

SECOND REGULAR SESSION New draft of: S.P. 384, L.D. 1358

ONE HUNDRED AND EIGHTH LEGISLATURE

Legislative Document

No. 2014

S. P. 653

In Senate, January 4, 1978 Reported by Minority of Committee on Health and Institutional Services pursuant to S. P. 599 and printed under Joint Rules No. 2

MAY M. ROSS, Secretary

STATE OF MAINE

IN THE YEAR OF OUR LORD NINETEEN HUNDRED SEVENTY-EIGHT

AN ACT Relating to Certificate of Need.

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

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; and

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

§ 303. Definitions

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

l. Ambulatory surgical facility. "Ambulatory surgical facility" means a facility, not part of a hospital, which provides surgical treatment to patients not requiring hospitalization. The term does not include the offices of private physicans 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 those 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:

2

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 such 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:

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;

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

E. The acquisition of any equipment by any person which involves a capital expenditure of \$75,000 or more and has been designated by the department pursuant to this section as subject to review under this Act.

For the purposes of this section, the department, after consultation with the Health

Systems Agency, shall designate in its rules and regulations as subject to review under this Act types of equipment:

(1) Which are associated with the diagnosis, treatment or rehabilitation of patients;

(2) Which contribute significantly to health care costs; and

(3) For which there is no demonstrated widespread need or for which there is insufficient data to demonstrate the need, or which would significantly reduce the utilization of similar equipment if the equipment were already available, and

2. Commitment for financing. No person shall enter into any commitment for financing a project which requires a certificate of need or incur an obligation for a project without having received a certificate of need.

§ 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 such 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

LEGISLATIVE DOCUMENT No. 2014

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 or 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 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 service; 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,

8

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

Appeals may be made from any final decision of the department following reconsideration, as provided in section 310, in accordance with Title 5, chapter 375, subchapter VII.

§ 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

10 LEGISLATIVE DOCUMENT No. 2014

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. Witholding 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. Witholding of funds

No health care facility or other provider shall be eligible to apply for or receive 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 the other action as may be appropriate to enforce this Act.

§ 321. Violation

A violation of any provision of this chapter or any rate, rule or regulation established hereunder shall be a civil violation for which a forfeiture not to exceed \$5,000 may be adjudged.

§ 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 the 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 of 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.

STATEMENT OF FACT

This bill was carried over from the First Regular Session and studied during the interim period by the Health and Institutional Services Committee.

The National Health Planning Resources Development Act of 1974 requires each state to establish a certificate of need program as a prerequisite for continuing to receive certain federal funds. This bill establishes a certificate of need program in Maine.

"Certificate of need" refers to a process which provides for a review and approval or denial of expenditures by health care facilities. The level and purpose of the expenditures and the scope of application of the term "health care facility" are specifically defined in the bill. In general, this bill follows the minimum requirements as set out in federal regulations.

This bill differs from the other report of the committee by requiring a certificate of need for expenditures on any equipment, exceeding \$75,000 which has been designated by the Department of Human Services as meeting criteria set out in the bill.

The general purpose of the bill is to encourage sound health care planning, and to avoid needless duplication of health care services facilities.