfortunately, there is no guarantee that the processes will work this way. Finally, if minority groups in low-income areas find that their hospitals cannot survive the regulatory contests, as appears to have been the case in New York, we may end up harming precisely those groups that many advocates of hospital regulation hope to help.[11]

2. Access as a Priority in Health Planning

Aside from the access problems inherent in health planning efforts is the simple fact that health planning and CON have evolved into cost-containment mechanisms (of extremely dubious worth, as demonstrated earlier) with little regard to access. The American Journal of Public Health clearly outlines this shift in priority:

"During the 1960s and early 1970s, the primary goal of national health policy was to improve access to health care, especially for the poor. The Medicare and Medicaid programs, the Office of Economic Opportunity

(OEO, and later HEW) neighborhood health centers, the federal support for health professions education and many other specific federal programs had that as their primary aim. Even the 1974 Health Planning Act (PL 93-641)--often considered to be primarily a cost-containment program--listed primary care services for underserved populations as the first of a number of national priorities.

"The thrust of national health policy has changed, as any casual observer of the health care scene knows. the emphasis is now on cost containment, almost to the exclusion of other considerations.[12]

SUMMARY

In summary, it appears that health planning and CON are of dubious worth on several counts. They are cost-containment tools which cost a great deal, directly and indirectly, and ultimately save little. As a mechanism to improve access they have done little and may have actually had a negative impact in many cases.

In view of the apparent shortcomings of federal health planning, the American Society of Internal Medicine believes that repeal of PL 93-641, or at the very least elimination of funding, would be a desirable goal.

Health planning is most effective when allowed to respond to local conditions and specific needs. The combination of local political forces and the market forces in the economy are the most effective agents of health care planning. There are several studies which substantiate this view, three of which are summarized below:

1. John W. Carr seeks to determine whether central planning and control or market methods of allocation result in a more efficient distribution of hospital resources. He concludes that the planning method has the potential of being more efficient in a technical sense. However, for many reasons, the planning method may not in actual practice be more efficient, and the market mechanism might be more practical. The market mechanism also has the advantage of automatic operation.[13]

2. In his paper, H. E. Frech discusses the choice between regulation and allowing the market to operate. Frech's recommendations include abolishing or modifying state CON programs. The paper concludes that the current form of regulation of the U.S. medical care system is partly responsible for its poor performance. Regulation of this industry is inherently difficult because of the complexity of its output and because the influence of providers over regulation is quite strong. Frech believes that regulatory reform to improve incentives, make the system more responsive to consumer preferences, and reduce the anti-competitive effects of existing regulation could be very beneficial.[14]

3. Finally, Clark Havighurst argues that private sector efforts to contain health care costs are likely to be more effective than government-sponsored controls. Therefore, Government efforts should be confined, at least initially, to untying and strengthening the private sector's hands.[15]

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Bureau of Health Planning

Program Information Letter

82-01

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • Public Health Service • Health Resources Administration

October 7, 1981

TO: State Health Planning and Development Agencies
Statewide Health Coordinating Councils
Health Systems Agencies
Centers for Health Planning

SUBJECT: The Effect of Formal and Informal Regulatory Actions on the Rate of Hospital Investment

Enclosed is a copy of the Abstract and Chapter 6, "Summary and Conclusions", of "Measuring the Effect of Economic Regulation: Certificate of Need Regulation of Hospitals in Massachusetts 1972-78", a recent dissertation at M.I.T. by Alvin Headen, Ph.D.

The study findings basically substantiate Dr. Julianne Howell's results, which were sent to you in summary form in PIL #81-38, dated April 15, 1981. In application of a two-stage analysis of both formal and informal CON decisions, Dr. Headen's empiric results indicate that informal actions of discouragement - leading to withdrawal of CON applications - were at least as important as the formal denial of projects in Massachusetts in the mid-1970's. This finding holds for both basic building and equipment, and for sophisticated technology, in contrast to earlier findings of several other studies which used national data bases.

Dr. Headen does not address the reallocation objective of CON, nor rule out the possiblity that major projects denied or withdrawn may have been reformulated and resubmitted, or substituted by a subset of less expensive capital projects, with uncertain operating cost implications. His study also suggests that

> "the CON/Planning model may not be able to achieve its reallocation objective directing resources to areas of need from areas where there is no need".

Nevertheless, his findings indicate that "the CON/Planning model can achieve a limited set of objectives."

I trust that you will find enclosed abstract and summary of this study of interest. Dr. Headen's full dissertation will be available within the next few weeks from the National Technical Information Service (NTIS), Springfield, VA 22161, telephone (703) 487-4650 in paper and, at a significantly lower price, in microfiche. Its accession number is HRP 0903514.

Barbara J. Holland

Colin C. Rorrie, Jr., Ph.D.
Director

Enclosure

MEASURING THE EFFECT OF ECONOMIC REGULATION: CERTIFICATE OF NEED REGULATION OF HOSPITALS IN MASSACHUSETTS 1972-1978

by
Alvin E. Headen, Jr.

Submitted to the Department of Economics on January 2, 1981 in partial fulfillment of the requirement for the Degree of Doctor of Philosophy in the subject of Economics.

ABSTRACT

Currently, the largest amount of the governments' efforts and resources earmarked for regulating the hospital sector of the economy has been allocated to the implementation of the CON/Planning model of direct review and approval or denial of individual planned capital projects. The majority of the previous empirical studies indicate that the CON/Planning model cannot achieve its regulatory objectives. However, these studies have serious measurement and methodological limitations in terms of appropriately evaluating the impact of the CON/Planning model. The purpose of this thesis is to provide additional empirical evidence on the impact of CON/Planning on hospital investment; using improved measures of CON agency activity and a dataset of individual hospitals confined to one CON jurisdictional area; the state of Massachusetts.

A two stage process was applied. First, an analysis of the CON decision-making process and actions was undertaken in order to determine the extent to which both formal and informal actions were exercised by the agency. The second stage used the results of stage one to construct an appropriate measure of CON activity and empirically address the question of whether the CON actions on planned hospital investment projects affected actual investment rates in the expected negative direction.

The basic results indicate that the informal actions taken by the CON agency which induce application withdrawals are at least as important as the formal denial of projects. When both formal and informal actions are included in the measure of CON activity, there is a statistically significant reduction from these actions in the rate of hospital investment in basic building and equipment and in sophisticated technology. This finding is unique in the health economics literature. It should be noted, however, that this does not constitute a sufficient condition to argue that the CON/Planning model can achieve its regulatory objectives.

CHAPTER 6: Summary and Conclusions

This dissertation began with the observation that the previous empirical literature did not support the proposition that the CON/Planning model of capital expenditure regulation - the oldest and most wide spread form of governmental regulatory intervention in the capital expenditure decisions of the hospital sector - had or could achieve its resource allocation and cost containment objectives. It then noted that a careful review of the CON/Planning model's design and regulatory process indicated that most of the critical studies have been flawed in their evaluation attempts. They failed to take into account both the formal and informal aspects of the regulatory decision-making process; suffered from specification problems; and did not provide direct test of hypotheses about necessary conditions for the program to work as intended. The dissertation derives a more precise set of necessary conditions for the CON/Planning model to work; and develops and uses an improved measure of CON actions and specifications of the relevant investment equation; and uses a more appropriate set of data to test a subset of the hypotheses concerning the necessary conditions.

The analysis was performed under the twin questions: (a) under what conditions could a model designed like the CON/Planning model achieve its stated objectives; and (b) to what extent do those conditions exist empirically. This leads to the two empirical questions explicitly addressed in the dissertation: (a) has the CON implementing agency actively exercised its options (policy tools) in ways that are consistent with the objectives

of the CON/Planning model; and (2) given measures of the options exercised by the CON agency, has hospital investment behavior responded in the manner predicted by the CON/Planning model?

The first empirical question was addressed in Chapter 4. The basic result of that analysis is that the CON agency in the state of Massachusetts has acted in ways that are consistent with the objectives of the CON/Planning model. The policy tools have been exercised through both the formal decisions of the Public Health Council toalter, impose conditions on, and deny applications; and through the informal actions of the Determination of Need staff which resulted in the withdrawal of applications and - by inference - the prevention of applications from being filed.

To recap briefly the specific results:

- The Public Health Council in Massachusetts has frequently exercised its option to alter projects planned by hospitals by the use of conditional and partial approvals of DON applications. Since 1975, the magnitude of the frequency of PHC decisions involving conditional approvals has consistently equaled or exceeded PHC approval of applications without alteration.
- For applications filed in all but the first full year of the program (1972), CON staff actions can be attributed with inducing the withdrawal of hospital applications in numbers that equal or exceed those applications formally denied by the PHC.
- When explicit account is taken of applications that were altered or denied by PHC actions or withdrawn, the data reveal that for the years 1975, 1976, and 1977; 34.17%, 49.26%, and 47.74% of the hospital applications filed were affected.

These results lead to the conclusion that the consolidated or simple denial rate method of measuring and evaluating CON/Planning activity is, by design, biased against favorable evaluation of the program. The method fails to include the ability to alter planned projects and to use informal actions to induce withdrawals of projects. A better, though still biased, measure would be one that included denials, as an indicator of formal actions, and withdrawals as an indicator of informal actions. This was done in developing the measure used to address the second empirical question.

The second empirical question cited above was addressed in Chapter 5. The general result of the analysis was that the cumulative effect of CON agency formal and informal actions (as measured by the proportion of the projected cost of projects filed by the individual hospital during the period 1972-1975 that was denied or withdrawn) on the hospital's investment plans was to produce a significant negative reduction in the rate of total investment in building and equipment and in the rate of investment in sophisticated capital projects. This is a unique finding in the health economics literature.

It should be cautioned, however, that while the -.067 short run elasticity of the rate of investment with respect to the CON measure is statistically significant and stable in all of the regression specifications, it seems to be relatively small and constitutes a test of only one necessary condition. The Nonsubstitution hypothesis, which was tested in

Chapter 5, constitutes only a necessary condition because it allows for some project substitution by the hospital in response to CON/Planning actions. Whether the allowed substitutes increase or retard hospital cost, inflation depends on the operating cost characteristics of specific substitutes. Even if it is demonstrated that the CON/Planning model can achieve its cost retardation objective, it still remains to be determined, if it can also achieve its reallocation objectives.

In order to determine the extent to which the CON/Planning model can achieve its objectives, additional empirical research is required. Studies are needed to determine the extent to which total hospital cost changes in response to changes in the rate and composition of investment induced by CON/Planning actions. While the results of this dissertation indicate that project substitution is not between basic investment and investment in sophisticated projects as argued by Salkever and Bice (1976), it does not rule out substitution between Major capital projects and a subset of less expensive in terms of the hospital's annual capital budget projects. Nor does this study rule out the possibility of intertemporal substitution with respect to the same project when a denied or withdrawn project is reformulated and later resubmitted for CON approval. Both cases can result in a more costly, and possibly inappropriate capital stock configuration when operating costs are included.

The ability of the CON/Planning model to achieve its reallocation objective depends not only on the hospital sector, but also on the financial markets which hospitals use to make their major capital purchases. This suggests that additional research is needed to determine

the extent to which the public and private financial markets operate to facilitate or hinder the reallocation of capital from hospital areas that have excess capacity to areas which have insufficient capacity. Very little information or empirical evidence has been developed on the potential impact of CON/Planning of the markets for financing health care facilities.

The final area for further research presented here concerns the theoretical basis upon which the CON/Planning model is founded, and upon which planners rely for aggressive implementation of the model in the absence of hard empirical evidence, "Roemer's Law". Roemer's Law is a statement of perverse causalty in which it is asserted that the availability of hospital bed and facilities and services causes hospital use to increase even when the additional capacity is not needed. From this basic premis, planners and CON regulators have asserted that there are too many hospital beds, even if most of them are filled, and that there are many days of unneeded care provided by the hospital. The problem is that no direct test of the causalty inherent in Roemer's has been presented. Given the result presented above that CON/Planning does reduce the rate of investment, then, if Roermer's Law is wrong, the aggressive implementation of the CON/Planning model may result in chronic shortages of facilities and services. This possibility is made more undesirable by the possibility that the CON/Planning model may not be able to achieve its reallocation objective directing resources to areas of need from areas where there is no need.

The possibility lack of validity of Roemer's Law as a causal model is suggested by the finding of support for the accelerator model, based on changes in inpatient days, reported in this study. It is also supported by the observation that a careful analysis of the original Shain and Roemer (1959) and Roemer (1961) reveals a model of hospital utilization in which doctors rank patients based on seriousness of illness then makes decisions about hospital admission, given the ranking, based on availability of treatment capacity. Such a model suggests that the availability of hospital beds and other treatment capacity represents constraints on utilization, rather than causes of utilization. If this is the case, then the correlation between bed changes and utilization, reported in the literature by Roemer, Shain and Roemer, Feldstein (1971), Klarman (1965 and 1970), and others, does not necessarily imply that "supply creates its own demand in the hospital sector", but may reflect the problem of the identification supply and demand curves from obsesrved data. This line of reasoning has been presented by Rosenthal (1972), and is apparently noted in a footnote in Sloan and Steinwald (1980; 83). What is needed is a direct test of Roemer's Hypothesis of causalty, possibly along the lines presented in Granger (1969) and Sims (1972) when sufficient data becomes available.

From a policy perspective, the results presented in this thesis indicate that the CON/Planning model can achieve a limited set of objectives. It can limit the concentration of identifiable pieces of technology and capacity in a given geographic area. It can also reduce the average rate of investment by hospitals in both plant and equipment, and sophisticated technology. While the analysis did not reveal the perverse

affect of CON on investment in sophisticated technology reported by Salkever and Bice (1976), it is consistent with the argument that some degree of project substitution in response to CON actions is exercised by the hospital.

Because of this substitution, it cannot be argued, based on these results, that the limited objectives achievable by the CON/Planning model will result in an overall improvement in the allocation of resources or in a reduction in the rate of hospital cost increases. The ability of the CON/Planning model to achieve the broader set of objectives depends crucially on the market behavior of the unique medical care delivery and financing system outlined in Chapter 2. Given the limited tools and information available to the CON/Planning model, and the high degree of autonomy retained by the states in exercising those tools; there is little reason to believe that the CON/Planning model constitutes an effective vehicle for national regulation of the medical care delivery and financing sector of the economy. However, states with limited objectives may find it a useful tool.

Maine Health Systems Agency Inc.
9 Green Street, Augusta, Maine 04330 Telephone 207 623-1182

MEMORANDUM

TO: Certificate of Need Study Committee

FROM: Stephen J. Mansfield, Executive Director

RE: Summary of Maine CON Activity

DATE: October 13, 1981

My staff and I have prepared a brief summary of recent CON activity for use by the Committee during its deliberations on proposed modifications to the State's CON Act. Before making some observations from the summary, I should explain how it was constructed.

First, only applications declared complete for review between June 1, 1979 and July 30, 1981 were included in the summary table.

Second, we attempted to aggregate projects according to the major review categories the Committee has been considering (i.e., major capital expenditures, acquisition of major medical equipment, establishment of new services, nursing home transfers and hospital mergers and consolidations). Unfortunately, while the last two categories are unambiguous, it is not always clear how to assign a project to one of the first three. For example, a project may include both a significant expenditure on physical plant and the purchase of an expensive piece of equipment; or, the acquisition of equipment and the development of a new health care service. The method we followed in allocating projects was to assign any project with a capital expenditure in excess of $150,000 for other than equipment to the "major capital expenditure" category. Next, projects which proposed the purchase of equipment not related to the establishment of a new service were placed in the "major medical equipment" component of the summary. The rest of the projects rather easily fell into the "new service" category.

(It should be noted that the first 14 projects listed in the "major capital expenditures" category were reviewed because of the "10 percent/ 5 bed" rule or because they exceeded the $100,000 review threshold established in Section 1122 of the Social Security Act.)

Lastly, the entry "Analyzed at staff and committee levels only", which appears in the "MHSA" column under "Review agency action" needs clarification. Our standard review procedure is to bring each complete project application

to the Agency's Project Review Committee to determine whether or not a public hearing on the proposal should be held by the Committee. Up to that time Agency staff have participated with the Bureau of Health Planning and Development in requesting additional information from the applicant to assure that sufficient information is available on which to make a review determination. Staff have carefully considered the merits and drawbacks to the project before going to the Committee with a recommendation to waive, or not to waive, public hearing and full formal review. Thus, staff do thorough investigations of each project, and the Project Review Committee is afforded an opportunity to consider a project, regardless of whether or not a hearing and formal review is held on the project.

Looking at the summary material we see that the Department of Human Services has disapproved 5 of 115 projects during the period covered by the report. (Another project recommended for disapproval by the MHSA was withdrawn by the applicant before DHS made its decision.) Four projects were in the "major capital expenditures" category and the fifth was a nursing home ownership transfer project. Of the four capital expenditures projects, two were valued over $700,000, but less than $1 million, and the other two exceeded $1 million.

A number of projects were modified through the action of the MHSA and the Bureau prior to final DHS approval. With one exception, these modifications all occurred in projects found in the "major capital expenditures" category. In each instance these projects were in excess of $1 million capital expenditure.

Most of the proposals to purchase major medical equipment were for replacement of existing units. All such proposals were approved during this two year interval.

Similarly, all proposals to establish new services have either been approved by the Department or are pending a final decision.

I have intentionally not attempted to draw from these data conclusions concerning desirable changes in the Maine Certificate of Need Act. My purpose in preparing this material was only to bring some useful history to the Study Committee's discussions. This information neither asks all the relevant questions nor provides all the answers to our general inquiry. However, it may provide some worthwhile reference points to help guide our study.

SJM/jp

Enclosures

MAINE HEALTH SYSTEMS AGENCY, INC.

MAINE CERTIFICATE OF NEED ACTIVITY

Applications Declared Complete for Review
Between June 1, 1979 and July 30, 1981

Type of Project	Number	Applications Withdrawn	Department of Human Services Disposition		
			Elect not to Review	Disapprove	Pending
Major capital expenditure	62	3	3	4	7
Acquisition of major medical equipment	9	0	1	0	0
Establishment of new service	32	1	1	0	2
Nursing home ownership transfers and hospital mergers and consolidations	12	1	0	1	1
	115	5	5	5	10

Establish New Services

SPONSOR/PROJECT TITLE	Original Capital Expenditure	Review Agency Action MHSA	DHS	Comments
A. R. Gould Memorial Hosp. Establish genetic counseling service	$ 0	Approved	Approved	
Aroostook Home Care Agency Homemaker/home health aids	0	Analyzed at staff and committee levels only.	Approved	
Cary Medical Center Establish a psychiatric clinic	0	Analyzed at staff and committee levels only.	Approved	
A. R. Gould Memorial Hosp. Establish a psychiatric clinic	0	Analyzed at staff and committee levels only.	Approved	
No. Cumberland Memorial Hosp. Establish speech therapy services	0	Analyzed at staff and committee levels only.	Determined not to be reviewable	
Houlton, Cary, No. Maine Medical Center Develop speciality clinics	0	Analyzed at staff and committee levels only.	Approved	
A. R. Gould Memorial Hosp. Establish occupational therapy services	0	Analyzed at staff and committee levels only.	Approved	

Establish New Services (Cont.)		Review Agency Action		(MAINE HEALTH SYSTEMS AGENCY)
SPONSOR/PROJECT TITLE	Original Capital Expenditure	MHSA	DHS	Comments
Cary Medical Center Establish occupational therapy services	$ 0	Analyzed at staff and committee levels only.	Approved	
Aroostook Home Care Establish occupational therapy services	0	Analyzed at staff and committee levels only.	Approved	
Calais Regional Hospital Manage Eastport Hospital's emergency services	0	Approved	Approved	Emergency 90-day CON granted.
Aroostook Medical Center Establish dermatology clinic	0	Analyzed at staff and committee levels only.	Approved	
Kno-Wal-Lin Community Health Services Provide speech therapy services	0	Analyzed at staff and committee levels only.	Pending	
Kno-Wal-Lin Community Health Services Hire a medical social worker	0	Analyzed at staff and committee levels only.	Pending	

Establish New Services (Cont.)

SPONSOR/PROJECT TITLE	Original Capital Expenditure	Review Agency Action: MHSA	Review Agency Action: DHS	Comments
Down East Community Hosp. Establish orthopedic services	$ 15,187	Analyzed at staff and committee levels only.	Approved	
Penbay Medical Center Establish neurological services	24,135	Analyzed at staff and committee levels only.	Approved	
Maine Medical Center Develop vascular lab	24,200	Approved	Approved	
Maine Medical Center Establish an evoked potential response system	26,100	Approved	Approved	
CMMC Establish an evoked potential response system	27,300	Analyzed at staff and committee levels only.	Approved	
Mayo Regional Hospital Establish ophthalmology services	40,500	Analyzed at staff and committee levels only.	Approved	
Franklin County Memorial Hospital Purchase Ultrasound equipment	65,000	Analyzed at staff and committee levels only.		After the Project Review Committee's determination to not conduct a full review of this proposal, the applicant requested an extension of the review process in order to explore the possibility of offering a joint ultrasound service with another hospital. The applicant later presented an application for a joint service - effectively withdrawing this proposal.

Establish New Services (Cont.)		Review Agency Action		(MAINE HEALTH SYSTEMS AGENCY)
SPONSOR/PROJECT TITLE	Original Capital Expenditure	MHSA	DHS	Comments
Houlton Regional Hospital Establish ultrasound services	$ 93,675	Analyzed at staff and committee levels only.	Approved	
Stephens Memorial Hosp. Establish a nuclear imaging service	114,047	Approved	Approved	
A.R. Gould Memorial Hosp. Retrospective review of previously established but unapproved ophthalmology services	140,032	Disapproved	Approved	This project was considered by MHSA to be a duplication of services as Cary Medical Center had ophthalmology services already established.
Eastern Maine Medical Ctr. Establish nuclear cardiology services	252,000	Analyzed at staff and committee levels only.	Approved	
Eastern Maine Medical Ctr. Purchase CT scanner	905,450	Approved	Approved	

Establish New Services (Cont.)		Review Agency Action		(MAINE HEALTH SYSTEMS AGENCY)
SPONSOR/PROJECT TITLE	Original Capital Expenditure	MHSA	DHS	Comments
Franklin County Memorial Hosp./Redington-Fairview Hospital Establish a joint ultrasound service	$ 70,000	Approved	Approved	
No. Maine Medical Center Establish ultrasound services	67,300	Analyzed at staff and committee levels only.	Approved	
Mercy Hospital Purchase ultrasound equipment	68,700	Analyzed at staff and committee levels only.	Approved	
Webber Hospital Establish ultrasound services	70,000	Approved	Approved	
Mayo Regional Hospital Establish ultrasound services	72,300	Analyzed at staff and committee levels only.	Approved	
Millinocket Community Hosp./ Penobscot Valley Hosp. Purchase ultrasound equipment	79,220	Approved	Approved	
Motivational Service, Inc. Develop & operate 6-bed ICF/MR	87,472	Analyzed at staff and committee levels only.	Approved	

Major Capital Expenditures		Review Agency Action		
SPONSOR/PROJECT TITLE	Original Capital Expenditure	MHSA	DHS	Comments
Orono Nursing Home Convert 41 SNF beds to ICF beds	$ 0	Analyzed at staff and committee levels only.	Approved	
Central Maine Medical Center Expand Neonatal Level II Unit	3,843	Approved	Approved	
Community General Hosp. Acute/ICF bed reclassification	5,000	Approved	Approved	
Bangor City Nursing & Health Center Add 3 ICF beds	5,870	Analyzed at staff and committee levels only.	Approved	
Eastern Maine Medical Ctr. Retrospective review of expansion of renal dialysis capabilities	24,055	Analyzed at staff and committee levels only.	Elected not to review	
High View Manor Renovation	56,594	Analyzed at staff and committee levels only.	Determined not to be reviewable	
Eastern Maine Medical Ctr. Renovation/temporary operation of 12-bed alcohol rehab. unit	62,400	Analyzed at staff and committee levels only.	Approved	
Maine Coast Memorial Hosp. Or renovations	108,918	Approved	Approved	

Major Capital Expenditures		Review Agency Action		(MAINE HEALTH SYSTEMS AGENCY)
SPONSOR/PROJECT TITLE	Original Capital Expenditure	MHSA	DHS	Comments
Hayden House Construct and operate an 18-bed ICF/MR	$ 109,947	Approved	Approved	
Clover Manor Construction/add 5 ICF beds	125,000			Withdrawn
Penobscot Nursing Home Add 6-ICF beds and replace 6 beds	130,325	Approved	Approved	
Augusta Mental Health Institute Relocate/decrease # of beds	140,000	Analyzed at staff and committee levels only.	Approved	
Eastern Maine Medical Ctr. Renal dialysis/correct deficiencies	143,150	Analyzed at staff and committee levels only.	Elected not to review	
Mid-Maine Medical Ctr. Exchange computer parts	147,477	Analyzed at staff and committee levels only.	Approved	
The Elms Residence Add 8-ICF beds	152,500	Approved	Approved	
St. Mary's General Hosp. Establish a chemical dependency program	173,900	Approved	Approved	

Major Capital Expenditures

(MAINE HEALTH SYSTEMS AGENCY)

SPONSOR/PROJECT TITLE	Original Capital Expenditure	Review Agency Action MHSA	DHS	Comments
Group Home Foundation Establish 6-bed ICF/MR	$ 174,960	Approved		The applicant has indicated their desire to find a new site for the proposed ICF/MR and, therefore, Department of Human Services has declared the application incomplete following MHSA recommendation.
-Amended		Pending	Pending	
St. Joseph Hosp. Replace Sisters residence	220,386	Approved	Approved	
CASA Construct and operate an 8-bed ICF/MR	250,926	Approved	Approved	
Evergreen Manor Add 20 ICF beds	363,800	Disapproved.		MHSA determined that additional ICF beds in the Coastal York area were not needed and disapproved the application. The application was withdrawn.
Maine Medical Center Purchase a waste disposal incinerator	365,000	Analyzed at staff and committee levels only.	Approved	
Central Maine Medical Ctr. Establish a physical rehab program	422,345	Approved	Approved	
Greater Portland Health Plan HMO pre-development	424,887	Approved	Approved	
Oceanview Nursing Home Construction/renovation; add 30 ICF beds/16 boarding care beds	479,000	Analyzed at staff and committee levels only.	Pending	Extension granted.
Maine Medical Center Add 2 emergency generators	480,000	Analyzed at staff and committee levels only.	Pending	

Major Capital Expenditures		Review Agency Action		(MAINE HEALTH SYSTEMS AGENCY)
SPONSOR/PROJECT TITLE	Original Capital Expenditure	MHSA	DHS	Comments
Marcotte Nursing Home Pre-development activities	$ 562,694	Approved	Approved	
Marshwood Associates Cost overrun on previously approved construction of a 120-bed ICF	646,116	Approved	Approved	
Augusta General Hospital Dietary renovations	728,110	Approved	Approved	
Eastern Maine Medical Ctr. Cost overrun on radiation therapy project	729,668	Approved	Disapproved	
Yesterdays Children Construct and operate a 20-bed ICF/MR	771,000	Approved	Approved	
Maine Medical Center Renovate/purchase linear accelerator	777,500	Approved	Approved	
Eagle Lake Home Construct and operate a 14-bed ICF/MR	789,011	Analyzed at staff and committee levels only.	Approved	
St. Mary's General Hosp. Expand radiation therapy services	864,354	Disapproved	Disapproved	Proposals by Central Maine Medical Center and St. Mary's General Hospital were reviewed competitively and both turned down by MHSA. Department of Human Services approved only the former proposal.
Central Maine Medical Ctr. Expand radiation therapy services	1,748,000	Disapproved	Approved	

Major Capital Expenditures (MAINE HEALTH SYSTEMS AGENCY)

SPONSOR/PROJECT TITLE	Original Capital Expenditure	Review Agency Action MHSA	Review Agency Action DHS	Comments
Maine Medical Center Add 8 SCU beds	$ 879,000	Analyzed at staff and committee levels only.	Approved	
St. Joseph Hospital Replace ICU/CCU	885,655	Approved	Approved	
Southern Maine Dialysis Facility Relocate	900,000	Analyzed at staff and committee levels only.	Approved	
Parkview Memorial Hosp. Construction/add 2 OR's	1,026,525	Approved for $828,192	Approved for $375,000	Before MHSA's decision the applicant revised its application by changing the proposed use of space in the present OR and other areas resulting in a new increase of only 1 OR at an estimated capital expenditure of $828,192. Through the use of different proposed financing arrangements and a modified construction plan, the estimated capital expenditure was reduced to $375,000. The project was approved at this level by the Department of Human Services.
Brunswick Manor Construct and operate a 50-bed replacement ICF	1,075,000	Approved	Approved	
Riverview Nursing Home Replacement of Cummings Nursing Home (35-bed ICF) with a new 66-bed ICF	1,134,125	Analyzed at staff and committee levels only.	Approved for $747,600	Before MHSA's Project Review Committee determined to not conduct a full review of this proposal, the applicant presented an amended application for a 35-bed replacement ICF with a capital expenditure of $746,660 and later modified the proposal again to a 40-bed ICF at a capital expenditure of $747,600. The Committee elected to not conduct a full review of the application in this form.
C.A. Dean Memorial Hosp. Construct a new wing to house 50 new ICF beds	1,243,400	Approved	Pending	Extension granted.

Major Capital Expenditures (MAINE HEALTH SYSTEMS AGENCY)

SPONSOR/PROJECT TITLE	Original Capital Expenditure	Review Agency Action: MHSA	Review Agency Action: DHS	Comments
Island Nursing Home Construct and operate a 50-bed ICF	$ 1,290,033	Approved	Approved	
Mt. Desert Island Hosp. Construction/renovation	1,470,000	Approved		Withdrawn
Maine Medical Center Renovate Vaughan Hall	1,583,041	Approved	Approved	
MaineCare Construct 72-bed ICF	1,683,950	Approved	Pending	
Conversions of various ICF/MRs statewide	1,775,119	Approved	Approved	
Jupiter IX Establish a 20-bed SNF/60-bed ICF	1,830,050			MHSA's Project Review Committee determined that there was a need for 20 SNF beds in the Waterville area but considered the proposed 20 SNF/60 ICF bed combination an inappropriate response to this need and recommended disapproval of the project. The applicant withdrew the application.
Wyman Memorial Manor Construct and operate a 90-bed ICF	1,872,858	Approved	Disapproved	
Sandy River Health Care Center Construct and operate a 95-bed ICF	2,331,200	Disapproved	Approved	The proposals to construct Sandy River Health Care Center and Wyman Memorial Manor were reviewed competitively. MHSA recommended approval of the latter project and Department of Human Services ultimately approved the former.
Mid-Maine Medical Center/ Augusta General Hospital Establish joint radiation therapy center	2,701,232 340,133	Approved	Approved	

(MAINE HEALTH SYSTEMS AGENCY)

Major Capital Expenditures

SPONSOR/PROJECT TITLE	Original Capital Expenditure	Review Agency Action: MHSA	Review Agency Action: DHS	Comments
Broadway Manor Construct and operate a 100-bed ICF	$ 2,500,000	Approved	Disapproved	MHSA approved 3 ICF proposals in the Bangor area (others were Bangor Convalescent Center and Bangor Nursing Home). The Department of Human Services approved the other two proposals but disapproved Broadway Manor's request.
Northern Cumberland Memorial Hospital Construction/renovation: Add 10 licensed acute care beds	2,925,000	Approved for $2,862,000	Approved for $2,862,000	MHSA's Project Review Committee disapproved the request for 10 additional licensed acute care beds. The applicant then amended its application to request just 6 additional licensed acute care beds at a capital expenditure of $2,862,000 - a level at which the project was approved by both MHSA and the Department of Human Services.
Regional Memorial Hosp. Construct/renovation	4,060,000	Approved for $4,005,000	Approved for $4,005,000	Staff from the MHSA and the Bureau of Health Planning and Development worked with the applicant to eliminate one proposed new operating room and some square footage from the project, thereby, reducing the capital cost to $4,005,000.
Portland City Hospital Construct and operate a 180-bed replacement ICF	5,413,000	Approved	Approved for $4,977,000	After MHSA recommended approval of this proposal, the applicant amended the application by reducing the project square footage through the omission of various use areas resulting in a reduction of the estimated capital expenditure to $4,977,000.
York Hospital Addition/renovation	5,725,000	Approved	Approved for $4,790,350	After MHSA's decision, financing arrangements were modified resulting in a new estimated capital expenditure of $4,790,350.
Maine Veterans Home Construct and operate a 200-bed ICF	6,000,000	Disapproved		After MHSA recommended disapproval of this project, the applicant presented an amended application for 120 ICF beds at a capital expenditure of $4,200,000. The amended application was approved by MHSA and the Department of Human Services.
-Amended		Approved for $4,200,000	Approved for $4,200,000	

(MAINE HEALTH SYSTEMS AGENCY)

Major Capital Expenditures		Review Agency Action		
SPONSOR/PROJECT TITLE	Original Capital Expenditure	MHSA	DHS	Comments
Community Care Systems Construct a 148-bed acute psychiatric and substance abuse hospital (Jackson Brook Institute)	$ 9,250,000	Approved		After MHSA recommended approval of this proposal, the applicant amended the application to a 105-bed facility at an estimated capital expenditure of $6,995,000.
-Amended	6,995,000	Analyzed at staff and committee levels only.	Pending	
Marcotte Nursing Home Construct and operate a 360-bed replacement ICF	12,727,306	Approved for $9,835,186	Approved for $9,620,186	Before MHSA's decision, this project was modified to a 280-bed facility at an estimated cpaital expenditure of $9,835,186. After MHSA's decision, a lower estimated cost of construction reduced the overall estimated capital expenditure to $9,620,186. The project was ultimately modified to a 250-bed ICF/30-bed SNF.
EMMC Construction/renovation: Add 62 acute beds and a parking garage	$ 14,160,000	Disapproved $12,416,000		Before MHSA's first Project Review Committee meeting, the estimated capital expenditure associated with this project was reduced to $12,416,000 through the deletion of a proposed new floor.
		Approved for $9,860,000	Approved for $9,860,000	Following the Committee's recommendation of disapproval, the applicant again modified the application by eliminating the construction of a new parking garage. This change and other related changes reduced the project's estimated capital expenditure to $9,860,000. The proposal was approved at this level.
Mid-Maine Medical Center Major consolidation project	$ 14,400,000	Approved	Approved	
Mid-Maine Medical Center Cost overrun on consolidation project	1,600,000	Analyzed at staff and committee levels only.	Approved	

Major Capital Expenditures — Review Agency Action — (MAINE HEALTH SYSTEMS AGENCY)

SPONSOR/PROJECT TITLE	Original Capital Expenditure	MHSA	DHS	Comments
Mercy Hospital Construction/modernization establish alcohol rehabilitation service	$ 14,990,775	Approved	Pending	

Acquisition of Major Medical Equipment		Review Agency Action		(MAINE HEALTH SYSTEMS AGENCY)
SPONSOR/PROJECT TITLE	Original Capital Expenditure	MHSA	DHS	Comments
Maine Medical Center Purchase gamma camera	133,791	Analyzed at staff and committee levels only.	Approved	
Camden Community Hospital Replace radiology unit	143,790	Analyzed at staff and committee levels only.	Approved	
Central Maine Med. Ctr. Replace coulter analyzer	144,190	Analyzed at staff and committee levels only.	Approved	
Maine Medical Center Purchase SMA II blood analyzer	148,250	Analyzed at staff and committee levels only.	Approved	
Maine Medical Center Replace coulter counters	158,591	Analyzed at staff and committee levels only.	Elected not to review	Before the Project Review Committee's determination not to conduct a full review of this proposal, the cost of the project was reduced to $147,737 due to an increase in the trade-in allowance granted by the vendor.
Stephens Memorial Hosp. Replace x-ray equipment	214,000	Approved	Approved	
Eastern Maine Medical Ctr. Purchase cardiac monitoring system	219,370	Approved	Approved	
Central Maine Medical Ctr. Purchase radiographic/ fluoroscopic equipment	225,000	Approved	Approved	
Maine Medical Center Replace x-ray equipment	282,000	Approved	Approved	

Nursing Home Ownership Transfers

(MAINE HEALTH SYSTEMS AGENCY)

SPONSOR/PROJECT TITLE	Original Capital Expenditure	Review Agency Action MHSA	Review Agency Action DHS	Comments
Camden Nursing Home Transfer of ownership	$ 112,579	Analyzed at staff and committee levels only.	Approved	
Sanford Nursing Home Transfer of ownership	170,000	Analyzed at staff and committee levels only.	Approved	
Camden Nursing Home Transfer of ownership	261,300	Approved	Approved	
Auburn Nursing Home Transfer of ownership	283,375	Analyzed at staff and committee levels only.	Pending	Extension granted
Kittery Convalescent Center Transfer of ownership	850,000	Analyzed at staff and committee levels only.	Approved	
Prospective Associates Purchase of Notre Dame unit of Webber Hosp. Construct new wing to relocate 36 ICF beds	1,000,000	Analyzed at staff and committee levels only.	Approved	
Sebasticook Valley Health Care Center Transfer of ownership	1,248,000			Withdrawn
Lakewood Manor Transfer of ownership	1,657,075	Analyzed at staff and committee levels only.	Disapproved	

Facility Mergers and Consolidations

(MAINE HEALTH SYSTEMS AGENCY)

SPONSOR/PROJECT TITLE	Original Capital Expenditure	Review Agency Action: MHSA	Review Agency Action: DHS	Comments
Mid-Maine Medical Center/ Marie-Joseph Hospital Merger	$ 0	Analyzed at staff and committee levels only.	Approved	
Aroostook Health Center/ A.R. Gould Memorial Hosp. Consolidation	5,000	Approved	Approved	
Blue Hill Memorial Hosp. Hospital/home health agency merger	6,058	Analyzed at staff and committee levels only:	Approved	
Augusta General Hosp./ Gardiner General Hosp. Consolidation	59,500	Approved	Approved	

Bureau of Health Planning

Program Information Letter

82-04

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • Public Health Service • Health Resources Administration

October 21, 1981

TO: State Health Planning and Development Agencies
Statewide Health Coordinating Councils
Health Systems Agencies
Centers for Health Planning

SUBJECT: Election Not to Review Under the Section 1122 Program

All capital expenditures (as defined in Federal regulations at 42 CFR 100.103) by or on behalf of a health care facility are subject to review by States that have entered into an agreement with the Secretary under Section 1122 of the Social Security Act. However, a State designated planning agency (DPA) may elect not to review certain capital expenditures (42 CFR 100.106(a)(4)).

On August 13, 1981, the Omnibus Budget Reconciliation Act (P.L. 97-35) was signed into law. Among other actions, this Act raised the minimum dollar thresholds for the Federal certificate of need program. As of October 1, 1981, the minimum Federal dollar threshold requirement for capital expenditures subject to review is $600,000 which figure may be adjusted from October 1979 if the State has the authority to adjust the minimum threshold according to the index designated by the Secretary of the Department of Health and Human Services. Also, as of the same date, the minimum Federal dollar threshold requirement for major medical equipment acquisitions subject to review is $400,000.

To ease the burden of operating two different regulatory programs, the Bureau of Health Planning wishes to note that the DPA may elect not to review a capital expenditure that would not be subject to review under the minimum dollar thresholds enacted by P.L. 97-35 unless that expenditure is required to be subject to review under the State's certificate of need program.

For further information contact Mr. James W. O'Donnell, Acting Director, Division of Regulatory Activities, Bureau of Health Planning, 3700 East-West Highway, Room 6-50, Hyattsville, Maryland 20782.

Colin C. Rorrie, Jr., Ph.D.
Director

New England Journal of Medicine, 19 Nov. 1981

SPECIAL REPORT

BUDGET RECONCILIATION

The New Legislative Process

In recent months, persons seeking to understand and influence health legislation in Washington have encountered a bewildering maze created by the Congressional Budget Act. Most major actions in Congress this year have been taken through recisions, deferrals, and reconciliation bills. The result for legislators and lobbyists alike has been an unfamiliar, unpredictable, and all but uncontrollable legislative process.

Budgetary procedures now serve as the means for determining not only the extent of federal financial commitment to health programs but also the substance of legislation that puts these programs in place. This fact has not been lost on a new, immensely popular President who seeks radical changes in social policy. Ironically, the changes he seeks — and the remarkable victories in Congress that he has achieved thus far — have been facilitated by procedures developed seven years ago by a Democratic Congress attempting to capture control of federal budgetary decisions.

To appreciate the development and implications of the new Congressional budget process, one must recall the classic confrontations between the legislative and executive branches during the presidency of Richard Nixon. President Nixon, far more than any previous president, attempted to change the course of domestic policy through control of the federal budget, without Congressional consent. When Congress appropriated more funds than he believed warranted, Nixon would veto the appropriations. When Congress overrode the vetoes, he would use the budget process to achieve the desired result anyway. For agency programs that he sought to change or dismantle, he would defer the release of funds to the agency. Alternatively, he would simply impound (refuse to spend) the "excess" monies appropriated by Congress.

An offended Congress proceeded to enact legislation to increase its own influence over the budgetary process. Led by liberal members who favored increased domestic spending and reinforced by the Judiciary, which found the impoundment of appropriated funds to be illegal, Congress developed the Anti-Impoundment and Congressional Budget Act of 1974 (P.L. 93-344). One part of the Act, involving recisions and deferrals of funds, became effective in 1974. The other part, involving budget reconciliation, was not fully implemented until last year.

Recisions and Deferrals

In response to President Nixon's budgetary maneuverings, the Budget Act requires Congressional action before the President can legally withhold or delay the expenditure of funds. No withholding or recision of funds can take place unless the President has first proposed it through a special presidential message. Congress, in turn, has 45 days to approve any recision bill; without such approval, the proposed recision cannot take place. If the President wishes instead to delay or defer expenditure of funds, he must again forward a proposal to Congress through a special presidential message. In this case, however, the deferral is authorized unless and until either house of Congress disapproves it through passage of an impoundment resolution.

Thus, the authority to make recisions and deferrals was granted to the President by the Budget Act, but only after Congressional scrutiny: recisions are effective only if Congress approves them; deferrals are ineffective if one house of Congress disapproves them.

One of the few bills sent to the President during the first six months of the 97th Congress was the Supplemental Appropriations and Rescissions Act of 1981 (P.L. 97-12), enacted in response to President Reagan's earlier requests for recision. Although it was mild in comparison to some of the President's proposals, the 1981 law rescinded almost $43 million in funds for the National Institutes of Health (NIH) (the President requested recision of over $125 million) and all capitation support for schools of medicine, osteopathy, and dentistry (totaling $55 million), and it reduced funds for health-planning agencies.

Budget Reconciliation Process

When the Budget Act was passed in 1974, most observers believed that the recision and deferral procedures were its most important aspects. On the contrary, it appears that the new reconciliation procedures constitute the most important change in legislative procedure in decades.

Last year, reconciliation produced major changes in the Medicare and Medicaid laws, including changes in methods of payment for the services of teaching physicians, limitations on payments to radiologists and pathologists, increased funding for state Medicaid-fraud control units, authorization for government access to the books and records of provider subcontractors, and removal of certain restrictions on the certification of proprietary home health agencies. This year, the impact of the reconciliation process was nothing short of revolutionary. After the dust settled, Congress presented President Reagan with the Omnibus Reconciliation Act of 1981, which projects substantial savings, yet at the same time preserves most government health programs developed during the less conservative 1960s and 1970s. Indeed, the health-related portion of the 1981 reconciliation package may well be the only Democratic trophy in a year that was otherwise marked by Congressional acquiescence to President Reagan's budgetary specifications.

The budget process that has emerged during the past two years requires that Congress enact substantive legislation to achieve specified savings of billions

of dollars. An understanding of this procedure, as distinguished from the more traditional legislative process, is critical to health professionals whose livelihoods — and whose institutions — depend on federal health programs.

Before 1974, only the executive branch prepared a federal budget for the upcoming year. The President's budget recommended specific levels of funding for federal programs, to be accomplished through changes in existing laws or new federal initiatives. There existed no requirement, however, for the President's recommendations to be followed by either the Appropriations Committees, which are responsible for funding federal programs, or the legislative committees, which craft substantive law. There was also no mechanism to ensure a coordinated effort among the various appropriations subcommittees for the purpose of consideration of the overall effect of appropriations action on the federal budget.

During the 1970s, most health-related committees in fact set priorities substantially at odds with the fiscal policies of the President. Several legislative-committee chairmen, including Rogers (D-Fla.) and Kennedy (D-Mass.), gained notoriety by shepherding through Congress measures proposing a federal role in health greater than that envisioned by the executive branch. Appropriations Committee chairmen such as Magnuson (D-Wash.) made certain that spending bills contained funds for health programs in excess of the President's requests. In turn, large percentages of health-appropriations measures were vetoed by Presidents Nixon and Ford, and many of Nixon's impoundments involved health-related appropriations that exceeded those recommended in his budgets.

The theory of the new budget law was simple: Instead of simply reacting to the federal budget prepared by the President, Congress would prepare and enforce its own budget. Unfortunately, implementation has not been as simple as Congress intended.

At the outset, the Budget Act created the now-powerful House and Senate Budget Committees. These committees develop and mandate the fiscal framework within which the appropriations and legislative committees must prescribe spending for federal programs.

Under the new law, Congress must adopt two Concurrent Budget Resolutions each year. The first concurrent resolution seeks to establish an overall budgetary framework within which Congress will operate as it considers revenue and spending legislation for the upcoming fiscal year. The second concurrent resolution, which is "binding," reaffirms or revises the budgetary totals of the first one. Prepared by the Budget Committees, budget resolutions undergo virtually the same legislative process as any bill, including hearings, committee votes, floor action, and House–Senate conferences. Unlike most other bills, however, the conference report, representing the final version of the budget resolution agreed on by both bodies, is not forwarded to the President for signature. It is the Congress' budget, not the President's, and thus his approval is not required.

Concurrent resolutions allocate funds among various categories of federal spending, such as national defense, agriculture, and health. Committee reports accompanying the concurrent resolutions specify levels of total budget outlays and new budget authority that must be met by appropriations and legislative committees. These committees, in turn, subdivide the budget outlays and new budget authorities among their subcommittees. Compliance with the budget assignment is mandatory. In the unlikely event that an appropriations bill recommends amounts in excess of those allocated, the originating committee can look forward to confrontation with the Budget Committee on the floor of the House or Senate.

The teeth of the Budget Act are found in its "reconciliation" provisions. Under this procedure, Congress can require House and Senate legislative committees to make changes in existing laws for the sole purpose of raising revenues or reducing federal spending to the level of its Concurrent Budget Resolution. This procedure involves "assigning" to various legislative committees specific amounts of money that must — through changes in laws under their jurisdiction — be raised or saved. In effect, the laws are "reconciled" to meet the Congressional Budget Resolution. Each committee crafts a reconciliation bill and refers it to the appropriate Budget Committee, where it is packaged with other bills and sent to the House or Senate floor. If a recalcitrant committee refuses to come up with legislation producing the budgetary targets assigned to it, then the Budget Committees have the extraordinary authority to write such legislation themselves.

Reconciliation Implemented

Countless observers contended that the budget-reconciliation procedure could never be implemented because it invaded the jurisdiction of many committees and, thus, the lifeblood of powerful committee chairmen. Nevertheless, in May of 1980 Congress adopted the first budget resolution covering fiscal year 1981. Over the howls (and dissenting votes) of numerous committee chairmen, the resolution included for the first time reconciliation instructions to eight House and 10 Senate committees. The instructions directed these committees to recommend specific changes in laws within their jurisdiction in order to achieve total savings of nearly $5 billion in budget authority and over $6 billion in outlays. In addition, the House Ways and Means and Senate Finance committees (the taxing committees) were directed to raise revenues by over $4 billion.

To the astonishment of many, all affected House and Senate committees did in fact report reconciliation legislation within six weeks. These committees included in their bills many of the Medicare and Medicaid reforms suggested by the Budget Committees, as

well as alternative savings provisions crafted hurriedly by staff of the legislative committees. Proposed total legislative savings and revenue increases met the requirements of the first budget resolution, and the resulting conference report was approved overwhelmingly by the Senate and House. On December 5, 1980, President Carter signed into law the Omnibus Reconciliation Act of 1980 (P.L. 96-4999).

Congress recently completed the second round of developing a Congressional budget and the reconciliation legislation to carry it out. Early in the year, a budget remarkably similar to President Reagan's was quickly adopted by the Senate Budget Committee and the full Senate. Subsequently, the House rejected by a substantial margin the Congressional Budget Resolution proposed by its Budget Committee and substituted for it one supported by President Reagan. The conference report, which was quickly approved by both houses of Congress, included reconciliation instructions to most committees of the House and Senate, calling for total spending reductions of over $50 billion in budget authority and over $35 billion in outlays for fiscal year 1982. The legislative committees were directed to report their reconciliation bills within four weeks.

Fifteen House and 14 Senate committees immediately began work under the watchful eye of administration lobbyists, who pushed for inclusion of President Reagan's legislative proposals within the various reconciliation measures. Health-related provisions were crafted by the four legislative committees having jurisdiction over the lion's share of federal health programs: Senate Finance, House Ways and Means, Senate Labor and Human Resources, and House Energy and Commerce. Each committee produced proposed legislation designed to achieve the savings assigned to it, but each accomplished this in a remarkably different fashion.

The Ways and Means and Finance Committees produced consensus easily and moved their reconciliation bills with dispatch. In Senate Labor and Human Resources, newly appointed Chairman Orrin Hatch (R-Utah) pushed administration proposals to the brink; at times he was defeated or forced to compromise by a coalition led by Senator Edward Kennedy, who had served previously as the Health Subcommittee chairman. In House Commerce, two dead heats ensued. The Health Subcommittee was split 10 - 10 between a proposal of Chairman Henry Waxman (D-Calif.) to preserve most health programs at substantially reduced levels and one advanced by Representative Edward Madigan (R-Ill.) — which closely parroted President Reagan's proposal — to terminate some programs, fold others into block grants to states, and cap Medicaid expenditures. In the full Commerce Committee, the Waxman and Madigan bills were incoporated into rival Democratic and Republican proposals sponsored by Representatives John Dingell (D-Mich.) and James Broyhill (R-N.C.), respectively. The result in the Commerce Committee was also a deadlock, this time by an informal 21 to 21 head count. Not surprisingly, the House Budget Committee adopted the Dingell proposal. Despite an administration victory on the House floor — in the form of the Gramm–Latta amendment, which substituted an administration-backed proposal for that of most provisions recommended by the Budget Committee — the Dingell provisions were left intact, with Representative Broyhill declining the opportunity to offer his proposal as a substitute, presumably on the basis of a vote count. The Dingell proposal was the only Democratic provision not amended by the Gramm–Latta proposal.

After the House and Senate passed their versions of the 1981 reconciliation legislation, conferees met in the biggest House–Senate conference ever held, to resolve differences in the two bills. The process was concluded after only five weeks and resulted in the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35).

1981 Reconciliation Provisions

The health provisions ultimately adopted by the reconciliation conference can perhaps best be characterized as an absence of disaster for proponents of a strong federal role in health. The proposed Medicaid caps — advanced by the administration, approved by the Senate, and proposed by Madigan and Broyhill in the House — were rejected in conference at Waxman's insistence in favor of a more lenient and flexible reduction in federal matching payments (3 per cent in fiscal 1982, 4 per cent in fiscal 1983, and 4.5 per cent in fiscal 1985). Estimated reductions in Medicaid payments to states total $1 billion per year. States will be permitted to lower the amounts reduced through several means, including operation of qualified hospital-cost review programs. At the insistence of Senate Finance Committee Chairman Dole (R-Kan.), the rate-review option for states applies only to the six or seven states that had such a program in effect on July 1, 1981 — a considerable reduction in scope from the House-approved bill.

Although recommended for termination by the Ways and Means and several proposals the professional standards review organization (PSRO) program survived, at least temporarily. Close scrutiny of PSROs has been required, however, and could result in termination of up to 50 per cent of existing PSROs by the end of fiscal year 1982.

For biomedical-research programs, the Senate had at first approved capping of funds for NIH and substantially reduced authorizations for training grants for biomedical and behavioral researchers. Ironically, Representative Waxman, who last year sought to cap authorizations on each NIH institute, this year succeeded in obtaining the removal of such caps. In addition, he was able to obtain higher authorizations for training grants than those proposed by the Senate.

Perhaps Mr. Waxman's greatest success involved his dogged resistance to the administration's proposal to lump major health programs into two block

grants to states and reduce funding from $2 billion to $1.4 billion. Such a plan, Waxman argued, would have threatened many of the categorical health programs established during and since the Great Society years. The conferees agreed to withhold 10 programs from block grants and place some 20 others into four block grants. Moreover, substantial restrictions have been placed on states to ensure preservation of the programs and congressional scrutiny of them.

Implications of Budget Reconciliation

The most immediate implication of the budget-reconciliation process is its potential to serve as the vehicle for radical changes in substantive laws carefully crafted by legislative committees over the past 20 years. In the absence of reconciliation, President Reagan could probably still have produced dramatic changes in federal spending by issuing veto threats and recision requests to Appropriations Committees. Because of the reconciliation process, however, he has succeeded not only in controlling federal spending for the year but also in modifying substantive laws that form the basis for federal spending, through his capture of procedures made available by the congressional budget process. In fact, as witnessed this year, reconciliation can operate to force cutbacks even in so-called entitlement programs, such as Medicare and Medicaid, as well as discretionary programs subject to annual appropriations, such as biomedical research and other categorical health programs.

For health professionals affected by federal policy, the 1974 law has other important implications. First of all, the new budget process diffuses power in Congress. The Budget Committees are at least as powerful, and sometimes more so, than the "regular" House and Senate committees — to the confusion and consternation of many Washington lobbyists. In turn, the budget process has eroded the authority of the other committee chairmen. Despite their strengths, such chairmen as Dole of Finance, Rostenkowski (D-Ill.) of Ways and Means, and Dingell of House Energy and Commerce are now charged with steering through their committees legislation having budgetary impacts consistent with Budget Committee instructions. Such instructions effectively mandate priorities within legislative committees — a function traditionally held, and indeed protected, by committee leaders. Committee chairmen now have less time, to say nothing of less money, for pursuing their special interests.

Similarly, the Budget Act has substantially reduced the power of Appropriations Committees. Legislative committees must establish more conservative ceilings on appropriations levels, and this, combined with direct restraints of the budget law itself, has substantially reduced the flexibility of the Appropriations Committees. At this point, they must now behave more like fiscal intermediaries than the powerful fiscal barons they once were.

Moreover, the budget process has the fascinating effect of pitting interest group against interest group, with each seeking savings reductions that will not hurt its own interests, perhaps by taking a slice out of someone else's fiscal pie. Early on, for example, the Blue Cross Association and the Federation of American Hospitals found themselves submitting rival proposals to the Ways and Means Committee, effectively pitting reductions in automatic payments to hospitals for some costs of nursing services against a requirement that private health insurers become first payers in some cases of dual coverage under Medicare.

Finally, it has become increasingly obvious that substantive legislation can be enacted extremely quickly through the budget-reconciliation procedure. As a result of deadlines imposed by the Budget Act, time constraints usually preclude thorough hearings on all proposals to achieve savings; these constraints, in turn, result in inadequate staff preparation and little time for the public to react to proposed changes in the law, or to determine fully the costs of proposals.

Despite its imperfections and dangerous implications, budget reconciliation will be the principal vehicle by which substantive revisions to federal health laws are crafted in future years. We are only now witnessing the full impact of a 1974 Act that has all but revolutionized lawmaking on Capitol Hill.

I am indebted to Elizabeth B. Carder, Esq., for her substantial contributions to the writing of this article.

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Stephan E. Lawton

CLINICAL NEUROPSYCHOLOGY

A course entitled "Recent Advances in Clinical Neuropsychology" will be held in New York on December 12 at 9:00 a.m. The fee is $45.

Contact Beverley R. Baptiste, Beth Israel Medical Ctr., 10 Nathan D. Perlman Pl., New York, NY 10003; or call (212) 420-2000.

CLINICAL PROBLEMS IN THE ELDERLY

A course entitled "Managing Clinical Problems in the Elderly" will be held at New York University Post-Graduate Medical School in New York, December 14-16. The fee is $375.

Contact the Registration Office, New York University Post-Graduate Medical School, 550 First Ave., New York, NY 10016; or call (212) 340-5295.

FELLOWSHIPS IN HEMOPHILIA

The National Hemophilia Foundation is accepting applications for two Judith Graham Pool postgraduate research fellowships in hemophilia, to be awarded competitively for the academic year beginning July 1, 1982. The deadline for application is December 15.

Contact the National Hemophilia Fdn., 19 W. 34th St., Rm. 1204, New York, NY 10001.

CALL FOR PAPERS

Abstracts are now being accepted for the 1982 National Conference on Rural Primary Care, which will be held in Jackson, Miss., April 4-6. The deadline for submission is December 15.

Contact Dr. Ben F. Banahan, III, Department of Community Medicine, School of Primary Medical Care, The University of Alabama in Huntsville, 109 Governors Dr., SW, Huntsville, AL 35801.

PAIN AND OFFICE MANAGEMENT

A symposium entitled "Current Concepts in Pain Management and Current Concepts in Office Management" will be held in Steamboat Springs, Colo., December 20-25, February 14-19, and July 18-23. The fee is $250.

Contact Current Concept Seminars, 9400 S. Dadeland Blvd., Suite 300, Miami, FL 33156; or call (305) 666-0401.

CALL FOR PAPERS

Abstracts are now being accepted for the eleventh annual meeting of the American College of Clinical Pharmacology, which will be held at the Shoreham Hotel in Washington, D.C., on May 6 and 7. The deadline for submission is December 18.

Contact Ms. Morie McFarlan, American College of Clinical Pharmacology, 19 S. 22d St., Philadelphia, PA 19103; or call (215) 563-9560.

EPIDEMIOLOGY

A course entitled "Epidemiology — Methods and Applications" will be held at the Linden Hill Hotel in Bethesda, Md., March 3-5. The fee is $650.

Contact Dr. Nancy Dreyer, New England Epidemiology Institute, Dept. SC-12, P.O. Box 57, Chestnut Hill, MA 02167; or call (617) 734-9100.

CORRECTION

Reproductive Potential after Treatment for Hodgkin's Disease (1981; 305:891). On page 891 the fifth sentence in the third paragraph of the letter by Dr. Chapman should read: "[In 1978, women 20 to 29 years old had a reported birth rate of 112 births per thousand women per year, and women 30 to 35 years old had one of 59.1 births]; in the Horning study the rate was 64 births per thousand women per year. . . .)

HEALTH POLICY REPORT

JOHN K. IGLEHART

The Administration Responds to the Cost Spiral

AT a time when the general economy is slowing, medical-care costs are rising at a virtually unprecedented rate. This dynamic is leading the Reagan administration to design new cost-control mechanisms for Medicare and Medicaid that would sharply limit reimbursement levels for providers and increase the cost of care for consumers. This phenomenon is also calling into serious question the effectiveness of the four-year-old "Voluntary Effort to Contain Health Care Costs," which the nation's major private health interests launched in their successful effort to thwart former President Carter's hospital-cost-control legislation.

Although the Reagan administration is firmly on record as being in favor of using the "invisible hand" of the marketplace to determine ultimately what society's investment in health care will be, it has come face to face, in its continuing war against federal spending, with a shorter-term reality: Unless current spending trends of Medicare and Medicaid are brought under control and other measures of retrenchment are taken, President Reagan has little hope of achieving his overriding domestic-policy goal of balancing the federal budget by 1984.

Federal budgetary-control proposals that will be unveiled over the next several months are likely to shatter what remains of the so-called "safety-net" concept that President Reagan created to protect selected social-entitlement programs that support the most vulnerable segments of the nation's population. Among health programs, Medicare, which has remained relatively unscathed to this point, seems destined to be the next major target of the administration. Once unveiled, the proposals for health-care cost control will demonstrate that President Reagan is prepared, in selected instances, to sacrifice his philosophical preference for deregulation to work toward a balanced federal budget. Many of the control proposals would impose a tighter form of governmental regulation on health-care providers and consumers, but any sweeping change would need the approval of Congress, which could well resist further cuts in social spending. The administration, however, will not characterize the proposals as increased regulation. Instead, the proposals will be described as efforts designed to make the government a more competitive purchaser.

The Reagan administration's approach to controlling medical costs, as it now appears under design, is considerably narrower but far tougher than the approach of the Carter government. Although President Carter sought — without success — to impose controls on both public programs and private insurance,

the clear emphasis of the new Republican stewards is on Medicare and Medicaid, the two largest governmental health programs, which together cost the federal treasury $60 billion in fiscal 1981. At current growth rates, this spending would more than triple by 1990.

The administration's preoccupation with checking public spending for medical care could well lead to several important policy consequences. Federal, state, and local governments devoted $104 billion of their tax revenues to health care, or about 42 per cent of all money spent for this purpose in fiscal 1980. Further tightening of Medicare and Medicaid will exacerbate the shift of costs that is already occurring between public and private programs. The Health Insurance Association of America estimates that the result of Medicare and Medicaid's not paying their full costs under current policies led hospitals to shift a total of $4.8 billion to private-sector payers in 1980.

Reducing Medicare and Medicaid reimbursement rates to hospitals and doctors could lead to greater problems of access if providers decided that it was not worth their economic while to see publicly financed patients. But the policy approach could also force private health interests to recognize more clearly what Health and Human Services Secretary Richard S. Schweiker pointed out on September 24 in a speech to the Health Industry Manufacturers Association: "Let's be frank about the health alternatives. The status quo is intolerable. I think we can agree on that. Unless we join together and allow market forces to control health costs, you know what could happen: the old scheme of regulatory overkill and mandatory price 'caps' could return."

Governmental concern over the rising cost of medical care is an old story. The 1970s were marked by a series of governmental efforts to moderate the cost spiral that were independent of the party in power. The most effective control program operated from 1971 to 1974 under Republican President Richard M. Nixon's wage and price controls, which affected all sectors of the economy, although the health controls lasted longer than those that applied to virtually all other sectors. Nixon's Republican successor, Gerald R. Ford, advanced (without success) legislation that would have tightened controls on both Medicare and Medicaid. These controls would have affected both consumers and providers, but, like the Reagan approach, they would not have applied to private purchasers of care.

The arrival of Jimmy Carter in January 1977 brought out of the Democratic policy closet a hospital-cost-control scheme that would have recreated a containment system much akin to the one that operated under Nixon, at least as it applied to hospitals. After a debate that spanned more than two years, the House of Representatives killed Carter's approach on November 15, 1979, ending (at least for a time) government's ever-tighter regulation of health care.

Prolonged congressional debate over the issue underscored the ambivalence with which Americans regard medical care. On the one hand, there is no service to which society attaches more value. As a consequence, many politicians sided with the health-care lobby's drive to kill Carter's cost-control initiative, embracing instead a voluntary program of restraints. On the other hand, as medical costs have consumed an ever larger portion of the gross national product — from 6.2 per cent in 1965 to 9.4 per cent in 1980 — major public and private purchasers have grown increasingly restive in coping with this trend, especially at a time when virtually all other sectors of the economy are being squeezed.

Twice in the 1970s, after governmental pressure to check the spiral of medical costs subsided, costs rose dramatically in comparison to other items measured by the consumer price index (CPI). For example, two years after Nixon's program of wage and price control expired, the medical-care component of the CPI had increased at an annual rate of 11.3 per cent, as compared with a 7.9 per cent rise for all items measured by the index. In 1980, after the demise of Carter's cost-control plan, total health-care expenditures increased 15.2 per cent — the largest annual rise in 15 years, and substantially above the 13.4 per cent growth rate between 1978 and 1979.

The 1980 annual increase in health-care expenditures occurred at a time when the overall economy grew by 8.8 per cent. Thus, the share of the gross national product devoted to health care jumped from 8.9 per cent in 1979 to 9.4 per cent in 1980. Total spending on health care in 1980 in the United States was $247 billion. The upward push in costs has continued in 1981. The largest increases derive from higher inpatient expenses in community hospitals. The American Hospital Association reported in its monthly publication[1] that monitors hospital performance:

> Community hospital inpatient expenses increased 19.5 per cent between July 1980-81, which was consistent with rates of increase of 18 per cent to 20 per cent experienced during the past seven months. Between July 1979-80 inpatient expenses had increased less rapidly (17.2 per cent), consistent with the generally lower expense trend during that period. Accelerated growth of inpatient expenses between July 1980-81 was due almost entirely to higher labor expenses; non-labor expenses increased at essentially the same rate in the current period (18.8 per cent) as between July 1979-80 (18.7 per cent). Admissions declined 0.4 per cent between July 1980-81. Despite a rise in length of stay, inpatient days increased at the slowest rate in 14 months (1.1 per cent).

Physicians' fees have been increasing at about the same rate as that of the CPI's all-items component. During the 12 months from September 1980 through September 1981, the index for physicians' services rose 11.2 per cent, as compared with an increase of 11 per cent in the all-items price index. The American Medical Association's cost-containment goal for physicians' fees during the first half of 1981 was to hold the percentage of increase in the physicians'-services index below that of the all-items index of the CPI.

The continued sharp escalation in the costs of

health care raises serious questions about the effectiveness of voluntarism as a long-range tool for restraining costs. Major private health interests created the "Voluntary Effort to Contain Health Care Costs" in late 1977 in the face of the prospect that Carter's hospital-cost-control legislation would impose mandatory controls on providers. The chief architects of what has become known as the voluntary effort were the American Hospital Association, the American Medical Association, and the Federation of American Hospitals.

Working behind the scenes in the fall of 1977 with Congressman Dan Rostenkowski (D-Ill.), who at the time was chairman of the House Ways and Means Subcommittee on Health, the three groups urged Rostenkowski to issue a challenge to health-care interests to deal with rising costs through voluntary means while Congress debated the Carter bill. The dialogue produced the "Rostenkowski challenge," which the Chicago Democrat issued in a statement that was published in the *Congressional Record* on November 2, 1977. Since that time, Rostenkowski has become chairman of the parent Ways and Means Committee.

During 1978 and 1979, while congressional debate on Carter's cost-containment legislation continued, the voluntary effort substantially met or exceeded the major goals that it had set in December 1977. The excess of the growth rate of hospital spending over that of the gross national product was halved, from more than 4 percentage points in 1977 to slightly over 2 percentage points by the end of 1979. More than three quarters of the nation's hospitals sought certification from their state voluntary effort committees as participants in the program; the growth in the number of the nation's hospital beds essentially stabilized, falling to an annual rate of increase of 0.4 per cent by the end of 1979; net capital investment dropped in 1978 to almost 20 per cent below the 1975-1977 average and continued to fall in 1979; the physicians'-services index of the CPI and price increases in medical supplies were substantially below the CPI by the end of 1979; the average length of hospital stays continued to decline each year; preadmission testing, ambulatory care, and outpatient surgery grew rapidly; private health insurers initiated new programs related to early detection and treatment of hypertension, alcoholism, and drug abuse; and, finally, hospitals rapidly expanded shared-service programs.

The early successes of the voluntary effort formed the basis for the most persuasive argument used against Carter's hospital-cost bill on the day in November 1979 when the House debated the issue, as the following excerpts from the dialogue suggest. Congressman Willis D. Gradison (R-Ohio), a force in shaping Republican thinking on health issues, argued that Carter's legislation "would undermine the voluntary effort which has made such great progress in restraining the upward movement of hospital costs." Congressman James T. Broyhill of North Carolina, ranking Republican on the House Energy and Commerce Committee, went on at some length to describe how the voluntary effort was working in his home state and nationally. "I would point out that the voluntary effort is working," Broyhill said.

Congressman Richard A. Gephardt (D-Mo.) introduced a substitute for Carter's mandatory cost-control bill that essentially would have placed a federal imprimatur on the voluntary effort. Gephardt's bill would have created a presidentially appointed national commission and charged it with reporting to the Congress every year on the voluntary effort's activities. Speaking on behalf of his bill, Gephardt told the House: "I submit . . . that the voluntary effort, which is really embodied in this substitute, has achieved substantial and tangible success." Congressman James R. Jones (D-Okla.), who, like Gephardt, is a member of the Ways and Means Committee and who became chairman of the House Budget Committee in January 1981, urged enactment of Gephardt's approach by saying: "We have here today a clear choice between a solution which encompasses the rigidity and expanded Washington bureaucracy of mandatory controls versus a solution that offers the flexibility, the ingenuity, and less bureaucracy of the voluntary effort."

Gephardt's substitute for Carter's mandatory controls was approved by the House, 234 to 166, but ultimately the bill died when the Senate declined to consider the issue after the House so decisively defeated the administration's proposal. In the previous Congress, the Senate approved Carter's bill, but at that point the House did not act. Shortly after the House killed Carter's bill in late 1979, health-care costs resumed their climb, despite the exhortations of the voluntary effort. Today the voluntary effort faces a genuine crisis, because health-care costs in general and hospital expenditures in particular are rising at rates far in excess of the voluntary effort's targets, and state hospital associations are increasingly ignoring the activities of the voluntary effort.

In an April 1981 letter to all state hospital associations, John Alexander McMahon, president of the American Hospital Association, assessed "the current economic and political environment" in which the voluntary effort operates:

> As you know, the results of the hospital industry's 1980 economic performance are now in, and they are not encouraging. Overall hospital inpatient expenditures were up 16.8 per cent. Adjusted for the impact of double-digit inflation, the rate of increase falls to 13.9 per cent. This compares . . . to the [Voluntary Effort's] target for 1980 of 11.8 per cent. With very few exceptions, the state-by-state and hospital-by-hospital increases echo the national average. I know that we are all tired of the pressures of the numbers game and the constant demands for belt-tightening. The National Steering Committee of the Voluntary Effort, in fact, has taken several key steps . . . to move the whole program in a much more positive direction. . . . In the meantime, the short-term pressures to restrain cost increases are becoming even more acute. Moreover, the government, business groups, and the general public are all caught up in the numbers game and are watching our performance from that narrow, one-sided perspective. . . . The overall need to cut the federal budget and the specific targets for cuts in the health-care

field have been well publicized. On the positive side, the Reagan Administration has expressed its support of decreased regulation and increased initiatives by the private sector. . . . This atmosphere provides us with the opportunity to demonstrate that voluntarism is the most effective means of setting standards for the efficient and effective cost and delivery of health care.

At the latest meeting of the National Steering Committee of the Voluntary Effort, held in Chicago on June 29, 1981, its members discussed the problems facing the voluntary effort. The steering committee is composed of representatives of the American Hospital Association, the American Medical Association, the Blue Cross and Blue Shield Associations, the Washington Business Group on Health, the Federation of American Hospitals, the Health Industry Manufacturers Association, the Health Insurance Association of America, Knauer and Associates, and the National Association of Counties. Knauer and Associates, a Washington-based public-relations firm enlisted by the voluntary effort to represent the consumer, was formerly headed by Virginia Knauer. She resigned from the voluntary effort's steering committee when she became a special assistant to President Reagan and director of the United States Office of Consumer Affairs, which falls under the Department of Health and Human Services.

Paul W. Earle, executive director of the voluntary effort, told the steering committee that time was running out on the program unless it could find means to reduce the cost escalation. After a discussion of the possible avenues that might be pursued in an effort to moderate costs, the steering committee settled on tougher review of use of medical services as an approach that seemed to hold the most promise. Dr. Lowell H. Steen, co-chairman of the steering committee and the AMA's representative, suggested that the AMA would assume the major responsibility for proposing a voluntary effort-sponsored program of utilization review.

In subsequent and separate interviews, Earle and Michael D. Bromberg, executive director of the Federation of American Hospitals, discussed the new emphasis of the voluntary effort, which will probably be unveiled publicly after the next steering-committee meeting on December 17. (Bromberg, McMahon of the American Hospital Association, and Dr. James H. Sammons, executive vice president of the AMA, have been the major architects of the voluntary effort since its beginning.) Bromberg anticipated that "a crash utilization review program, led by county and state medical societies, will be launched with a focus on about five states that have high hospital utilization rates for Medicare beneficiaries."

Earle, who worked for the American Hospital Association before becoming the staff director of the voluntary effort, has said that patterns of Medicare use are "unreal." He pointed out that in 1979 the over-65 population's hospital-use rate ranged from 3394 patient-days per thousand population in Pacific Coast states to 4748 in Middle Atlantic states. "We're trying to figure out a way to reduce these numbers," Earle said. "There is no question in my mind that we're in a real political crisis because, with Medicare representing the third largest item in the federal budget, these numbers are just not acceptable to government."

Earle, referring to a recent publication of the American Hospital Association's office of public-policy analysis,[2] noted that the United States population used 25.5 million more days of hospital care in 1979 than in 1970. Days used by elderly patients accounted for 94 per cent of the increase, or 23.9 million days of care. Of these 23.9 million days, 80 per cent was due to population growth, and 20 per cent stemmed from an increase in the patient-day use rate. In designing the voluntary effort's utilization-review effort, Earle said, "We're talking about reducing the usage of hospitals. That's not easy to sell to a constituency of hospital administrators," but he, too, predicted that the voluntary effort would move forward with "a crash program in utilization review."

Unlike the Carter administration, which sought to affect the medical-cost spiral through provocative public rhetoric and a hospital-cost-containment bill, Reagan and his lieutenants have not engaged in either approach. Bromberg, addressing the Texas Hospital Association's Forum on Major Hospital and Health System Reforms on October 5, 1981, characterized the nature of the Reagan administration's reaction:

During the past few weeks, hospital association leaders have received private warnings from Administration officials that short-term methods — administrative or legislative — for holding down Medicare reimbursement may well be proposed if costs are not voluntarily curtailed. These warnings have not been widely publicized through the kind of loud rhetoric we became used to during the Carter Administration. There have been no public confrontations or combative attacks. There have been no threats issued at press conferences or name calling. Indeed, the warnings have been characteristic of the Reagan Administration — quiet but clear, professional, and very real.

One such warning came from Dr. Robert J. Rubin, assistant Health and Human Services secretary for planning and evaluation, who is Schweiker's liaison with the voluntary effort. At the June meeting of the voluntary effort's steering committee, Rubin, according to the minutes,

expressed great concern about the recent rates of increase in hospital costs and in physician fees and the adverse impact these trend lines will have on the budget. . . . Dr. Rubin noted that the Reagan Administration was watching the trend lines very closely and that they were counting on the [voluntary effort] to turn around these adverse trends, and bring hospital spending and physician fee increases down to more acceptable levels. . . . He stated that if no substantial progress is made by the health care field in the very near future, the next "solution" suggested by the Congress to the cost problem would likely be a regulatory one. He said that failure by the private sector this time would bring controls that "would make the Carter hospital cap proposal look like a free market approach."

In its role as a provider of medical assistance to eligible old and poor people and as a large employer with responsibility for financing a large part of the

health-insurance premiums of its 10 million employees and annuitants and their family members, the federal government faces many problems as a consequence of rising medical-care costs. The administration, followed by a less enthusiastic Congress, is moving on multiple fronts to stem the cost spiral. As a first step, Congress enacted the Omnibus Reconciliation Act of 1981, which imposes new cost-sharing requirements on Medicare beneficiaries and makes substantial reductions in the federal contribution to Medicaid. Medicaid is a federal and state program that finances medical assistance to 24 million low-income persons who are aged, blind, disabled, or members of families with dependent children. The Act reduces federal payments to states for Medicaid by 3 per cent in fiscal 1982, 4 per cent in fiscal 1983, and 4.5 per cent in fiscal 1984. Congress adopted this approach in lieu of a more stringent administration proposal to cap federal contributions to Medicaid. The Act also allows states to establish their own methods of hospital reimbursement under Medicaid instead of simply following those of Medicare.

The Reagan administration is concerned about the budgetary consequences of maintaining current levels of coverage in the Federal Employees Health Benefits Program. Its concern and its subsequent actions to reduce the federal budgetary impact have led to a pitched battle between the Office of Personnel Management, which administers the program, and the health insurers who provide the coverage, together with several federal-employee unions. This battle is important enough to be the subject of another article, because the administration considers the Federal Employees Health Benefits Program to be an organization that includes a number of the philosophical tenets of a competitive health-care model. At this point, however, suffice it to say that Donald J. Devine, director of the Office of Personnel Management, summarized the administration's cost concerns while testifying on October 19 before the Senate Governmental Affairs Subcommittee on Civil Service, Post Office and General Services:

> The problem we are addressing today was first recognized when I reviewed the insurance carrier's estimates for next year's program. As I reviewed these data it became obvious that to maintain the proposed level of health coverage would require an increase in insurance rates during 1982 of more than 30 per cent in the six largest plans. [The government's annual contribution is calculated on the basis of the average high-option premium of the six largest insurance plans.] Because the federal government pays 60 per cent of the premiums for employees, the cost implications would be immense: continuing the projected level of benefits would increase the government's share of fiscal year 1982 program costs by almost $500 million above the amount in the President's budget.

Rising medical-care costs have also led to a hemorrhaging of cost projections in Medicare. The latest projections of the Social Security Administration's actuary, provided to the House Ways and Means Committee in a report dated October 20, showed that Medicare costs have been rising much faster than predicted earlier this year. As a consequence, the whole Social Security system, of which Medicare is one part, is in worse financial condition than was previously believed. The actuary's report said that Medicare spending was at least $1 billion a year more than was projected as recently as early October, when the Senate passed a bill that reallocated the tax rates between the three Social Security trust funds and permitted inter-trust-fund borrowing between the old age and survivors' trust fund and the disability trust fund. In future years, the Medicare funding problem becomes far worse than that of even Social Security. Under current financing arrangements, the income of Medicare's hospital insurance trust fund would fall short of the outgo by 1986.

Faced with these projections and determined to reduce federal spending, the Reagan administration is developing steps to cut the size of social-welfare entitlement programs substantially. Only Social Security will remain largely unscathed. At this point, it seems that the administration will unveil its cost proposals in several steps, one in late 1981 and another as a part of the budget for fiscal 1983. President Reagan, following the traditional procedure, will unveil his budget and legislative package for fiscal 1983 in late January 1982.

The administration is seeking budget reductions of $15 billion in the entitlement programs in fiscal 1983 and 1984. Of that two-year total of $15 billion, estimated budget reductions deriving from Medicare and Medicaid would total between $4 and $5 billion.

The first set of controls, according to administration officials who are involved, will come largely in the form of regulations that do not require the consent of Congress. Legislation for greater authority to restrain Medicare will also be sought. Many of these proposals would shift costs to private-sector payers rather than reduce total expenditures. Final decisions have not been made on specific proposals, but there appears to be every likelihood that the administration will move on most of them. The administration is considering elimination of the nursing differential that Medicare currently pays hospitals, at an estimated saving of $100 million to the government in fiscal 1983. The differential, which the 1981 Budget Reconciliation Law has already reduced from 8.5 to 5 per cent, is a supplemental reimbursement calculated on the basis of the percentage of a hospital's routine nursing costs that derives from serving Medicare patients. The rationale for eliminating the supplement would be based on a new study conducted by the Health Care Financing Administration, which maintains that older people take no more nursing time in a hospital than do other patients.

The administration also is considering what amounts to a one-third reduction in the return that Medicare allows on a for-profit hospital's equity capital. Medicare allows for such payment on the basis of the argument that proprietary hospitals pay taxes and do not have access to tax-exempt funding instruments and government grants, as their nonprofit

counterparts do. Medicare pays the allowance on the portion of equity (which is defined as total assets minus the sum of current liabilities, long-term debt, deferred credits, and other debts) that is attributable to a hospital's Medicare caseload. The current Medicare allowance for equity capital is based on a return that is 1.5 times the yield obtained from the investment of Social Security trust funds. Also under consideration by the administration is a reduction of what Medicare currently pays nonprofit hospitals for funded depreciation. The percentage of reduction would equal the interest that hospitals earn today on those monies. The estimated savings to the government through these proposed new policies would be $80 million in fiscal 1983.

The President's Office of Management and Budget, which is overseeing the development of new control proposals, is also considering a reduction of Medicare's hospital-reimbursement levels. Specifically, the administration may propose new limits on what Medicare will pay hospitals for ancillary services under the authority of Section 223 of the Social Security Act. Estimated savings would total $240 million in fiscal 1983. At present, reimbursement limits under this authority extend only to routine hospital costs, such as room and board.

Another proposal under consideration by the administration is deferring what amounts to an annual cost-of-living increase in Medicare's Part B physician fees. This budget-cutting proposal, which would save an estimated $190 million on a one-time basis, would come through delaying for three months (from July to October) an increase in the maximum fee that Medicare will pay doctors for covered services.

The administration is also weighing proposals to impose higher cost-sharing requirements on Medicare beneficiaries. There is a widely held belief among administration policy makers that if consumers would contribute more substantially to the cost of care, they would be more conscious of the economics. Dr. Rubin, the chief health-policy planning officer at the Department of Health and Human Services said in a speech on November 19, "It seems clear from the results of the Rand national health-insurance study that people with comprehensive health insurance spend 50 per cent more than people with an income-related catastrophic insurance plan."

David A. Stockman, Director of the Office of Management and Budget, said on September 27 that Medicaid's coverage of all costs encourages excess medical services: "There's overuse of emergency rooms, there's overuse of hospitals, there's overuse of doctors." Imposing a small fee of even $1.00 a visit would, he said, "substantially reduce this excessive and abusive utilization and not jeopardize the low income person."

The Reagan administration will move more cautiously before imposing new cost-sharing requirements on Medicare beneficiaries, given their political influence, than it will in proposing new controls on providers, states, or the low-income beneficiaries of Medicaid. Indeed, whether new Medicare consumer cost-sharing requirements are proposed by the administration is likely to be a decision made at the highest levels of the White House staff.

The importance of these budget proposals is less in their particular detail than in their expression of the administration's willingness to focus totally on Medicare and Medicaid and let the private sector take care of its own problems. The reasoning for this approach goes beyond simply a philosophical belief that government should limit its role in society. There is also a political motive: to shock the private health sector into recognizing that the status quo is unacceptable.

The administration's makers of health policy have been surprised at the general lack of enthusiasm that the private sector has displayed about embracing a competitive model as the way to infuse the health-care system with more effective incentives. Thus, the administration seems to be saying that if competition is opposed as a future direction, the government has a responsibility to the public to husband tax dollars more wisely in Medicare and Medicaid, even if the private sector resists.

The general attitude of many administration officials on this point was accurately described in an administration budget-study document that was developed to outline issues facing the executive branch in the spending cycle for fiscal 1983:

> While limitations on increases in Medicare costs might make it somewhat more difficult for private insurers to offer a more attractive package than Medicare at equivalent cost, short term budget costs to the government would be reduced in any event. Imposing rigorous limits of this type would place a significant administrative burden on both the federal government and hospitals and would meet vociferous opposition from providers. Such limits, however, could make a significant contribution to achieving budget targets, and would give additional impetus to market forces in the health care industry. Most importantly, in the view of some observers, such policies are essential to gain enactment of pro-competitive legislation. The reasoning is that only if hospitals know they will face a bleak and unpleasant future from increasingly restrictive Medicare payments would they be willing to risk taking chances with competition. On the other hand, if providers believe the choice is a pro-competitive approach or the status quo, which is nearly the best of all possible worlds for them, they will probably try to defeat the competition proposals.

As this interpretation suggests, the administration seems likely to adopt a short-term, highly regulatory cost-control approach as a weapon to control Medicare and Medicaid spending and also as a lever to gain greater favor for its longer-term goal, a competitive model. In any event, governmental pressure on health-care providers and publicly financed consumers will not subside as long as costs of health care are rising faster than those of other goods and services on which the society depends.

References

1. American Hospital Association, Office of Public Policy Analysis. Community hospital indicators. Trends. October 1981; 47:2.
2. *Idem.* Demographic trends and hospital utilization. Policy Brief. September 14, 1981; 41:1.

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MEMORANDUM

TO: Certificate of Need Study Committee

FROM: Stephen J. Mansfield, Executive Director

RE: New Services Operating Costs

DATE: November 23, 1981

One of the exependiture thresholds the State can incorporate into its Certificate of Need Act concerns annual operating costs of new health services developed by covered provider groups. I thought it would be useful for the committee to have some sense of the projected operating costs associate with the new services which have been recently reviewed under CON. I have enclosed these data for projects reviewed during the two year period between the summers of 1979 and 1981. (These are the same projects covered in the CON activity summary materials distributed to the Committee a month ago).

The projects are arranged on the sheets chronologically by date on which the service was to begin. Operating expenditures are segregated into those to be borne by the applicant and costs and fees accruing to entities other than the applicant. (In some instances these other "costs and fees" were not detailed in the application.) These other entities are usually physicians, or other professionals, who play an integral role in the provision of the new service, but who are not in the employ of the applicant. It should be noted, too, that the "institutional costs" components are not always comparable from one project to the next. This is because some applicants included overhead or indirect costs in their projections, and others did not do so, providing instead only direct or new costs generated by the undertaking.

These distinctions and caveats present some interesting and significant questions regarding which costs we wish to assign to proposed new service in determining whether or not it is subject to review when measured against an operating cost threshold criterion. Do we include total operating costs, which include both new and old costs; or, should we consider only the new or incremental costs resulting from development of a new service? (A hospital, for example, will apportion some of its existing overhead costs to a new cost center in order to establish total operating costs and charge to cover these costs. These overhead expenses are not new and are not "caused by" the new service.)

Should we include the fees of professionals not employed by the institution in determining new service operating costs? From a systems-wide perspective such expenses are certainly a part of running a service. However, if we do decide to include professional fees in our computations we should realize that we are in a fashion implicitly extending CON coverage to physicians and other professionals.

Unfortunately, the federal regulations offer little guidance in these matters. It would appear that Maine is at liberty to exercise some judgement in defining costs applicable for CON consideration.

Enclosure

DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
1978	$ 140,032	A.R. Gould Memorial Hospital Establish Ophthalmology Service						This was a retrospective review. The service had been in operation since early 1978. No separate fee structure was established for this service. Expenses were derived from the application which showed the entire hospital expenses for 1979-1980-1981. This table included projections of expenses with the ophthamology service and without it. Certificate of Need was issued November 26, 1980.
		Institutional Costs	$ 69,563	$ 69,255	$ 72,464	$	$	
		Professional Fees		UNKNOWN				
		Totals	69,563	69,255	72,464			
Nov., 1979	79,220	Millinocket Community Hospital/Penobscot Valley Hospital Purchase ultrasound equipment						The applicants projected 1,000, 1,200 and 1,500 procedures annually for the first 3 years of operation. One new technologist was hired between the two hospitals.
		Institutional Costs		45,570	46,938	49,531		Certificate of Need was issued October 30, 1979.
		Professional Fees			UNKNOWN			
		Totals		45,570	46,938	49,531		
Dec., 1979	68,700	Mercy Hospital Purchase ultrasound equipment		(Part Year)				Mercy estimated 350 (part of a year), 760 and 760 procedures respectively for the first 3 years of operation.
		Institutional Costs		30,295	46,366	48,228		Certificate of Need was issued November 29, 1979.
		Professional Fees		9,450	20,520	22,367		
		Totals		39,745	66,886	70,595		

MAINE HEALTH SYSTEMS AGENCY, INC.

DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
Feb., 1980	$ 24,200	Maine Medical Center Develop vascular lab						The applicant projects approximately 1,600 cases per year. All expenses are being borne by Maine Medical Center. They will compensate the physician involved. The service was to begin operation in February, 1980.
		Institutional Costs	$	$ 50,700	$ 54,832	$ 59,218	$	
		Professional Fees						
		Totals		50,700	54,832	59,218		
March, 1980	26,100	Maine Medical Center Establish evoked potential response system						The applicant expected to perform 210, 420 and 660 procedures during the first 3 years of operation. Project slated to begin operation in March, 1980.
		Institutional Costs		24,980	42,760	69,320		
		Professional Fees						
		Totals		24,980	42,760	69,320		
March, 1980	40,500	Mayo Regional Hospital Establish ophthalmology services						Applicant states there will be no additional charges due to the addition of this service. Professional fees will be billed by the ophthalomologist directly. The only expense will be the yearly depreciation expense of $11,333. The service began in March, 1980.
		Institutional Costs		11,333	11,333	11,333		
		Professional Fees			UNKNOWN			
		Totals		11,333	11,333	11,333		

MAINE HEALTH SYSTEMS AGENCY, INC.

DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
April, 1980	-0-	A. R. Could Memorial Hospital Establish Genetic Counseling Clinic						This clinic will be provided one day per month, ten months per year. The applicant anticipates 100 visits/ year. Two physicians from Eastern Maine Medical Center in Bangor will staff the clinic. Salaries and fringes for the geneticist, director of Medical Program and genetic coordinator and air travel fees are included in the professional fees. In-kind services from Eastern Maine Medical Center and A. R. Gould will offset the deficits anticipated. Eastern Maine Medical Center will provide approximately $10,000 in grant funds which they received from The Department of Human Services. The service has been provided since April, 1980.
		Institutional Costs	$	$ 960	$ 1,066	1,170	$	
		Professional Fees		6,500	7,134	7,830		
		Totals		7,460	8,200	9,000		
July, 1980	$ 70,000	Webber Hospital Establish ultrasound service			(Part Year)			Webber Hospital anticipated 500, 700 and 750 procedures respectively during the first 3 years of operation.
		Institutional Costs			27,364	30,997	34,943	Certificate of Need was issued June 27, 1980.
		Professional Fees			7,425	11,529	13,770	
		Totals			34,789	42,526	48,713	
Aug., 1980	-0-	Aroostook Home Care Agency Homemaker/Home Health Aides						Applicant anticipates approximately 3,600 visits the first year, 4,320 visits the second year and 5,184 visits the third year.
		Institutional Costs		70,225	81,877	104,780		
		Totals		70,225	81,877	104,780		

DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
Sept. 1, 1980	$ 15,187	Down East Community Hospital Establish Orthopedic Service						Separate figures for the orthopedic surgery service were not provided, however, figures for the entire facility, assuming the establishment of an orthopedic service, were provided. It was estimated that on a hospital wide basis the establishment of an orthopedic service would require the addition of 8.9 F.T.E. per year. Expenses for this service were derived by using facility-wide projections that included orthopedic surgery and an alternative which assumed orthopedic surgery would not be implemented. The service was implemented approximately on October 1, 1980.
		Institutional Costs	$	$ 164,000	$ 181,000	$ 196,000	$	
		Professional Fees			U N K N O W N			
		Totals		164,000	181,000	196,000		
Oct., 1980	-0-	Cary Medical Center Establish a psychiatric clinic. Non-competitive, complimentary reviews						The clinics will operate at least one day per week and will be staffed by personnel working for the Aroostook Mental Health Center. It is anticipated the clinics will provide between 200-300 visits per year for the first several years of operation. The cost per visit was not stated in the application. Applicants state there will be no new operating costs for the hospitals. Professional fees which will be paid by the applicants and the applicants will in turn bill the patients.
		Institutional Costs		-	-	-		
		Professional Fees		NOT INDICATED IN APPLICATION				
		Totals						

DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
Withdrawn	$ 65,000	Franklin Memorial Hospital Establish ultrasound service						The applicant projected 400, 580 630 examinations respectively in the first 3 years of operation. Professional fees will be billed separately.
		Institutional Costs	$	$	$ 19,983	$ 31,462	$ 30,912	
		Professional Fees			U N K N O W N			
		Totals			19,983	31,462	30,912	This proposal was withdrawn after the Maine Health Systems Agency determined not to conduct a full review. Subsequently Franklin Memorial Hospital submitted a joint application with Redington-Fairview Hospital in Skowhegan.
Dec. 1, 1980	70,000	Franklin Memorial Hospital/ Redington-Fairview Hospital Establish a joint ultra-sound service						Projected procedures are 700, 850 and 1,000 respectively for first 3 years of operation. Professional fees will be billed separately. Services were to begin upon receipt of Certificate of Need.
		Institutional Costs			48,369	57,388	57,804	
		Professional Fees			U N K N O W N			
		Totals			48,369	57,388	57,804	Certificate of Need was issued November 26, 1980.

MAINE HEALTH SYSTEMS AGENCY, INC.

DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
Feb. 20, 1981		Houlton Regional Hospital, Cary Medical Center, A. R. Gould Memorial Hospital Establish specialty clinics						The specialty clinics will be in the area of neurology, dermatology and endocrinology. The clinics will be offered 1-2 days per month upon approval and will increase based on need. It is estimated that the neurology and endocrinology clinic will see fifteen patients and the dermatology clinic will see thirty patients per clinic. Support staff will be provided by the hospitals. Professional fees include air travel since the number of clinics offered will be adjusted based on need, three years operational budgets were not prepared. The service was to begin upon approval. Approval was granted February 20, 1981.
		Institutional Costs	$	$ 150	$	$	$	
		Professional Fees		660				
		Totals		810				
April, 1981	-0-	A. R. Gould Memorial Hospital Establish occupational therapy services						This proposal was submitted in conjunction with the applications submitted by Cary Medical Center and the Aroostook Home Care Agency for the provision of full-time occupational therapy services. A. R. Gould estimates approximately 1,050, 1,100 and 1,155 visits to inpatients during the first 3 years of operation. In addition, 350, 375 and 396 outpatient visits through Aroostook Home Care Agency are anticipated. The project's anticipated start up date was April, 1981.
		Institutional Costs			28,100	29,860	33,890	
		Professional Fees						
		Totals			28,100	29,860	33,890	

DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
May, 1981	$ -0-	Cary Medical Center Establish occupational therapy services						As stated on page 6, this proposal was submitted in conjunction with applications from A. R. Gould Memorial Hospital and Aroostook Home Care Agency. Cary Medical Center estimates 1,030, 1,082 and 1,136 visits to inpatients during the first 3 years. Another 359, 377 and 396 outpatient visits are expected to be generated through the Aroostook Home Care Agency. The project was slated to begin in May, 1981.
		Institutional Costs	$	$	$ 28,400	$ 29,774	$ 32,936	
		Professional Fees						
		Totals			28,400	29,774	32,936	
May, 1981	-0-	Aroostook Home Care Agency Establish occupational therapy servlces						Again, as stated on page 6, this application was submitted in conjunction with applications from A. R. Gould Memorial Hospital and Cary Medical Center. Aroostook Home Care Agency is expected to provide 709, 752 and 792 outpatient visits the first 3 years of operation. Payment will be made through contractual agreement with Gould and Cary. The project was due to begin May, 1981.
		Institutional Costs			4,640	4,870	5,116	
		Professional Fees			12,800	13,794	15,277	
		Totals			17,440	18,664	20,393	
May 1, 1981	24,135	Pen-Bay Medical Center Establish neurological services						It is estimated that during the first year approximately 1,770 patients would require neurological services. Numbers were not available for additional years. The hospital has attracted a board certified neurologist to its staff. They will also hire a technician and a Ph.D. electrocephalographer. The service was due to bein in May, 1981.
		Institutional Costs			22,995	92,154	106,160	
		Professional Fees						
		Totals			22,995	92,154	106,160	

MAINE HEALTH SYSTEMS AGENCY, INC.

DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
May, 1981	$ 67,300	Northern Maine Medical Center Establish ultrasound service						It is estimated by the applicant that 914, 948 and 983 procedures will be done in the first 3 years of operation.
		Institutional Costs	$	$	$ 38,815	$ 40,604	$ 43,257	
		Professional Fees			UNKNOWN			
		Totals			38,815	40,604	43,257	Professional fees will be billed separately. Services were anticipated to begin upon receipt of the Certificate of Need approval.
		Calais Regional Hospital Manage Eastport Hospital emergency services						No application submitted as yet. Approved as an emergency Certificate of Need.
June, 1981	-0-	Aroostook Medical Center Establish dermatology clinic						
		Institutional Costs			-	-	-	Initially, the dermatology clinic will be staffed one day every other week. The Aroostook Medical Center will pay the dermatologist and bill the patients for services rendered. No amount was indicated but the application states that professional fees will be consistent with fees charged by other professionals. The project was slated to begin July, 1981.
		Professional Fees						
		Totals						

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DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
June 15, 1981	$	Stephens Memorial Hospital Establish a nuclear imaging service						Applicant assumed 300, 315 and 326 procedures annually for the first 3 years of operation. Professional fees were stated as ranging between $20 to $40 per procedure. $30 was used in calculation.
		Institutional Costs	$	$	$ 26,783	$ 35,520	$ 37,575	
		Professional Fees			9,000	9,450	9,780	
		Totals			35,783	44,970	47,355	
								Certificate of Need was issued January 29, 1981.
July, 1981	93,675	Houlton Regional Hospital Establish ultrasound service						Applicant forecasts 400, 500 and 600 procedures annually during first 3 years of operation. Radiologist fees are fixed at $20 per procedure.
		Institutional Costs			19,324	30,354	33,779	
		Professional Fees			8,000	10,000	12,000	Certificate of Need was issued
		Totals			27,324	40,354	45,779	July 20, 1981.
July 21, 1981	72,300	Mayo Regional Hospital Establish ultrasound service						Mayo anticipated 500, 600 and 750 procedures respectively during the first 3 years of operation.
		Institutional Costs			30,320	35,110	37,351	Certificate of Need was issued
		Professional Fees			U N	K N O W N		May 1, 1981.
		Totals			30,320	35,110	37,351	
July, 1981	252,000	Eastern Maine Medical Center Establish nuclear cardiology services						Applicant anticipates 850, 930 and 1,025 procedures annually for the first 3 years operation.
		Institutional Costs			134,456	157,442	182,568	Certificate of Need was issued
		Professional Fees			58,000	64,125	70,515	June 29, 1981.
		Totals			192,456	221,567	253,083	

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DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
Oct. 1, 1981	$ -0-	Kno-Wal-Lin Community Health Services Hire a medical social worker						The medical social worker is expected to make 600 visits the first year. The first year start-up costs were being sought through a $40,000 federal grant from the Special Programs Unit of Health Services Delivery. The Maine Health Systems Agency recommended approval of this PUFF review upon receipt of the Certificate of Need. Anticipated date of beginning of project was July 1, 1981.
		Institutional Costs	$	$	$ 24,000	$ 25,200	$ 28,000	
		Professional Fees						
		Totals			24,000	25,200	28,000	
Oct. 1, 1981		Kno-Wal-Lin Community Health Services Provide speech therapy services						Applicant indicates a need for 20% of F.T.E. for speech therapy services - approximately 200 visits during the first year. As stated above, first year start-up costs have been requested from Special Program Unit of Health Services Delivery. Anticipated start-up date was October 1, 1981.
		Institutional Costs			6,400	8,640	9,600	
		Professional Fees						
		Totals			6,400	8,640	9,600	
Oct., 1981	27,300	Central Maine Medical Center Establish evoked potential response system						Applicant projects 270, 450 and 600 tests respectively during first 3 years of operation. The service was to begin upon approval of the Certificate of Need.
		Institutional Costs			24,823	36,372	45,996	
		Professional Fees						
		Totals			24,823	36,372	45,996	

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DATE PROJECT BEGAN	CAPITAL EXPENDITURE	SPONSOR/PROJECT TITLE	1979	1980	1981	1982	1983	COMMENTS
April, 1981	$ 905,450	Eastern Maine Medical Center Purchase CT scanner						Applicant estimates 1974, 2,072 and 2,176 procedures annually for first 3 years of operation.
		Institutional Costs			$ 295,509	$ 390,020	$ 418,077	
		Professional Fees			U N K N O W N			Certificate of Need was issued March 31, 1981.
		Totals			295,509	390,020	418,077	

SPECIAL ARTICLE

THE REGULATION STRATEGY FOR CONTROLLING HOSPITAL COSTS

Problems and Prospects

WILLIAM B. SCHWARTZ, M.D.

Abstract Three regulatory mechanisms have been used to control the rise in hospital costs: assessments of patients' records by professional standards review organizations (PSROs), approval of capital expenditures by certificate-of-need agencies, and limits on hospital reimbursement by state rate-setting groups. The available evidence indicates that neither PSROs nor certificate-of-need programs have exerted an appreciable influence on costs. However, rate setting through mandatory "prospective reimbursement" appears to slow the growth of hospital expenditures and seems to be the only regulatory tool that has been effective. Any regulatory process that markedly restrains expenditures can ultimately be expected to affect patient care adversely and to create social and political tension within the health-care system. (N Engl J Med. 1981; 305:1249-55.)

THE spread of insurance that provides full or nearly full coverage for care is a key factor in the progressive increase in hospital costs.[1] Extensive insurance coverage has broken the link between prices and the actual costs of services, with the result that patients, physicians, and hospital administrators have become largely indifferent to expenditures. Over the past decade, regulation has been the major strategy employed to compensate for this erosion of the medical marketplace. Although regulation is now out of favor on the Washington scene, it remains a central concern at the state level and will probably be so for the indefinite future. Given this prospect, an evaluation of both the effectiveness and the problems of the regulatory strategy seems highly desirable.

Of the three approaches to cost control that have been used most extensively, the first attempts to reduce days of hospitalization through utilization review by a professional standards review organization (PSRO). The second requires that capital expenditures be approved by a certificate-of-need agency. The third determines and limits the amounts that hospitals receive for their services.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

The PSRO program, established under the Social Security Amendments of 1972, is designed to control the cost of health services provided by the Medicare, Medicaid, and Maternal and Child Health programs and to improve the quality of care provided to beneficiaries of these programs. In practice, however, PSROs have focused on controlling expenditures by reducing the length of stay in short-term hospitals. Little is known about the effects of PSRO review on the costs of ambulatory care or ancillary services. However, there is anecdotal evidence that the program has reduced the inappropriate use of certain types of ancillary services,[2,3] and a forerunner of the PSRO program has been shown to decrease the improper use of antibiotics in ambulatory practice.[4] Review of nursing homes has been limited to demonstration projects and their evaluation.[5,6] Quality assurance by means of an audit process has received considerable attention,[7] but the effects of the program on the quality of care are beyond the scope of this discussion.

The PSRO program has, until recently, exerted its control through concurrent review of each admission. Since 1979, this review has been focused on a subset of cases that PSRO data indicate are most likely to involve inappropriate care.[8] The appropriateness of a given admission and the estimated length of stay are determined shortly after the patient enters the hospital; any hospital stay that is longer than the period that initially seemed warranted is scrutinized at a later review. If either the admission itself or a subsequent extension of the stay is considered unjustified, reimbursement for further care is denied.

Studies of the Medicare portion of the PSRO program by both the Health Care Financing Administration[7] and the Congressional Budget Office[9,10] for the years 1977 and 1978 indicated a 1.5 to 2 per cent reduction in days of hospitalization for the country as a whole.

The data on dollar savings are ambiguous. The Health Care Financing Administration estimated that the saving in Medicare reimbursement had exceeded the cost of the program by some 10 to 25 per cent.[7] However, reductions in expenditures on Medicare cannot be considered equivalent to reductions in hospital costs. Hospitals face costs that are independent of the patient load in the short term. Thus, when Medicare payments are reduced, it can be anticipated that these costs will be transferred to other patients. When a correction is made to account for this fact, the apparent saving produced by the PSRO program is converted to a substantial net loss.[10] Over the long run, of course, the system can presumably adapt to a reduced patient load in a way that will eliminate

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the excess fixed costs. At that point, a reduction in the Medicare expenditures should actually reflect a reduction in hospital costs, not just a reduction in payments by the federal government.

Even when measured by reimbursement costs, however, the saving that has been achieved by the PSRO program appears minimal: approximately $20 million a year.[7] Such a figure represents only 0.1 per cent of Medicare outlays for hospital insurance and is hardly likely to lower hospital costs appreciably. Moreover, the studies uncovered no evidence that PSROs became more effective with the passage of time — i.e., that experience led to greater reduction in hospital use.[9,10] Thus, there is no reason to believe that the savings can be greatly increased as PSROs "mature."

Even this limited conclusion about the effectiveness of PSROs must be regarded as tentative, because PSRO and control groups have not necessarily been comparable. Areas with an active PSRO program have been matched with inactive areas, but this process provides no assurance that the two groups were similar in character. Active groups selected themselves into the program, and the control groups did not. Various statistical methods have been used to compensate partially for the distortions that may have resulted,[7] but none appears to be fully satisfactory.[10] For example, differences in physicians' attitudes toward participation in the program is a variable that may have importantly influenced the results, but this is impossible to capture.

Information on the Medicaid portion of the PSRO effort does not permit conclusions about its effectiveness. Data are not available for non-PSRO areas; thus, comparative analysis is impossible. Moreover, states differ in eligibility requirements, payment structures, and data systems, so that any evaluation is extremely difficult.

To summarize, it appears unlikely that the influence of PSROs on Medicare outlays, even in the long run, will have more than a slight effect on health-care expenditures. However, it is not possible to judge the full potential effect of the program on costs, because data on Medicaid are not yet available, and because the possible effect on the costs of ancillary services, ambulatory care, and nursing homes is not yet known. Moreover, any improvement in the quality of care as a result of the PSRO program must be considered a true saving to society, and its value should be included in assessments of the program.

Certificate-of-Need Programs

Certificate-of-need regulation has now been implemented in 49 of 50 states.[11] The regulatory mechanism is typically called into play when a hospital wishes to make a capital expenditure in excess of $100,000 or $150,000 a year (the latter is the minimum set by the federal government). The object of certificate-of-need procedures has been to prevent duplication of facilities by ensuring that costly excess capacity is not constructed. Need is determined according to guidelines established by the Department of Health and Human Services[12] and by the individual states.

Potential Saving

A recent analysis has examined in detail the potential saving that could be expected from consolidating the four kinds of hospital facilities that have been singled out most often as costly and redundant[13]: computerized axial-tomographic (CAT) scanners, open-heart-surgery and cardiac-catheterization units, megavoltage-radiation units, and general hospital beds. This study shows that at current levels of demand, the theoretical (maximum) saving that could be achieved by meeting the Health Resources Administration's guidelines would be approximately $1 billion, or less than 2 per cent of hospital costs. Moreover, much of the saving would be "one-shot" in character: it would reduce the base level of expenditures once, but it would have a relatively small effect on the rate of increase.[13]

The poor prospect for a large saving stems from several factors. Most facilities are already operating above the minimum case load indicated in the guidelines. Care provided to patients who are transferred to a consolidated facility is often almost as expensive as care provided in an underused facility. Many types of facilities (e.g., laundries and laboratories) do not fall under the guidelines, and it is unlikely that general usage criteria for these facilities, as set by the guidelines, would either be feasible or save money.

The analysis[13] also indicates that the net saving would be much smaller than the theoretical saving, because the regulatory agencies themselves incur substantial costs, because additional costs are incurred by the applicant in the process of collecting data and filing the appropriate forms, because lawsuits brought by dissatisfied communities or applicants are themselves expensive, and because consolidation forces some patients to seek care further from home, adding the costs of travel and time. Reducing the number of facilities can also lead to longer delays in treatment and a resulting social cost that must be subtracted from the theoretical benefits.

For all these reasons, it seems likely that certificate-of-need programs, directed primarily toward eliminating duplicated facilities, would yield a net saving of no more than several hundred million dollars per year.

The Use of Certificate-of-Need to Limit the Supply of Services

The certificate-of-need process could be used, of course, to do more than prevent duplication of facilities. Rather than merely striving to ensure that services are produced efficiently, it could limit capital expenditures to a level that prevents the demand for care from being fully satisfied. The degree of constraint would then determine the saving that could be achieved.

The Carter cost-containment bill,[14] for example, in-

cluded provisions for a ceiling on capital expenditures; such legislation would have required certificate-of-need agencies to ration facilities. Under such circumstances, the agencies would presumably allocate investment dollars to facilities producing the highest yield relative to costs.

To carry out this function successfully would be extremely difficult. Estimating costs is relatively easy, but placing a dollar value on the benefits of various types of health care is a formidable task.[15] Even ordering the benefits by rank would be a complex effort. The problems of the regulators would be further complicated because the same beds and facilities yield different benefits to different patients.[15] A CAT scanner or artificial kidney used for one patient has a large benefit, whereas the benefit for another is negligible. The agency would thus have to project a profile of the patients likely to have access to each type of facility in each hospital. To assemble such information would be difficult and costly, and perhaps impossible. Moreover, it would be necessary to assume that a given hospital would use its limited facilities in the care of the patients who are predicted to benefit the most. Obviously, such constraints would require that each hospital develop a rationing procedure to ensure that the right patients are assigned positions at the head of the queue. Clearly, such a procedure could not ensure this result, and charges of unfairness would undoubtedly be common.

Constraining the supply of services through certificate-of-need programs has the further drawback of focusing on individual projects and denying the hospital the opportunity to use its overall capital funds in the way that it considers most cost effective. It seems unlikely that an outside agency dealing with allocations on a piecemeal basis could do this as well as the hospital staff and the administration itself, provided that hospitals have the incentive to do so.

Actions denying persons care to which they feel entitled will have the further effect of creating widespread resentment. In the past 10 or 15 years, few patients have been refused hospital care that could yield them benefits.

Thus, controlling costs by rationing facilities would undoubtedly lead to political battles and litigation of a scope and intensity much greater than that already encountered in the attempt to eliminate duplicated facilities through certificate-of-need programs.

Perverse Effects

Any regulatory effort can produce a wide range of perverse effects,[16,17] and the certificate-of-need program is probably no exception. By focusing only on capital expenditures, certificate-of-need regulation can be expected to increase a hospital's demand for labor. Expenditures may simply be shifted from providing more facilities to providing new or more intensive diagnostic and therapeutic services. The certificate-of-need program may also give the hospital an incentive to admit more patients and extend the length of stay in order to demonstrate that it is meeting the guidelines for use set down by state and federal authorities. The same desire to meet the standards may also stimulate an increased use of other facilities, such as CAT scanners.

The certificate-of-need process carries the further risk that politically powerful institutions will acquire undue influence over the decision-making process. Well-organized and well-funded hospitals, or groups of hospitals, may be able to prevent competitors from expanding facilities and restrict the entry of new organizations or innovative delivery systems. More efficient ways of providing a service might be barred by a regulator concerned that the facilities of existing providers would be made obsolete. Continued interactions between a hospital's administration and the certificate-of-need agency could increase the likelihood of favored treatment. Agency "capture" might well occur, with the result that attempts by others to produce services at a lower cost might be stifled.

Finally, the very existence of an agency creates a large bureaucracy with a vested interest in the continuing survival of the organization. One could imagine, for example, that a certificate-of-need bureaucracy might attempt to protect itself by opposing competing approaches to cost containment, such as moves designed to stimulate competition. Whether these problems have actually occurred within the certificate-of-need process is not known, but analogous difficulties are commonly encountered in governmental regulation of business.[16,17]

Observed Saving

It should not be surprising, therefore, to learn that certificate-of-need regulation has had little effect on hospital expenditures. The effect of this regulation has been estimated through statistical control for other factors that may influence investment. Comparisons between states with and without certificate-of-need programs have been made by means of multiple regression analysis. Studies that analyzed data from the late 1960s and early 1970s indicated that certificate-of-need programs did not reduce total dollar investments by hospitals.[18,19] Expansion of the supply of beds was retarded, but capital funds were simply shifted into new services and equipment.[18] Studies of more recent certificate-of-need experience have confirmed these findings. Growth in the bed supply was affected,[20] but there was no demonstrable effect on overall hospital costs.[21-23] A recent study of the Massachusetts experience has also concluded that the certificate-of-need program has not established a binding constraint on hospitals' capital expenditures.[24] Moreover, there has been no difference between programs that have been in place for some years and those that have been implemented only recently,[21,22] suggesting that a learning period has not improved the effectiveness of the agencies in controlling costs.

In summary, it appears that certificate-of-need programs designed to eliminate duplication of facilities have little prospect of exerting a meaningful effect on hospital costs. Not only is the anticipated theoreti-

cal saving relatively small, but experience with certificate-of-need programs also indicates that even this small saving is not likely to be achieved. Given that an effect on expenditures has not been detected and that certificate-of-need regulation involves substantial administrative costs, it appears probable that the program is imposing an appreciable net cost on society.

Mandatory Prospective Reimbursement

By the late 1970s, cost control had been attempted in eight states by means of mandatory prospective reimbursement.[22] Typically, this regulatory approach requires that either the total amount to be paid to the hospital or the rate of payment for a given unit of service be established in advance of the coming year. The hospital is then reimbursed according to these predetermined standards, regardless of the costs it actually incurs.[25] Any expenditure in excess of the prescribed reimbursement must be absorbed by the hospital. Ideally, prospective reimbursement should give institutions an incentive to be more cost conscious. Two basic strategies have been employed to control reimbursement[25]: the so-called formula method and the budget-review method.

The formula method compares the costs of a unit of service in a given hospital (e.g., per diem expenditures) with the costs in a group of similar hospitals. Categorization of hospitals can be based on factors such as size, character of facilities, types of services, and teaching status. Any hospital in a given cluster might be reimbursed for a unit of service only up to a level equal to the mean cost in the entire hospital group or slightly above it.

In New York, the state in which prospective reimbursement has been in effect the longest, the control of reimbursement through the formula method is accomplished in essentially the following way.[26] First of all, to determine allowable inpatient costs, routine costs per patient-day for the hospital are compared with the costs for the peer group, and costs over 100 per cent of the mean are disallowed. Secondly, ancillary costs per admission are analyzed in the same fashion, and costs in excess of the group mean are also disallowed. Thirdly, the average length of stay for the hospital is compared with the group's average length of stay plus half a day, and the costs for any excess days are disallowed. Fourthly, educational costs are added to the other operating expenses. Finally, an adjustment is made for predicted inflation, and a value for allowable capital costs is added.

The allowable costs are then divided by the number of patient-days to obtain the per diem rate of payment. However, in calculating the per diem rate, a penalty is exacted if the hospital's occupancy rate is below the accepted standard. In the case of the medical or surgical services, for example, the minimal figure for occupancy is set at 85 per cent. By and large, hospitals do not like the formula method of rate setting, because the process is objective and mechanical, leaving them little opportunity to influence the outcome.

The budget-review strategy is quite different in character. Each hospital constructs a budget for the coming year and submits it to the rate-setting agency; the agency, in turn, reduces or eliminates any expenditures that it considers excessive. The revised budget is used to determine the payment rate for the future year. Hospitals prefer this system. Because budget review involves a direct discussion with the commission, the hospital has the opportunity to emphasize its individual characteristics and to make the case that elements not included in the equation justify special budgetary adjustments. As a result, the budget-review method tends to be easier on the hospital than the formula method.[25] However, the formula and budget-review methods are commonly combined: an initial rate is set through the budget method, and reimbursement limits are subsequently updated through the application of a formula.[27,28]

By projecting a lower inflation rate than that generally anticipated, the effectiveness of prospective reimbursement in limiting expenditures can be considerably increased under both strategies. In the presence of rapid inflation, a conservative projection or a delay in adjusting the rate will increase the pressure on the hospital. Thus, a decision by the regulator to understate the rate of inflation can serve the conscious but unstated purpose of tightening the regulatory screw.

The unit of payment employed in prospective reimbursement may create perverse incentives that have an important and unwelcome influence on hospital behavior.[25] For example, per diem payment schemes may encourage hospitals to increase the length of stay and to admit more patients. Payments by episode of illness may also encourage more admissions and may, in addition, lead to the hospitalization of patients who are most unlikely to require a long stay. If a given clinical department or the hospital as a whole is to be paid a fixed amount for its services, the incentives will be quite different. The tendency will be to admit fewer patients rather than more and to reduce the total amount of care provided.

Case Mix as a Method for Determining Reimbursement

A considerable body of evidence indicates that prospective reimbursement based on hospital characteristics does not adequately reflect the costs of the case mix in a particular institution.[29-31] Far more information can be obtained by looking at a hospital's costs in terms of patient-related variables — i.e., the resources necessary to care for specific kinds of illnesses.[29-31] As a result, widespread interest has developed in case-mix measures as the basis for reimbursing hospitals and controlling hospital costs. In several experimental efforts, most notably in New Jersey and Maryland, the hospital's revenue is determined by the number and types of patients treated.[32-34] The basis for appraising performance is diagnostic related grouping (DRG), a coding system that identifies classes of patients requiring similar services. The DRG system consists of 383 categories that group pa-

tients according to primary diagnosis, secondary diagnosis, age, and factors employed in the process of care, such as surgical procedures.[35] In the New Jersey experiment, which involves over 20 hospitals, a dollar value has been set for each of the DRGs, and the hospital is paid the predetermined flat rate for each type of admission, regardless of the actual services provided or the costs incurred.[32-34] Except to the extent that a hospital's own costs are included, the average rate of reimbursement for a given DRG is based on the average costs of all hospitals in the system.[32,34] The revenue limits imposed by the DRG payment constrain the hospital's expenditures.

Despite the many attractive features of the DRG system, important criticisms can be leveled against it.[34,36] Several examples illustrate this point. First of all, a single DRG includes patients whose illnesses may vary greatly in severity and who may require care of widely differing intensity. Thus, all patients with myocardial infarction are classified under one heading and are covered at the same rate. This can lead to great inequities: the sickest patients may be "dumped" on urban and university hospitals, for example. Secondly, the system encourages an activist approach to surgical operations and other procedures because they alter the DRG classification and lead to higher payments. Thirdly, it gives the hospital an incentive to maximize revenues by manipulating the sequence of diagnoses or otherwise classifying the illness in a way that is financially most advantageous.[37] Fourthly, it imposes heavy costs of data collection and processing that yield no medical benefits. Such issues must be faced before the value of the case-mix approach to cost control can be adequately evaluated.

An Overall Limit on Hospital Expenditures

Rochester, New York, is implementing a strategy in which each hospital agrees to accept an overall revenue limit within which it must live.[38,39] The revenue base for the area was arrived at by summing the expenditures of each hospital for the base year 1978. An adjustment was then made to account for expected inflation, and a further 2 per cent was added to cover increases in the volume of patients and the costs of new and improved technology. This aggregate pool of money (minus a reserve) was then divided among the various hospitals: each hospital received its 1978 base revenue plus adjustments for inflation, for its particular workload, and for approved new projects. The individual hospital must operate within its revenue limit and is thereby stimulated to find ways to produce services as efficiently as possible. A hospital that spends less than its allotted revenues can keep the savings. During the first year of operation, expenditures by the Rochester hospital group rose by 9 per cent — a few tenths of a per cent less than that for New York State hospitals as a whole, and far below the national average for hospitals.[40] The long-term effectiveness of this effort remains to be determined.

The voluntary effort in Rochester is similar to the strategy embodied in the cost-containment bill submitted to Congress by the Carter administration.[14] The Carter bill took the approach of setting a binding budget limit based on the hospital's current expenditures. If real expenditures were anticipated to increase by 5 per cent in the coming year without cost constraints, for example, the government might set a 2 per cent limit on the real increase in hospital revenues.

Constraints on revenues can be used not only to deal with inefficiencies in the production of services but also to reduce the availability and quality of care. If policy makers so desire, they can set rates of reimbursement or overall budget limits at a level that forces hospitals to eliminate care that yields small benefits relative to costs. However, patients who believe that they have been cheated out of promised services may attempt to remedy the situation by applying political pressures. Teaching hospitals can also be expected to complain, arguing that their special characteristics are not being adequately taken into account. Disadvantaged hospitals will also protest; those in the southern or rural parts of the country, where expenditures are low, will argue that the system locks them into an inferior position. All this can be anticipated to induce a rash of administrative appeals and court actions contesting the fairness of the regulatory actions. The prospects are dismal: delay, political turmoil, high administrative and legal costs, and dissatisfaction among a generation of patients accustomed to receiving whatever care may have value. Policy makers must clearly reckon with these issues if they contemplate expenditure restrictions that are severe enough to reduce benefits.

The Effect of Rate Setting on Hospital Costs

Studies using statistical methods to control for relevant variables (e.g., demographic differences) all show unequivocally that states that have introduced programs of mandatory prospective reimbursement have a slower rate of increase in hospital costs than that of states that do not. Such limits on reimbursement have reduced the rate of growth in expenditures by approximately 3 to 5 percentage points, relative to no regulation at all.[22,28,41] The effect of prospective reimbursement has been seen only in programs that have been in place for at least three years.[22]

To summarize, the available evidence suggests that prospective reimbursement can be used effectively to slow the rise in hospital costs. A word of caution is in order, however. Prospective reimbursement has been used in only a handful of states, and it cannot be confidently concluded that the program would be equally effective in the rest of the country. The political and legal environment in some states might not be as receptive to the imposition of severe constraints. Furthermore, states in which mandatory rate setting has been imposed are generally those in which costs per admission have been highest[42] and in which there has presumably been a greater intensity of care. This set of circumstances may have facilitated the effective implementation of a belt-tightening effort. Despite these

caveats, it seems fair to say that prospective reimbursement is the only regulatory mechanism that has shown real promise to date.

Experience with the Medical and Social Costs of Rate Setting

The actual consequences of a severe constraint on expenditures are illustrated most dramatically by the experience in New York State, where rate setting has been imposed most rigorously and effectively. Nine of 10 voluntary hospitals in the state operated in the red for at least two of the five years from 1974 to 1978.[43] Moreover, during this period, 90 voluntary hospitals suffered operating losses that amounted to more than $500 million in the aggregate. As a result, from 1974 to 1978, $0.5 billion of the $2 billion equity of community hospitals was used to underwrite operating losses.[43]

State Medicaid payments to New York City hospitals are said by the Greater New York Hospital Association to be more than $265 million in arrears, sharply cutting the flow of cash to many institutions[44] and compounding operational problems. In New York City, which has been hit the hardest, 25 hospitals with a total of 4000 beds have been forced to close because of the financial difficulties encountered in caring for Medicaid patients, working poor who could not afford insurance, and illegal aliens.[45] There are widespread complaints that equipment is scarce and poorly maintained, that basic supplies are often unavailable, and that there are critical shortages of nurses and other personnel.[45] Morale and the quality of care are said to be low, and tempers short. Teaching hospitals have apparently fared better than others, either because they are liquidating their endowments to meet their deficits or because they have few indigent patients.[45] The consumption of endowments cannot continue indefinitely, however, and a day of reckoning with further cutbacks in the quality or quantity of services must eventually occur.

Hospitals in New York State have also been subjected to numerous changes in their rates during the course of a single year. For example, over a three-year period, Medicare and Medicaid rates for inpatient care changed more than seven times per year, adding to the difficulties in hospital planning and operations.[46]

All these problems have led to a large number of appeals and lawsuits, which have led in turn to further rate changes.[46] Hospital appeals have alleged that the rate-setting authorities made arithmetical errors in their calculations. Even more often, hospitals have argued that apparently inadequate levels of use can be explained by extenuating circumstances. Suits have also been brought on the grounds that rate-setting bodies did not comply with due process or exceeded their legislative authority. Hospitals have further complained that the trend (inflationary) factor used by the payer was not appropriate.[46] As the state review process has become more stringent, lengthy and costly appeals and court cases have become ever more numerous. Thus, as of January 1, 1978, there was a backlog of 2400 appeals before the rate-setting bureau.[26]

In addition, important political problems have emerged. Opposition by the black and Hispanic communities has been intense when attempts to close inner-city hospitals have been made as cost-cutting measures.[45,47,48] Money has been saved, to be sure, but only at considerable political and social cost.

The situation in New York City has been compounded by the large number of indigent and chronically ill patients with whom hospitals are confronted. However, even a community not facing such difficulties can be expected to arrive at the same straits, provided that the reimbursement strictures are made severe enough. The ultimate determinant of the stress on the delivery system is the overall revenue made available to hospitals for care. If the financial squeeze is sufficiently tight, problems analogous to those in New York can be anticipated. A painless regulatory strategy that effectively controls cost is thus almost certainly out of reach.

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MEDICAL INTELLIGENCE

DRUG THERAPY

JAN KOCH-WESER, M.D., *Editor*

Drugs to Decrease Alcohol Consumption

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MANY drugs have been used with the expectation of reducing alcohol consumption. A few seem to be associated with a reduction in alcohol use for up to three to six months in some patients, but none is associated with a reduction in alcohol consumption for longer periods.[1,2] In spite of uncertainty about efficacy, over 90 per cent of physicians in private practice prescribe drugs for the treatment of alcoholism.[3] The effectiveness of drug therapies for alcohol-related problems is seriously compromised by the difficulty of characterizing patients according to the cause of their alcohol problems, by the large number of nonpharmacologic modulators of alcohol consumption, by the lack of general agreement on the definition of a successful treatment outcome, and finally by the lack of specific and potent drugs directed at the primary neurochemical antecedent of persistent excessive drinking. Even if a drug has been proved effective during controlled testing, failure of drug treatment to be effective in practice can often be attributed to poor compliance, use in an inappropriate alcoholic population, the lack of a predefined and systematized treatment strategy, or a failure to optimize the conditions under which the drugs are administered.

In defining a successful treatment, one or more of the following variables are used: the amount of alcohol consumed, retention of the patient in treatment, improvement of social and family relations, and financial or employment status. Some therapists and patients believe that abstinence is the only acceptable criterion for therapeutic success.[4,5] However, this goal

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Commissioner Petit DH
to Maine Hospital Class
Jan. 14, 1982

GOOD EVENING LADIES AND GENTLEMEN. THANK YOU FOR INVITING ME TO PARTICIPATE IN THESE PROCEEDINGS.

THESE ARE DIFFICULT TIMES ... TIMES WHICH DEMAND WE CONFRONT A NUMBER OF ISSUES THAT HAVE REMAINED UNRESOLVED FOR FAR TOO LONG. I APPRECIATE THIS OPPORTUNITY TO DISCUSS MY VIEWS REGARDING SEVERAL OF THESE ISSUES WITH YOU. I KNOW THEY WILL NOT BE SUCCESSFULLY RESOLVED UNLESS THE PEOPLE OF THE STATE - AND THE PUBLIC AND PRIVATE INSTITUTIONS WHICH HAVE BEEN CREATED TO SERVE THEM - ARE WILLING AND ABLE TO FORGE A PRODUCTIVE RELATIONSHIP AND WORK TOGETHER TOWARD THAT END. IT IS MY HOPE THAT THE COMMENTS I WILL SHARE WITH YOU THIS EVENING WILL HELP TO DEVELOP THE MUTUAL UNDERSTANDING AND RESPECT UPON WHICH SUCH A RELATIONSHIP MUST BE BASED.

LET ME BEGIN BY STATING THAT I FULLY RECOGNIZE AND APPRECIATE THE MANY STRENGTHS OF OUR EXISTING HEALTH CARE SYSTEM. WE ARE SERVED BY MANY FINE INSTITUTIONS STAFFED BY WELL QUALIFIED AND COMMITTED PROFESSIONALS WHOM WE HAVE EQUIPPED WITH INCREASINGLY SOPHISTICATED TOOLS WITH WHICH TO DIAGNOSE AND TREAT OUR AFFLICTIONS. MEDICAL SERVICES HAVE BEEN EXTENDED TO MANY OF THE MORE REMOTE AND IMPOVERISHED AREAS OF THE STATE. PRIVATE HEALTH INSURANCE AND PREPAYMENT PROGRAMS, ALONG WITH MEDICARE AND MEDICAID, HAVE REMOVED THE FINANCIAL BARRIERS WHICH ONCE PREVENTED MANY FROM RECEIVING THE CARE THEY NEEDED.

WHILE WE CAN TAKE JUSTIFIABLE PRIDE IN WHAT WE HAVE ACCOMPLISHED WE MUST ALSO RECOGNIZE THAT THE PRICE OF OUR PROGRESS HAS BEEN STAGGERING. THE COST OF PROVIDING HEALTH CARE SERVICES TO MAINE PEOPLE INCREASED FROM LESS THAN $300 MILLION TO MORE THAN $1 BILLION DURING THE PAST DECADE AND, UNLESS THE PRESENT RATE OF INCREASE IS DIMINISHED, CAN BE EXPECTED TO EXCEED $2 BILLION WITHIN FIVE YEARS.

SUCH INCREASES IN SPENDING HAVE BROUGHT US TO THE POINT AT WHICH WE MUST CONFRONT THE MOST FUNDAMENTAL LAW OF ECONOMICS - NAMELY, THAT WHILE THE WAYS IN WHICH WE MIGHT ENHANCE THE STRENGTHS OF OUR HEALTH CARE SYSTEM AND SHORE UP ITS WEAKNESSES ARE ALMOST WITHOUT LIMIT,

THE RESOURCES AVAILABLE TO US TO CONTINUE OUR PROGRESS ARE MOST DEFINITELY LIMITED.

AND, GIVEN THE DRIVE TO REDUCE FEDERAL SPENDING TO DIMINISH THE MASSIVE DEFICITS WHICH ARE NOW PROJECTED, THERE IS EVERY REASON TO BELIEVE THAT THE DISPARITY BETWEEN OUR LEGITIMATE NEEDS AND EXPECTATIONS AND OUR RESOURCES WILL GROW MUCH LARGER - SO MUCH SO THAT IT MAY SOON BE NECESSARY TO REDEFINE THE CHALLENGE BEFORE US AS THE PRESERVATION OF THAT WHICH WE HAVE ALREADY ACHIEVED RATHER THAN THE CONTINUATION OF OUR PROGRESS TOWARD A FAIRER, MORE COMPASSIONATE AND MORE EFFECTIVE HEALTH CARE SYSTEM.

UNDER SUCH CIRCUMSTANCES IT SEEMS TO ME THAT WE MUST COMMIT OURSELVES TO A DISCIPLINE WHICH HAS TOO OFTEN BEEN LACKING IN OUR EFFORTS. MY COLLEAGUES AND I MUST, FOR EXAMPLE, ASSURE THAT EACH DOLLAR ENTRUSTED TO US FOR THE SUPPORT OF THE PROGRAMS WE ADMINISTER IS USED TO ITS MAXIMUM ADVANTAGE.

I CAN TELL YOU THAT THE VAST MAJORITY OF MY TIME AND THAT OF MY STAFF IS SPENT TRYING TO FIND WAYS TO DO MORE WITH LESS. WHILE WE CERTAINLY HAVE NO REASON TO BE COMPLACENT, OUR EFFORTS HAVE YIELDED A NUMBER OF NOTEWORTHY SUCCESSES.

THREE YEARS AGO, AT THE TIME WE ASSUMED OFFICE, PRECIOUS LITTLE ATTENTION WAS GIVEN TO THE FACT THAT THE MAINE MEDICAID PROGRAM WAS FREQUENTLY PAYING FOR SERVICES FOR WHICH OTHER PARTIES WERE LEGALLY RESPONSIBLE. THIS YEAR OUR THIRD PARTY LIABILITY PROGRAM WILL SAVE MORE THAN $30 MILLION, APPROXIMATELY A THIRD OF WHICH WOULD HAVE BEEN DRAWN FROM THE GENERAL FUND.

SIMILARLY, WE BELIEVE THE SUCCESSFUL IMPLEMENTATION OF THE MEDICAID MANAGEMENT INFORMATION SYSTEM HAS RESULTED IN CONSIDERABLE SAVINGS. OUR ABILITY TO IDENTIFY DUPLICATE BILLINGS AND STOP PAYMENT OF CLAIMS WHICH ARE INCONSISTENT WITH OUR POLICIES HAS BEEN GREATLY ENHANCED - AS HAS BEEN OUR EFFORT TO CHECK FRAUDULENT AND WASTEFUL PRACTICES. AND, ALTHOUGH I AM NOT SO NAIVE AS TO BELIEVE THAT ALL IS IN PERFECT ORDER, I AM CONFIDENT THAT WE ARE PAYING CLAIMS FASTER AND MORE ACCURATELY THAN EVER BEFORE WHICH SHOULD DIMINISH YOUR NEED FOR SHORT TERM BORROWING AND, CONSEQUENTLY, YOUR EXPENSES AND OUR SHARE OF THEM.

PERHAPS THE BEST EVIDENCE OF THE SUCCESS OF OUR EFFORTS CAN BE FOUND IN THE FOLLOWING COMPARISON. AFTER INCREASING BY MORE THAN 35 PER CENT DURING THE LAST TWO YEARS OF GOVERNOR LONGLEY'S ADMINISTRATION, AND APPROXIMATELY 30 PER CENT DURING THE FIRST TWO YEARS OF GOVERNOR BRENNAN'S ADMINISTRATION, THE APPROPRIATIONS FROM THE GENERAL FUND FOR THE SUPPORT OF ALL THE PROGRAMS ADMINISTERED BY THE DEPARTMENT OF HUMAN SERVICES WILL INCREASE BY BUT 13% DURING THE CURRENT BIENNIUM. IN SHORT, WE HAVE BEEN ABLE TO REDUCE THE RATE OF INCREASE IN STATE SPENDING FOR THE PROGRAMS WE ADMINISTER BY MORE THAN HALF WHILE AT THE SAME TIME EXPANDING AND STRENGTHENING MANY OF THEM.

THE SAME REALITIES WHICH MAKE IT INCUMBENT UPON US TO USE EACH DOLLAR ENTRUSTED TO STATE GOVERNMENT TO ITS MAXIMUM ADVANTAGE CONFRONT THOSE OF YOU WHO MANAGE HEALTH SERVICES, OF COURSE. FACED WITH THE UNHAPPY PROSPECT OF AN INCREASED DEMAND FOR SERVICES AND DIMINISHED RESOURCES - WHICH ARE THE INEVITABLE RESULTS OF THE REAGAN ADMINISTRATION'S CURTAILMENT OF FUNDING FOR NUTRITION AND PREVENTIVE HEALTH PROGRAMS, MEDICAID AND MEDICARE - WE ARE COMPELLED TO SPEND EACH DOLLAR WISELY.

IT IS IN THIS REGARD THAT THE FINDINGS AND RECOMMENDATIONS OF THE HEALTH FACILITIES COST REVIEW BOARD - WHICH I UNDERSTAND YOU HAVE DISCUSSED AT LENGTH TODAY - ASSUME GREAT SIGNIFICANCE. IN MY JUDGEMENT THE KEY FINDING OF THE BOARD WAS <u>NOT</u> THAT THE PRESENT METHOD OF FINANCING HOSPITAL CARE IN MAINE FAILS TO ENCOURAGE THAT DISCIPLINE. WE HAVE ALL BEEN PAINFULLY AWARE OF THAT FACT FOR QUITE SOME TIME.

INSTEAD, THE KEY FINDING OF THE BOARD WAS THAT THE VOLUNTARY EFFORT TO RESTRAIN THE RATE OF INCREASE IN HOSPITAL SPENDING HAS NOT PRODUCED THE RESULTS WE ALL HAD REASON TO HOPE WOULD BE ACHIEVED AND, GIVEN ITS INSUFFICIENCY, THE METHOD BY WHICH WE PAY FOR HOSPITAL CARE MUST BE ALTERED TO ASSURE THAT THE NECESSARY DISCIPLINE IS EXERCISED.

I AM SURE THAT MOST OF YOU HAVE ALREADY HEARD THAT GOVERNOR BRENNAN HAS INFORMED THE LEGISLATURE THAT HE WILL SUBMIT A RESPONSE TO THE BOARD'S FINDINGS AND RECOMMENDATIONS FOR ITS CONSIDERATION. ALTHOUGH THE EXACT NATURE OF THAT RESPONSE HAS NOT YET BEEN DETERMINED, I FULLY EXPECT THAT IT WILL REFLECT MANY OF THE KEY ELEMENTS OF THE APPROACH PROPOSED BY THE BOARD.

I EXPECT, FOR EXAMPLE, THAT IT WILL INCLUDE PROVISION FOR THE BOARD, OR A PUBLICLY APPOINTED BODY VERY MUCH LIKE IT, TO ESTABLISH AN ANNUAL STATEWIDE MAXIMUM REVENUE AUTHORIZATION. THIS BODY WOULD DIRECTLY ADMINISTER OR OVERSEE THE ESTABLISHMENT OF A PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL SERVICES. I ALSO EXPECT THAT PARTICIPATION IN THAT SYSTEM WOULD BE MANDATORY FOR HOSPITALS AND PAYERS ALIKE, AND THAT EVERY EFFORT WILL BE MADE TO PRESERVE THE ABILITY OF HOSPITAL TRUSTEES AND MANAGERS TO USE THE AMOUNTS APPORTIONED TO THEIR RESPECTIVE INSTITUTIONS IN WHATEVER MANNER THEY DEEM TO BE IN THE BEST INTEREST OF THOSE THEY SERVE.

THERE ARE ASPECTS OF THE BOARD'S RECOMMENDATIONS WHICH DO GIVE ME REASON FOR PAUSE. FOR EXAMPLE, I REMAIN TO BE CONVINCED OF THE NEED FOR THE CONTINUED INVOLVEMENT OF THE VOLUNTARY BUDGET REVIEW ORGANIZATION. IT SEEMS TO ME THAT THERE ARE SERIOUS QUESTIONS REGARDING THE DELEGATION OF SIGNIFICANT PUBLIC AUTHORITY TO A PRIVATE CORPORATION, QUESTIONS WHICH HAVE NOT BEEN FULLY EXPLORED OR RESOLVED.

I UNDERSTAND THAT YOU ALSO ARE CONCERNED BY THE FACT THAT A NUMBER OF KEY QUESTIONS, SUCH AS THE MANNER IN WHICH YOUR FINANCIAL REQUIREMENTS WILL BE DEFINED, HAVE NOT BEEN RESOLVED AND WOULD, THEREFORE, BE ADDRESSED IN THE DEVELOPMENT OF REGULATIONS RATHER THAN CODIFIED IN LAW.

FRANKLY, I SHARE THOSE CONCERNS. THERE IS AS GREAT A RISK THAT THEY WOULD BE RESOLVED IN A MANNER WHICH IS NOT TO MY LIKING AND THE

BENEFIT OF THE MEDICAID PROGRAM AS THERE IS THAT THEY WOULD BE RESOLVED IN WAYS THAT YOU MIGHT CONSIDER TO BE DETRIMENTAL TO YOUR INTERESTS. THAT UNCERTAINTY IS UNCOMFORTABLE.

HOWEVER, AFTER REFLECTING UPON THE BOARD'S REPORT I HAVE COME TO BELIEVE THAT IT IS NECESSARY. WE SIMPLY DO NOT HAVE THE TIME FOR A PROTRACTED DEBATE IN VIEW OF THE URGENCY OF THESE ISSUES.

ACTION IS NECESSARY DURING THIS SESSION. WE NEED TO CREATE THE FRAMEWORK WITHIN WHICH THE UNANSWERED QUESTIONS CAN BE THOUGHTFULLY AND FAIRLY RESOLVED. WE NEED TO SET IN MOTION THE IMPLEMENTATION OF A PROSPECTIVE PAYMENT SYSTEM OPERATING WITHIN A DEFINED SET OF LIMITS WHICH WE CONSIDER REASONABLE GIVEN INFLATION, OUR CHANGING POPULATION AND OUR MUTUAL DESIRE TO CONTINUE TO IMPROVE HOSPITAL CARE.

UNLESS SUCH ACTION IS TAKEN I BELIEVE IT WILL BE NECESSARY FOR US TO ACT UNILATERALLY. WE HAVE ALREADY LOST MORE THAN $6 MILLION OF FEDERAL SUPPORT FOR THE MEDICAID PROGRAM. PRESIDENT REAGAN HAS MADE IT CLEAR HE INTENDS TO PURSUE FURTHER REDUCTIONS IN THE FEDERAL GOVERNMENT'S PARTICIPATION IN THE PROGRAM.

UNDER SERIOUS CONSIDERATION ARE FURTHER REDUCTIONS IN THE FEDERAL MATCHING RATE, ARBITRARY LIMITS ON THE INCREASED AMOUNT OF FEDERAL SUPPORT SUCH AS THE FIVE PER CENT "CAP" WHICH WAS PROPOSED BY THE PRESIDENT A YEAR AGO AND SO SOUNDLY REJECTED BY THE CONGRESS, AND THE DEVELOPMENT OF A LONG-TERM CARE BLOCK GRANT.

THE COMMON DENOMINATOR OF THESE PROPOSALS IS THAT THEY WILL DEPRIVE US OF THE REVENUE WE WILL NEED TO SUSTAIN THE MEDICAID PROGRAM IN ITS CURRENT FORM. FOR EXAMPLE, HAD EITHER THE FIVE PER CENT CAP PROPOSED BY THE PRESIDENT OR THE LESS RIGOROUS NINE PER CENT CAP PROPOSED

BY THE SENATE BEEN ADOPTED WE WOULD HAVE BEEN COMPELLED TO DISCONTINUE THE MEDICALLY NEEDY PROGRAM WHICH INSURES MORE THAN TWENTY-THOUSAND LOW-INCOME INDIVIDUALS.

AS A PRACTICAL MATTER, THERE IS NO REASON TO BELIEVE THAT WE WILL BE EITHER WILLING OR ABLE TO REPLACE THE FEDERAL FUNDS WHICH ARE LOST. EVERY PROGRAM WE ADMINISTER HAS ALREADY BEEN AFFECTED. I CONSIDER MANY OF THEM TO BE EVERY BIT AS IMPORTANT TO THE HEALTH AND WELFARE OF THE PEOPLE OF MAINE AS THE MEDICAID PROGRAM.

CERTAINLY OUR EFFORTS TO PROTECT ABUSED AND NEGLECTED CHILDREN, TO IMPROVE THE WOEFUL CIRCUMSTANCES IN WHICH MANY OF THOSE WHO HAVE BEEN DISCHARGED FROM OUR MENTAL HEALTH INSTITUTES FIND THEMSELVES AND TO DEVELOP A SYSTEM OF SERVICES ENABLING GREATER NUMBERS OF ELDERLY AND DISABLED INDIVIDUALS TO REMAIN AT HOME WILL CONTINUE TO DEMAND THEIR RIGHTFUL SHARE OF ANY ADDITIONAL STATE FUNDS WHICH DO BECOME AVAILABLE.

SINCE I DO NOT BELIEVE THAT GOVERNOR BRENNAN IS PREPARED TO EITHER SEEK OR ACCEPT A TAX INCREASE, AND I AM NOT PREPARED TO CONSIDER A RETURN TO THE TIME WHEN THE FINANCIAL REQUIREMENTS OF THE MEDICAID PROGRAM WERE MET AT THE EXPENSE OF EVERY OTHER SOCIAL SERVICES AND PUBLIC HEALTH PROGRAM WE ADMINISTER, THE MEDICAID PROGRAM WILL HAVE TO STAND ALONE.

REDUCTIONS IN FEDERAL SUPPORT WILL HAVE TO BE ACCOMMODATED BY REDUCING THE NUMBER OF INDIVIDUALS ELIGIBLE FOR ASSISTANCE, NARROWING THE SCOPE OF THE SERVICES WE COVER OR PAYING LESS FOR THEM. I WOULD BE LESS THAN CANDID IF I DID NOT TELL YOU THAT I CONSDER THE FIRST OF THOSE OPTIONS, REDUCING THE NUMBER OF INDIVIDUALS ELIGIBLE FOR ASSISTANCE, TO BE THE LEAST ACCEPTABLE OF THE THREE AND WILL PURSUE IT ONLY AFTER THE OTHERS ARE EXHAUSTED.

THOSE SERVICES WHICH WE MUST COVER, PLUS NURSING HOME CARE AND PRESCRIPTION DRUGS, TOGETHER ACCOUNT FOR MORE THAN 98 PER CENT OF THE COST OF THE PROGRAM. THUS, THE POTENTIAL SAVINGS TO BE REALIZED BY PURSUING THE SECOND OPTION - NARROWING THE SCOPE OF SERVICES - PALE IN COMPARISON TO THE MAGNITUDE OF THE FINANCIAL PROBLEM WE ARE LIKELY TO FACE. WE ALSO KNOW THAT THE ELIMINATION OF CERTAIN OF THOSE OPTIONAL SERVICES WOULD BE LIKELY TO INCREASE, RATHER THAN DECREASE, OUR EXPENSES.

THAT, OF COURSE, LEAVES ONLY THE THIRD OPTION, REDUCING THE AMOUNTS WE PAY FOR THE SERVICES WE CONTINUE TO COVER. IN THAT REGARD I WOULD LIKE TO MAKE TWO POINTS.

FIRST, WE WOULD MUCH RATHER ACT AS PART OF A SYSTEM-WIDE RESPONSE TO THE PROBLEM THAN ACT ALONE. WE RECOGNIZE THAT WE ARE BUT A SMALL

PART OF THE SYSTEM, ACCOUNTING AS WE DO FOR AS LITTLE AS 10 PER CENT OF YOUR REVENUES. NEVERTHELESS, WE ALSO UNDERSTAND THAT A CHANGE IN ANY OF ITS PARTS CAN HAVE A SIGNIFICANT EFFECT ON THE ENTIRE SYSTEM.

THERE IS A CLEAR DANGER IN THE SCATTERGUN APPROACH TO REDUCING THE COST OF THE MEDICARE AND MEDICAID PROGRAMS WHICH IS EMBODIED IN THE OMNIBUS BUDGET RECONCILIATION ACTS OF 1980 AND 1981. BY OUR COUNT THEY CONTAIN AS MANY AS FORTY DIFFERENT PROVISIONS WHICH AFFECT YOUR REIMBURSEMENT. SCANT ATTENTION HAS BEEN PAID TO THEIR CUMULATIVE IMPACT. WE WOULD PREFER NOT TO HAVE TO ADD TO THAT PROBLEM.

FOR JUST THAT REASON WE HAVE NOT IMPLEMENTED OUR PROPOSAL TO LIMIT THE RATE OF INCREASE IN OUR REIMBURSEMENT FOR YOUR SERVICES TO 10 PER CENT PER ANNUM. IT IS OUR EXPECTATION THAT THE CONGRESS' DECISION TO REDUCE THE ESTABLISHED LIMITS ON YOUR REIMBURSEMENT

FOR ROUTINE SERVICES AS OF OCTOBER 1,1981, WILL HAVE ROUGHLY THE SAME IMPACT ON OUR EXPENSES AS THE IMPLEMENTATION OF OUR PROPOSAL WOULD HAVE HAD. WE SAW NO NEED TO PROCEED AND COMPOUND YOUR LOSSES. WHETHER WE CAN CONTINUE TO HOLD SUCH AN ACTION IN ABEYANCE REMAINS TO BE SEEN.

THE SECOND POINT I WOULD LIKE TO MAKE IS THAT WE ARE NOT INSENSITIVE TO YOUR NEEDS AND CONCERNS. AS I AM SURE YOU WILL RECALL, LATE LAST SUMMER WE SOUGHT COMMENT ON THE POSSIBILITY THAT MEDICAID BENEFICIARIES WOULD BE REQUIRED TO MAKE SMALL CONTRIBUTIONS TO THE COST OF THE CARE THEY RECEIVE. WHILE THAT SUGGESTION WAS STRONGLY SUPPORTED IN PRINCIPLE, MANY COMMENTERS, INCLUDING YOUR REPRESENTATIVES, POINTED OUT THAT ITS IMPLEMENTATION WOULD CREATE A SUBSTANTIAL ADMINISTRATIVE PROBLEM WITH ITS OWN ATTENDANT COSTS. WE CONCLUDED THAT THE CONCERNS WHICH HAS BEEN EXPRESSED WERE VALID AND ELECTED NOT TO PROCEED.

SHOULD THE REAGAN ADMINISTRATION FOLLOW THROUGH ON ITS COMMITMENT TO RELAX THE RULES WHICH STILL SEVERELY RESTRICT THE STATE'S AUTHORITY TO IMPOSE COST SHARING REQUIREMENTS, WHICH WE CONTINUE TO BELIEVE REPRESENT SOUND PUBLIC POLICY, WE INTEND TO ACCEPT YOUR OFFER TO WORK WITH US TO DESIGN AN APPROACH WHICH MINIMIZES THE POTENTIAL ADMINISTRATIVE BURDEN. WE WOULD LIKE TO FOLLOW THE SAME COOPERATIVE APPROACH TO OTHER ACTIONS WE MIGHT TAKE TO COPE WITH THE CONTINUED EROSION OF FEDERAL SUPPORT.

LET ME CONCLUDE THIS DISCUSSION WITH A FEW COMMENTS REGARDING THE FUTURE OF HEALTH PLANNING IN MAINE AND OUR ADMINISTRATION OF THE CERTIFICATE OF NEED PROGRAM. AS YOU KNOW, THERE ARE SOME IN WASHINGTON WHO WOULD SEEK TO ELIMINATE THE HEALTH PLANNING PROGRAM AND ITS REGULATORY RESPONSIBILITIES IN ORDER TO ALLOW UNFETTERED "COMPETITIVE FORCES" TO RESHAPE THE HEALTH CARE SYSTEM. IN MY OPINION, SUCH THINKING IS EXTREMELY NAIVE.

I SEE NO REASON TO BELIEVE THAT SUCH FORCES WILL ASSURE THAT ONLY NEEDED SERVICES ARE DEVELOPED AND RESTRAIN COST INCREASES. IN FACT, I SEE LITTLE REASON TO BELIEVE THAT SUCH COMPETITIVE FORCES CAN BE INTRODUCED TO OUR HEALTH CARE SYSTEM, AT LEAST NOT TO THE DEGREE WHICH WOULD BE NECESSARY FOR THEM TO HAVE ANY APPRECIABLE IMPACT. THIS SEEMS ESPECIALLY TRUE IN RURAL STATES LIKE MAINE WHICH ARE CHARACTERIZED BY MARKETS THAT ARE DOMINATED BY A SINGLE INSTITUTION AND THE MEMBERS OF ITS MEDICAL STAFF.

THE HEALTH PLANNING PROGRAM HAS BEEN CRUCIAL TO OUR EFFORTS TO FORMULATE A HEALTH POLICY WHICH IS RESPONSIVE TO THE NEEDS OF THOSE WE SERVE. THE THOUGHTFUL APPROACH TO THE EXPLORATION OF PROBLEMS, AND THE CHARTING OF THE BEST COURSE OF ACTION WHICH IT EMBODIES, IS EVEN MORE NECESSARY IN THESE DIFFICULT TIMES THAN IT HAS BEEN IN THE PAST. FOR THAT REASON ALONE I AM CONFIDENT THAT IT WILL BE CONTINUED AND STRENGTHENED RATHER THAN DIMINISHED.

WITH THE LAWSUITS WHICH CLOUDED THE FIRST VERSION OF THE STATE HEALTH PLAN BEHIND US AND A STRONG, HEALTHY RELATIONSHIP BETWEEN THE (MAINE) STATE HEALTH COORDINATING COUNCIL AND THE DEPARTMENT WE ARE PREPARED TO MOVE AHEAD. WE NEED AND WELCOME YOUR INVOLVEMENT IN THAT EFFORT.

THE CERTIFICATE OF NEED PROGRAM IS ONE OF THE MOST IMPORTANT TOOLS WE HAVE TO ASSURE THAT OUR HEALTH CARE SYSTEM EVOLVES IN A MANNER WHICH IS CONSISTENT WITH THE COURSE WE HAVE CHARTED. IT IS A TOOL WHICH HAS SERVED THE PUBLIC WELL.

TWO YEARS AGO, IN AN ADDRESS TO THE BOARD AND CORPORATORS OF THE VOLUNTARY BUDGET REVIEW ORGANIZATION, I INDICATED THAT WE INTENDED TO SEGREGATE THOSE PROPOSALS WHICH WERE TRULY NECESSARY FROM THOSE WHICH WERE MERELY DESIRABLE AND APPROVE ONLY THE FORMER. SINCE THAT TIME OUR DECISIONS HAVE HELPED TO HOLD THE STAGGERING AND UNPLANNED GROWTH OF THE NURSING HOME INDUSTRY AND SAVED MILLIONS OF DOLLARS, DOLLARS

WHICH DID NOT NEED TO BE SPENT AND REMAIN AVAILABLE FOR THE SUPPORT OF THOSE PROGRAMS AND SERVICES WE DO NEED.

ALTHOUGH I WILL BE THE FIRST TO ADMIT THAT THERE ARE TIMES WHEN IT IS EXTREMELY DIFFICULT TO MAKE THE DISTINCTION BETWEEN NECESSARY AND DESIRABLE, I BELIEVE THAT THE TIMES DEMAND THAT OUR DECISIONS CONTINUE TO REFLECT THAT DISCIPLINE. THUS, YOU CAN EXPECT THAT WE WILL CONTINUE TO SUBJECT CERTIFICATE OF NEED PROPOSALS TO RIGOROUS ANALYSIS AND WE WILL STRENUOUSLY OPPOSE ANY ATTEMPTS TO MODIFY THE PRESENT LAW IN WAYS WHICH WOULD DIMINISH THE STATE'S ABILITY TO EFFECTIVELY DISCHARGE ITS RESPONSIBILITIES TO THE PUBLIC.

IN CLOSING, I HOPE THESE COMMENTS HAVE HELPED CLARIFY OUR PERSPECTIVE. SUCH AN UNDERSTANDING IS ESSENTIAL TO THE ESTABLISHMENT OF THE PRODUCTIVE RELATIONSHIP I DESIRE AND BELIEVE IS CRUCIAL IN OUR MUTUAL EFFORTS TO IMPROVE SERVICES FOR THOSE WHO ARE OUR COMMON CONCERN.

THANK YOU.

CH

Memorandum

TO: Members, Study Group for Certificate of Need

FROM: Tom Gorham, Blue Cross and Blue Shield of Maine

DATE: January 25, 1982

SUBJECT: Remaining Issues

Below are what we consider to be the important issues yet to be resolved. They are listed in the order in which we feel they should be addressed.

1. Should the purchase of existing health care facilities be reviewable under the CON law?

2. Should the law retain a role for the Health Systems Agency (or a private agency which would replace it)?

3. How should the provisions in the law about public participation be changed? In other words, what should the public hearing process be?

4. How should the criteria for review, or principles governing CON reviews, be changed? How specifically should such criteria be set forth in the law?

5. What should happen, under the Maine CON law, in the event of a repeal of the federal health planning law?

6. Should the State of Maine continue to participate in the Section 1122 program?

Tom

Tom Gorham

TG/kh

MAINE HOSPITAL ASSOCIATION

January 25, 1982

Christine Holden
Legislative Assistant
Committee on Health & Institutional Services
State House
Augusta, ME 04333

Dear Chris:

The following is our response to Senator Gill and Representative Nelson's request that each party to our CON Study Order Committee submit a list of those issues which have not yet been resolved with an indication of our priorty as to their level of importance to our undertaking:

1. Public Participation and Hearing Requirements
2. 1122 Program
3. Role of Health Systems Agency
4. Criteria and Standards for Review
5. Determination of Completeness of Application
6. Relationship between Maine CON law and Federal law
7. Sunset of Maine CON Act
8. Role of State Health Coordinating Council (SHCC)
9. Batching of CON Applications

Let me know if I can be of any further assistance.

Sincerely,

Ted Hussey

Ted Hussey
Senior Vice President

TH/bab
cc: W. Grant Heggie, Jr.
John P. Doyle

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AREAS OF NON-AGREEMENT RANKED IN DHS PRIORITY ORDER

Mandatory Changes

1. Maximums on approved capital expenditures. (See LD 939 § 19-2)
2. Proposed changes, within one year, to a previously approved project (not involving a cost overrun; LD 939 § 19-2).
3. Provision to permit batching where desirable.

Permissive Changes

1. Continuation of the Maine Certificate of Need Act if the National Health Planning and Resources Development Act of 1974, as amended, is repealed by Congress.
2. Acceptance of an application as complete
3. Review process (including provision for the discontinuation of the MHSA).
4. Role of the (M)SHCC and the SHP
5. Waiver of review (LD 939 § 12).

Prepared by the Department of Human Services
January 25, 1982

Areas of Agreement Regarding
Changes in the Maine Certificate
of Need Act

Nature of Change	Description of Change	Reference
Required	HMO provisions	LD 939 § 15-3 LD 939 § 17-2
Required	Required approvals to eliminate or prevent imminent safety hazards, etc.	LD 939 § 19-4
Permitted	Coordination of scope and process of Section 1122 reviews	language to be drafted
Permitted	Date of filing of letter of intent reduced from 60 days prior to receipt of application to 30 days	LD 718 § 5