

MAINE STATE LEGISLATURE

The following document is provided by the
LAW AND LEGISLATIVE DIGITAL LIBRARY
at the Maine State Law and Legislative Reference Library
<http://legislature.maine.gov/lawlib>



Reproduced from scanned originals with text recognition applied
(searchable text may contain some errors and/or omissions)



120th MAINE LEGISLATURE

FIRST REGULAR SESSION-2001

Legislative Document

No. 1799

S.P. 619

In Senate, May 14, 2001

An Act to Strengthen the Certificate of Need Law.

Reference to the Committee on Health and Human Services suggested and ordered printed.

A handwritten signature in cursive script, reading 'Joy J. O'Brien'.

JOY J. O'BRIEN
Secretary of the Senate

Presented by President MICHAUD of Penobscot. (GOVERNOR'S BILL).
Cosponsored by Senators: GOLDTHWAIT of Hancock, LONGLEY of Waldo, SMALL of
Sagadahoc, TREAT of Kennebec, Representatives: BRUNO of Raymond, KANE of Saco.

2 G. Support the development and availability of health care
3 services regardless of the consumer's ability to pay;

4 H. Seek a balance, to the extent a balance assists in
5 achieving the purposes of this subsection, between
6 competition and regulation in the provision of health care;
7 and

8 I. Promote the development of primary and secondary
9 preventive health care services.

10 **§328. Definitions**

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

13 1. Access to care. "Access to care" means the timely
14 ability to obtain needed personal health services to achieve the
15 best possible health outcomes balanced by the health system's
16 resource limitations. Access to care may be influenced by many
17 factors, including, without limitation, travel, distance, waiting
18 time, available resources, availability of a source of care and
19 the health status of the population served.

20 2. Ambulatory surgical facility. "Ambulatory surgical
21 facility" means a facility, not part of a hospital, that provides
22 surgical treatment to patients not requiring hospitalization.
23 "Ambulatory surgical facility" does not include the offices of
24 private physicians or dentists, whether in individual or group
25 practice.

26 3. Annual operating costs. For purposes of section 329,
27 subsection 4, paragraph B, "annual operating costs" means the
28 total incremental costs to the institution that are directly
29 attributable to the addition of a new health service.

30 4. Capital expenditure. "Capital expenditure" means an
31 expenditure, including a force account expenditure or
32 predevelopment activities, that under generally accepted
33 accounting principles is not properly chargeable as an expense of
34 operation and maintenance and, for the purposes of this chapter,
35 includes capitalized interest on borrowed funds and the fair
36 market value of any property or equipment that is acquired under
37 lease or comparable arrangement or by donation.

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

41

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

6 7. Expenditure minimum for annual operating costs.
"Expenditure minimum for annual operating costs" means, for
8 services commenced after October 1, 1998, \$350,000 for the 3rd
fiscal year, including a partial first year.

10 8. Generally accepted accounting principles. "Generally
12 accepted accounting principles" means accounting principles
approved by the American Institute of Certified Public
14 Accountants.

16 9. Health care facility. "Health care facility" means a
hospital, psychiatric hospital, nursing facility, kidney disease
18 treatment center including a free-standing hemodialysis facility,
rehabilitation facility, ambulatory surgical facility,
20 independent radiological service center, independent cardiac
catheterization center or cancer treatment center. "Health care
22 facility" does not include the office of a private physician or
physicians or a dentist or dentists, whether in individual or
24 group practice.

26 10. Health maintenance organization. "Health maintenance
organization" means a public or private organization that:

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

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

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

44 11. Health need. "Health need" means a situation or a
46 condition of a person, expressed in health outcome measures such
as mortality, morbidity or disability, that is considered
48 undesirable and is likely to exist in the future.

2 12. Health planning. "Health planning" means data assembly
and analysis, goal determination and the formulation of action
4 recommendations regarding health services.

6 13. Health services. "Health services" means clinically
related services that are diagnostic, treatment, rehabilitative
8 services or nursing services provided by a nursing facility.
"Health services" includes alcohol abuse, drug abuse and mental
10 health services.

12 14. Health status. "Health status" means patient or
population measures, or both, of good and poor health practices,
14 rates of death and disease, both chronic and infectious, and the
prevalence of symptoms or conditions, or both, of illness and
16 wellness.

18 15. Hospital. "Hospital" means an institution that
primarily provides to inpatients, by or under the supervision of
20 physicians, diagnostic services and therapeutic services for
medical diagnosis, treatment and care of injured, disabled or
22 sick persons or rehabilitation services for the rehabilitation of
injured, disabled or sick persons. "Hospital" also includes
24 psychiatric and tuberculosis hospitals.

26 16. Major medical equipment. "Major medical equipment"
means a single unit of medical equipment or a single system of
28 components with related functions used to provide medical and
other health services that costs \$1,000,000 or more. "Major
30 medical equipment" does not include medical equipment acquired by
or on behalf of a clinical laboratory to provide clinical
32 laboratory services if the clinical laboratory is independent of
a physician's office and a hospital and has been determined to
34 meet the requirements of the United States Social Security Act,
Title XVIII, Section 1861(s), paragraphs 10 and 11. In
36 determining whether medical equipment costs more than \$1,000,000,
the cost of studies, surveys, designs, plans, working drawings,
38 specifications and other activities essential to acquiring the
equipment must be included. If the equipment is acquired for
40 less than fair market value, the term "cost" includes the fair
market value.

42 17. Nursing facility. "Nursing facility" means any
44 facility defined under section 1812-A.

46 18. Modification. "Modification" means the alteration,
improvement, expansion, extension, renovation or replacement of a
48 health care facility or health maintenance organization or
portions thereof, including the initial equipment, and the
50 replacement of equipment or existing buildings.

2 19. Obligation. An "obligation" for a capital expenditure
that is considered to be incurred by or on behalf of a health
care facility:

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

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

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

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

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

30 22. Predevelopment activity. "Predevelopment activity"
means any appropriately capitalized expenditure by or on behalf
32 of a health care facility made in preparation for the offering or
development of a new health service for which a certificate of
34 need would be required and arrangements or commitments made for
financing the offering or development of the new health service
36 and includes site acquisitions, surveys, studies, expenditures
for architectural designs, plans, working drawings and
38 specifications.

40 23. Primary and secondary preventive services. "Primary
preventive services" means health care services including,
42 without limitation, health education that seeks to prevent the
occurrence of disease or injury, generally reducing exposure or
44 risk factor levels that cause disease. "Secondary preventive
services" means health care services that seek to treat and
46 control the severity of disease processes in their early stages
before the onset of acute symptoms and events.

48 24. Project. "Project" means any acquisition, capital
50 expenditure, new health service or change in a health service.

2 predevelopment activity or other activity that requires a
3 certificate of need under section 329.

4 **25. Rehabilitation facility.** "Rehabilitation facility"
5 means an inpatient facility that is operated for the primary
6 purpose of assisting in the rehabilitation of disabled persons
7 through an integrated program of medical services and other
8 services that are provided under competent professional
9 supervision.

10 **26. Replacement equipment.** "Replacement equipment" means a
11 piece of capital equipment that replaces another piece of capital
12 equipment that performs essentially the same functions as the
13 replaced equipment.

14 **§329. Certificate of need required**

15 A person may not enter into any commitment for financing a
16 project that requires a certificate of need or incur an
17 expenditure for the project without having sought and received a
18 certificate of need, except that this prohibition does not apply
19 to obligations for financing conditioned upon the receipt of a
20 certificate of need or to obligations for predevelopment
21 activities.

22 A certificate of need from the department is required for:

23 **1. Transfer of ownership; acquisition by lease, donation,**
24 **transfer; acquisition of control.** Any transfer of ownership or
25 acquisition under lease or comparable arrangement or through
26 donation or any acquisition of control of a health care facility
27 under lease, management agreement or comparable arrangement or
28 through donation that would have required review if the transfer
29 or acquisition had been by purchase, except in emergencies when
30 that acquisition of control is at the direction of the department;

31 **2. Acquisitions of certain major medical equipment.**
32 Acquisitions of major medical equipment with a cost in the
33 aggregate of \$1,000,000 or more. The use of major medical
34 equipment on a temporary basis in the case of a natural disaster,
35 major accident or equipment failure and the use of replacement
36 equipment do not require a certificate of need;

37 **3. Capital expenditures.** Except as provided in subsection
38 6, the obligation by or on behalf of a health care facility of
39 any capital expenditure of \$2,000,000 or more. Capital
40 expenditures in the case of a natural disaster, major accident or
41 equipment failure for replacement equipment or for parking lots
42 and garages, information and communications systems and physician
43 office space do not require a certificate of need;

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

6 A. The obligation of any capital expenditures by or on
behalf of a health care facility of \$100,000 or more that is
8 associated with the addition of a health service that was
not offered on a regular basis by or on behalf of the health
10 care facility within the 12-month period prior to the time
the services would be offered; or

12 B. The addition of a health service that is to be offered
14 by or on behalf of a health care facility that was not
offered on a regular basis by or on behalf of the health
16 care facility within the 12-month period prior to the time
the services would be offered and that, for the 3rd fiscal
18 year of operation, including a partial first year, following
addition of that service, is projected to entail annual
20 operating costs of at least \$350,000.

22 A certificate of need is not required for a health care facility
that extends a current service within the defined primary service
24 area of the health care facility by purchasing within a 12-month
time period new equipment costing in the aggregate less than
26 \$1,000,000;

28 5. Changes in bed complement. An increase in the existing
licensed bed complement or an increase in the licensed bed
30 category of a health care facility greater than 10%;

32 6. Nursing facilities. The obligation by a nursing
facility, when related to nursing services provided by the
34 nursing facility, of any capital expenditures of \$500,000 or more.

36 A certificate of need is not required for a nursing facility to
convert beds used for the provision of nursing services to beds
38 to be used for the provision of residential care services. If
such a conversion occurs, public funds are not obligated for
40 payment of services provided in the converted beds;

42 7. Other circumstances. The following circumstances:

44 A. Any proposed use of major medical equipment to serve
inpatients of a hospital, if the equipment is not located in
46 a health care facility and was acquired without a
certificate of need, except acquisitions exempt from review
48 under subsection 2 or 3; or

2 B. If a person adds a health service not subject to review
4 under subsection 4, paragraph A and not subject to review
6 under subsection 4, paragraph B at the time it was
8 established and not reviewed and approved prior to
10 establishment at the request of the applicant, and its
12 actual 3rd fiscal year operating cost exceeds the
14 expenditure minimum for annual operating costs in the 3rd
16 fiscal year of operation following addition of these
18 services; and

20 8. Related projects. Any projects that the department
22 determines are related projects if such projects, considered in
24 the aggregate, would otherwise require a certificate of need
26 under this section.

28 **§330. Exceptions**

30 Notwithstanding section 329, the requirements of this Act do
32 not apply with respect to:

34 1. Healing through prayer. A health care facility operated
36 by a religious group relying solely on spiritual means through
38 prayer for healing;

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

50 3. Home health care services. Home health care services
52 offered by a home health care provider;

54 4. Hospice. Hospice services and programs;

56 5. Assisted living. Assisted living programs and services
58 regulated under chapter 1665; and

60 6. Existing capacity. The use by an ambulatory surgical
62 facility licensed on January 1, 1998 of capacity in existence on
64 January 1, 1998.

66 **§331. Subsequent review**

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

2 1. Criteria for subsequent review. The following activities
3 require subsequent review and approval, if the department has
4 previously issued a certificate of need and if within 3 years
5 after the approved activity is undertaken:

6 A. There is a significant change in financing;

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

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

14 D. There is a change in the site or the location of the
15 proposed health care facility; or

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

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

26 A. The nature of the proposed change;

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

31 C. Other pertinent detail subject to the procedures and
32 criteria set forth in section 334.

36 The department shall, within 30 days of receipt of the
37 information, advise that person in writing whether the proposed
38 change is approved. If not approved, the application must be
39 treated as a new application under this Act. If approved, the
40 department shall amend the certificate of need as appropriate.

42 **§332. Procedures after voluntary nursing facility reductions**

44 1. Procedures. A nursing facility that voluntarily reduces
45 the number of its licensed beds for any reason except to create
46 private rooms may convert the beds back and thereby increase the
47 number of nursing facility beds to no more than the previously
48 licensed number of nursing facility beds, after obtaining a
49 certificate of need in accordance with this section, as long as
50 the nursing facility has been in continuous operation and has not

2 been purchased or leased. To convert beds back to nursing
3 facility beds under this subsection, the nursing facility must:

4 A. Give notice of its intent to preserve conversion options
5 to the department no later than 30 days after the effective
6 date of the license reduction; and

8 B. Obtain a certificate of need to convert beds back under
9 section 334, except that, if no construction is required for
10 the conversion of beds back, the application must be
11 processed in accordance with subsection 2.

12 2. Expedited review. Except as provided in subsection 1,
13 paragraph B, an application for a certificate of need to reopen
14 beds reserved in accordance with this section must be processed
15 on an expedited basis in accordance with rules adopted by the
16 department providing for shortened review time and for a public
17 hearing if requested by a directly affected person. The
18 department shall consider and decide upon these applications as
19 follows:

22 A. Review of applications that meet the requirements of
23 this section must be based on the requirements of section
24 334, subsection 3, except that the determinations required
25 by section 334, subsection 3, paragraph B must be based on
26 the historical costs of operating the beds and must consider
27 whether the projected costs are consistent with the costs of
28 the beds prior to closure, adjusted for inflation; and

30 B. Conversion of beds back under this section must be
31 requested within 4 years of the effective date of the
32 license reduction. For good cause shown, the department may
33 extend the 4-year period for conversion for one additional
34 4-year period.

36 3. Effect on other review proceedings. Nursing facility
37 beds that have been voluntarily reduced under this section must
38 be counted as available nursing facility beds for the purpose of
39 evaluating need under section 334 as long as the nursing facility
40 retains the ability to convert them back to nursing facility use
41 under the terms of this section, unless the nursing facility
42 indicates, in response to an inquiry from the department in
43 connection with an ongoing project review, that it is unwilling
44 to convert them to meet a need identified in that project review.

46 4. Rulemaking. Rules adopted pursuant to this section are
47 major substantive rules as defined by Title 5, chapter 375,
48 subchapter II-A.

50 **§333. Nursing facility projects**

2 Nursing facility projects that propose to add new nursing
4 facility beds to the inventory of nursing facility beds within
6 the State may be grouped for competitive review purposes
8 consistent with appropriations made available for that purpose by
10 the Legislature. A nursing facility project that proposes
12 renovation, replacement or other actions that will increase
14 Medicaid costs may be approved only if appropriations have been
16 made by the Legislature expressly for the purpose of meeting
18 those costs, except that the department may approve, without a
20 prior appropriation for the express purpose, projects to reopen
22 beds previously reserved by a nursing facility through a
24 voluntary reduction pursuant to section 332, if the annual total
26 of reopened beds approved does not exceed 100.

16 **§334. Approval; record**

18 1. Basis for decision. The commissioner shall approve an
20 application for a certificate of need if the commissioner
22 determines that the project meets the conditions set forth in
24 subsection 3.

26 The commissioner shall make a determination on whether conditions
28 set forth in subsection 3 have been met based solely upon the
30 record created by the department in the course of its review of
32 an application.

34 Except as otherwise provided in this Act, only a person who is a
36 full-time employee of the department with responsibilities for
38 the certificate of need program, a consultant to the project on
40 matters or a member of the Maine Health Policy Advisory Committee
42 pursuant to section 337 may communicate with the commissioner
44 regarding any application for a certificate of need or any letter
46 of intent. Nothing in this section limits the authority and
48 obligation of the staff of the department with responsibility for
50 the certificate of need program to meet with, or otherwise
communicate with, any person who is not a department employee and
who wants to provide information to be considered in connection
with an application for a certificate of need. A person who is
not a department employee may not communicate with any department
staff regarding the merits of a certificate of need application
except for the purpose of placing that person's views in the
application record. All communications with department staff
responsible for the certificate of need program from any person,
who is not a department employee, that the department staff
reasonably believes is intended to influence the analyses
relating to or the decision regarding any application for
certificate of need must be memorialized by that department staff
and that memorial must be made part of the application record.

2 The commissioner's determination must be in writing and must
4 contain appropriate references to the record. If the application
6 is denied, the decision must specifically address comments
8 received and made part of the record that favor granting the
application. If the application is approved, the decision must
specifically address comments received and made part of the
record that favor denial of the application.

10 2. Record. The record created by the department in the
course of its review of an application must contain the following:

12 A. The application and all other materials submitted by the
14 applicant for the purpose of being made part of the record;

16 B. All information generated by or for the department in
18 the course of gathering material to assist the commissioner
20 in determining whether the conditions for granting an
22 application for a certificate of need have or have not been
24 met. This information may include, without limitation, the
report of consultants, memoranda of meetings or
conversations with any person interested in commenting on
the application, letters, memoranda and documents from other
interested agencies of State Government and memoranda
describing officially noticed facts;

26 C. Stenographic or electronic recordings of any public
28 hearing held by the commissioner or the staff of the
30 department at the direction of the commissioner regarding
the application;

32 D. Stenographic or electronic recording of any public
informational meeting held by the department pursuant to
34 section 336, subsection 4;

36 E. Any documents submitted by any person for the purpose of
38 being made part of the record regarding any application for
40 a certificate of need or for the purpose of influencing the
42 outcome of any analyses or decisions regarding an
application for certificate of need, except documents that
have been submitted anonymously. Such source-identified
documents automatically become part of the record upon
receipt by the department; and

44 F. Preliminary and final analyses of the record prepared by
46 the staff.

48 The record first opens on the day the department publishes its
50 notice that an application for a certificate of need has been
filed. From that day, all of the record is a public record, and
any person may examine that record and purchase copies of any or

2 all of that record during the normal business hours of the
3 department.

4 The record is closed 10 days after a public notice of the closing
5 of the record has been published in the a newspaper of general
6 circulation in Kennebec County, in a newspaper published within
7 the service area of the project and on the department's publicly
8 accessible site on the Internet, as long as such notice is not
9 published until after the preliminary staff analysis of the
10 application is made part of the record.

11 3. Review; approval. Except as provided in section 335,
12 the commissioner shall issue a certificate of need if the
13 commissioner determines and makes specific written findings
14 regarding that determination that:

15 A. The applicant is fit, willing and able to provide the
16 proposed services at the proper standard of care as
17 demonstrated by, among other factors, whether the quality
18 of any health care provided in the past by the applicant or
19 a related party under the applicant's control meets industry
20 standards;
21 standards;

22 B. The economic feasibility of the proposed services is
23 demonstrated in terms of the:

24 (1) Capacity of the applicant to support the project
25 financially over its useful life, in light of the rates
26 the applicant expects to be able to charge for the
27 services to be provided by the project; and
28 services to be provided by the project; and

29 (2) Applicant's ability to establish and operate the
30 project in accordance with existing and reasonably
31 anticipated future changes in federal, state and local
32 licensure and other applicable or potentially
33 applicable rules;
34 applicable rules;

35 C. There is a public need for the proposed services; as
36 demonstrated by, among other things:

37 (1) Whether, and the extent to which, the project will
38 substantially address specific health problems as
39 measured by health needs in the area to be served by
40 the project;
41 the project;

42 (2) Whether the project will have a positive impact on
43 the health status indicators of the population to be
44 served;
45 served;
46 served;
47 served;
48 served;

2 (3) Whether the services affected by the project will
be accessible to all residents of the area proposed to
be served; and

4 (4) Whether the project will provide demonstrable
improvements in quality and outcome measures applicable
to the services proposed in the project;

8 D. The proposed services are consistent with the orderly
and economic development of health facilities and health
resources for the State as demonstrated by:

12 (1) The impact of the project on total health care
expenditures after taking into account, to the extent
practical, both the costs and benefits of the project
and the competing demands in the local service area and
statewide for available resources for health care;

18 (2) The availability of state funds to cover any
increase in state costs associated with utilization of
the project's services; and

22 (3) The likelihood that more effective, more
accessible or less costly alternative technologies or
methods of service delivery may become available; and

26 E. The applicant will dedicate the equivalent of 5% of the
first full-year operating expenses and 3% of operating
expenses each year thereafter that the project is in service
to measurable primary or secondary prevention programs
relevant to the service or technology of the certificate of
need application and available at no cost to uninsured
individuals with incomes at or below 150% of the federal
poverty level.

30 4. Conditional approvals. The commissioner may grant an
application subject to conditions that relate to the criteria for
approval of the application.

36 5. Emergency certificate of need. Upon the written or, if
more practical, the oral request of an applicant, the department
shall immediately determine whether an emergency situation exists
and upon finding that an emergency situation does exist shall
issue a certificate of need for a project necessary on account of
the emergency situation. The scope of the certificate of need may
not exceed that which is necessary to remedy or otherwise
effectively address the emergency situation. The certificate of
need may be subject to conditions consistent with the purpose of
this Act that do not interfere with the applicant's ability to
respond effectively to the emergency.

2 The commissioner shall find an emergency situation exists
4 whenever the commissioner finds that an applicant has
demonstrated:

6 A. The necessity for immediate or temporary relief due to a
8 natural disaster, a fire, an unforeseen safety
10 consideration, a major accident, equipment failure,
foreclosure, receivership or an action of the department or
other circumstances determined appropriate by the department;

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

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

20 **§335. Simplified review and approval process**

22 Notwithstanding the requirements set forth in section 334,
24 the department shall conduct a simplified review and approval
process in accordance with this section.

26 1. Maintenance projects. The commissioner shall issue a
28 certificate of need for a project that primarily involves the
maintenance of a health facility if the commissioner determines
30 that the project:

32 A. Will result in no or a minimal additional expense to the
public or to the health care facility's clients;

34 B. Will be in compliance with other applicable state and
36 local laws and regulations; and

38 C. Will significantly improve or, in the alternative, not
significantly adversely affect the health and welfare of any
40 person currently being served by the health care facility.

42 2. Life safety codes; previous certificate of need. The
commissioner shall issue a certificate of need for a project that
44 is required solely to meet federal, state or local life safety
codes if the project involves a health facility, major medical
46 equipment or a new health service that has previously received a
certificate of need.

48 3. Acquisition of control. The commissioner shall issue a
certificate of need for a project that involves the acquisition
50 of control of a health facility when the acquisition consists of

2 a management agreement or similar arrangement and primarily
3 involves the day-to-day operation of the facility in its current
4 form, if the commissioner determines that:

6 A. The applicant is fit, willing and able to provide the
7 project services at the proper standard of care as
8 demonstrated by, among other factors, whether the quality of
9 health care provided by the applicant or a related party
10 under the applicant's control meets or in the past met
11 industry standards; and

12 B. The project is economically feasible in light of its
13 impact on:

14 (1) The operating budget of the facility and the
15 applicant;

18 (2) The applicant's ability to establish and operate
19 the facility in accordance with federal and state
20 licensure rules; and

22 (3) The applicant's ability to operate the facility
23 without increases in the facility's rates beyond those
24 that would otherwise occur absent the acquisition.

26 4. Capital expenditures. The commissioner shall issue a
27 certificate of need for a proposed capital expenditure upon
28 determining that:

30 A. The capital expenditure is required to eliminate or
31 prevent imminent safety hazards, as defined by applicable
32 fire, building or life safety codes and regulations; to
33 comply with state licensure standards; or to comply with
34 accreditation or certification standards that must be met to
35 receive reimbursement under the United States Social
36 Security Act, Title XVIII or payments under a state plan for
37 medical assistance approved under Title XIX of that Act;

38 B. The economic feasibility of the project is demonstrated
39 in terms of its effects on the operating budget of the
40 applicant, including its existing rate structure;

42 C. There remains a public need for the service to be
43 provided; and

46 D. The corrective action proposed by the applicant is the
47 most cost effective alternative available under the
48 circumstances.

50 **§336. Application process for certificate of need**

2 1. Letter of intent. Prior to filing an application for a
certificate of need, an applicant shall file a letter of intent
4 with the department. The letter of intent forms the basis for
determining the applicability of this chapter to the proposed
6 expenditure or action. A letter of intent is deemed withdrawn
one year after receipt by the department, unless sooner
8 superseded by an application, except that the applicant is not
precluded from resubmitting the same letter of intent.

10 2. Application filed. Upon a determination by the
12 department that a certificate of need is required for a proposed
expenditure or action, an application for a certificate of need
14 must be filed with the department if the applicant wishes to
proceed with the project. Prior to filing a formal application
16 for a certificate of need, the applicant shall meet with the
department staff in order to assist the department in
18 understanding the application and to receive technical assistance
concerning the nature, extent and format of the documentary
20 evidence, statistical data and financial data required for the
department to evaluate the proposal. Prior to the technical
22 assistance meeting, but subsequent to receipt of the letter of
intent, the department shall issue a letter or checklist, or
24 both, to an applicant that stipulates and clarifies what will be
required in the application. The department may not accept an
26 application for review until the applicant has satisfied this
technical assistance requirement. The technical assistance
28 meeting must take place within 30 days after receipt of the
letter of intent.

30 3. Application content. An application for a certificate of
32 need must describe with specificity how the proposed project
meets each of the conditions for granting a certificate of need
34 required by this Act. A statement or statements that the project
will meet the conditions without supporting facts backed by
36 relevant documentation and analyses constitute sufficient cause
to deny the application. An application subject to full review
38 must contain, among other information:

40 A. Measures of health status relevant to the services or
42 technology of the application in the service area of the
applicant. These measures must, to the extent possible, be
44 the same as those contained in relevant reports issued by
the United States Department of Health and Human Services;

46 B. Valid and replicable quantitative measures of public
48 health need relevant to the new services or technology in
the service area of the applicant for the services. The
50 department may adopt a specific set of measures for certain
services when there is consensus in the literature;

2 C. Quality assurance processes, including measures to be
3 used to assess the new services or technology. The
4 applicant shall specify the quality assurance process
5 including the measures to be used, the time period for
6 reporting and the mechanism that will be used to disseminate
7 quality assurance information to the State and the public.
8 Quality assurance information that the applicant does not
9 consider appropriate for public dissemination must be
10 justified. When possible, quality measures must be similar
11 to those required by hospital accreditation organizations;

12
13 D. Current and planned prevention programs relevant to the
14 services or technology of the application and the population
15 to be served. To the extent possible, this information must
16 contain effectiveness measures for existing and planned
17 programs; and

18
19 E. Information as to how the proposed services or
20 technology fits into any relevant published health planning
21 report specifically identified by the department.

22
23 **4. Public notice; public informational meeting.** Within 5
24 business days of the filing of a certificate by an applicant that
25 a complete certificate of need application is on file with the
26 department, public notice that the application has been filed and
27 that a public informational meeting must be held regarding the
28 application must be given by publication in a newspaper of
29 general circulation in Kennebec County and in a newspaper
30 published within the service area in which the proposed
31 expenditure will occur. The notice must also be provided to all
32 persons who have requested notification by means of asking that
33 their names be placed on a mailing list maintained by the
34 department for this purpose. This notice must include:

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

37 B. A description of the review process and schedule;

38
39 C. A statement that any person may examine the application,
40 submit comments in writing to the department regarding the
41 application, and examine the entire record assembled by the
42 department at any time from the date of publication of the
43 notice until the application process is closed for comment;
44 and
45 and

46
47 D. The time and location of the public informational
48 meeting and a statement that any person may appear at the
49 meeting to question the applicant regarding the project or
50 the project.

2 the department regarding the conditions that the applicant
3 must satisfy in order to receive a certificate of need for
4 the project.

5 An application is certified as complete when the applicant
6 delivers to the department a certification in writing that states
7 that the application should be considered complete by the
8 department. Nothing in the foregoing sentence precludes an
9 applicant from submitting information subsequent to the
10 applicant's certification that is responsive to any concern,
11 issue, question or allegation of facts contrary to those in the
12 application by the department or any person whether or not those
13 concerns, issues, questions or allegations have been made part of
14 the record.

15 The department shall make an electronic or stenographic record of
16 the public informational meeting.

17 5. Voluntary withdrawal of application. During the review
18 period, prior to the date that department staff submit a final
19 report to the commissioner, an applicant may withdraw an
20 application without prejudice. Written notice of the withdrawal
21 must be submitted to the department. A withdrawn application may
22 be resubmitted at a later date, as a new application, requiring a
23 new letter of intent and new filing fees, docketing and review.

24 6. Filing fee. A nonrefundable filing fee must be paid at
25 the time an application is filed with the department.

26 A. The department shall establish minimum and maximum
27 filing fees, pursuant to section 341, to be paid per
28 application.

29 B. If the approved capital expenditure or operating cost
30 upon which the fees were based is higher than the initially
31 proposed capital expenditure, then the filing fee must be
32 recalculated and the difference in fees, if any, must be
33 paid before the certificate of need may be issued.

34 **§337. Maine Health Policy Advisory Committee**

35 The commissioner may establish a Maine Health Policy
36 Advisory Committee to:

37 1. Review. Review proposed rules, criteria, standards and
38 procedures; and

39 2. Evaluate. Evaluate new services, technology or research
40 that could affect the cost, quality and access to care for
41 residents of the State and that results, or is likely to or
42 is likely to affect the cost, quality and access to care for
43 residents of the State and that results, or is likely to or
44 is likely to affect the cost, quality and access to care for
45 residents of the State and that results, or is likely to or
46 is likely to affect the cost, quality and access to care for
47 residents of the State and that results, or is likely to or
48 is likely to affect the cost, quality and access to care for
49 residents of the State and that results, or is likely to or
50 is likely to affect the cost, quality and access to care for

2 should result, in keeping with the intent of this Act, in a
3 certificate of need application. This evaluation may involve
4 holding public meetings.

6 **§338. Review process**

8 **1. Review process.** The review process consists of an
9 evaluation of the project application for a certificate of need
10 by the department in light of:

12 A. The application itself;

14 B. Material collected or developed by or for the department
15 staff to test the assertions in the application; and

16 C. All comments received by any person regarding the
17 project and any other material made part of the record.

18 **2. Public hearing.** The commissioner or the commissioner's
19 designee may hold a public hearing regarding the application. An
20 electronic or stenographic record of the public hearing must be
21 made part of the record.

24 **3. Preliminary staff analyses.** The department staff shall
25 provide, as soon as practicable, its preliminary analyses of the
26 application and the record to the applicant, the commissioner and
27 any interested person. Notice of the availability of the analyses
28 must be published in the Kennebec Journal and a newspaper of
29 general circulation serving the area in which the project is to
30 be located and on the department's publicly accessible site on
31 the Internet.

32 **4. Final department staff analysis.** A final department
33 staff analysis must be submitted to the commissioner, together
34 with the documentary record described in section 334, subsection
35 2, as soon as practicable after the closing of the record.

38 **5. Reviews.** To the extent practicable, a review must be
39 completed and the commissioner shall make a decision within 90
40 days after the application has been certified as complete by the
41 applicant. The department shall establish criteria for
42 determining when it is not practicable to complete a review
43 within 90 days. Whenever it is not practicable to complete a
44 review within 90 days, the department may extend the review
45 period for up to an additional 60 days.

46 The department may delay action on an otherwise complete
47 application for up to 180 days from the time the application has
48 been certified as complete by the applicant if the department
49 finds that a public necessity exists. For purposes of this
50 section, the department may delay action on an otherwise complete

2 subsection, the department shall find that a public necessity
3 exists if:

4 A. The application represents a new service or technology
5 not previously provided within the State;

6 B. The application represents a potential significant
7 impact on health care system costs;

8 C. The application represents a new service or technology
9 for which a health care system need has not been previously
10 established; or

11 D. There are several applications for the same or similar
12 projects before the department.

13 The department shall notify in writing the applicant and any
14 other person who has requested in writing information regarding
15 the application of the delay.

16 **§338. Reconsideration**

17 1. Reconsideration. Any person directly affected by a
18 review may, for good cause shown, request in writing a hearing
19 for the purpose of reconsideration of the decision of the
20 department to issue or to deny a certificate of need. The
21 department, if it determines that good cause has been
22 demonstrated, shall hold a hearing to reconsider its decision. A
23 request for hearing for consideration must be received within 30
24 days of the department's decision. If the department determines
25 that good cause for a hearing has been demonstrated, the hearing
26 must commence within 30 days of receipt of the request. A
27 decision must be rendered within 60 days of the commencement of
28 the hearing. The decision may be rendered beyond this time
29 period by mutual consent of the parties. For purposes of this
30 section, a request for a hearing is considered to show good cause
31 if it:

32 A. Presents significant, relevant information not
33 previously considered by the department;

34 B. Demonstrates that there have been significant changes
35 in factors or circumstances relied upon by the department in
36 reaching its decision;

37 C. Demonstrates that the department has materially failed
38 to follow its adopted procedures in reaching its decision; or

39 D. Provides other bases for a hearing that the department
40 has determined constitute good cause.

2 2. "Person directly affected by a review" defined. For
3 purposes of this section, a "person directly affected by a
4 review" includes:

6 A. The applicant;

8 B. A group of 10 taxpayers residing or located within the
9 health service area served or to be served by the applicant;

10 C. A health care facility, a health maintenance
11 organization or a health care practitioner that can
12 demonstrate that it provides similar services or, by timely
13 filing a letter of intent with the department for inclusion
14 in the record, has indicated an intention to provide similar
15 services in the future to patients residing in the health
16 service area and whose services would be directly and
17 substantially affected by the application under review;

20 D. A 3rd-party payor, including, without limitation, a
21 health maintenance organization, who pays health care
22 facilities for services in the health service area in which
23 the project is proposed to be located and whose payments
24 would be directly and substantially affected by approval or
25 disapproval of the application under review; and

26 E. A person who can demonstrate a direct and substantial
27 effect upon that person's health care as a result of
28 approval or disapproval of an application for a certificate
29 of need.

32 **§340. Remedy**

34 Any person aggrieved by a final decision of the department
35 made under the provisions of this Act is entitled to review in
36 accordance with Title 5, chapter 375, subchapter VII. A decision
37 of the department to issue a certificate of need or to deny an
38 application for a certificate of need is not considered final
39 until the department has taken final action on a request for
40 reconsideration under section 339.

42 A decision by the department is not final when opportunity
43 for reconsideration under section 339 exists with respect to
44 matters involving new information or changes in circumstances.
45 When new information or changes in circumstances are not alleged
46 by the applicant or other person aggrieved by the decision, a
47 person aggrieved by a decision of the department may, at its
48 option, seek reconsideration under section 339 or may seek direct
49 judicial review under this section.

2 In civil actions involving competitive reviews of proposals
3 to construct new nursing facility beds, the court shall require
4 the party seeking judicial review to give security in such sums
5 as the court determines proper for the payment of costs and
6 damages that may be incurred or suffered by any other party who
7 is found to have been wrongfully delayed or restrained from
8 proceeding to implement the certificate of need, except that, for
9 good cause shown and recited in the order, the court may waive
10 the giving of security. A surety upon a bond or undertaking under
11 this paragraph submits the surety to the jurisdiction of the
12 court and irrevocably appoints the clerk of the court as the
13 agent for the surety upon whom any papers affecting liability on
14 the bond or undertaking may be served. The liability of the
15 surety may be enforced on motion without the necessity of an
16 independent action. The motion and such notice of the motion as
17 the court prescribes may be served on the clerk of the court who
18 shall mail copies to the persons giving the security if their
19 addresses are known.

20 **§341. Rules**

21 The department shall adopt any rules, standards, criteria,
22 plans or procedures that may be necessary to carry out the
23 provisions and purposes of this Act. The department shall
24 provide for public notice and hearing on all proposed rules,
25 standards, criteria, plans, procedures or schedules pursuant to
26 Title 5, chapter 375. Unless otherwise provided by this chapter,
27 rules adopted pursuant to this chapter are routine technical
28 rules as defined by Title 5, chapter 375, subchapter II-A. The
29 department is authorized to accept any federal funds to be used
30 for the purposes of carrying out this chapter.

31 **§342. Public information**

32 The department shall prepare and publish at least annually a
33 report on its activities conducted pursuant to this Act.

34 **§343. Conflict of interest**

35 In addition to the limitations of Title 5, section 18, a
36 member or employee of the department who has a substantial
37 economic or fiduciary interest that would be affected by a
38 recommendation or decision to issue or deny a certificate of need
39 or who has a close relative or economic associate whose interest
40 would be so affected is ineligible to participate in the review,
41 recommendation or decision-making process with respect to any
42 application for which the conflict of interest exists.

43 **§344. Division of project to evade cost limitation prohibited**

44

2 No health care facility or other party required to obtain a
3 certificate of need may separate portions of a single project
4 into components, including, but not limited to, site facility and
5 equipment, to evade the cost limitations or other requirements of
6 section 329.

8 **§345. Scope of certificate of need**

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

14 2. Maximum expenditure. In issuing a certificate of need,
15 the department shall specify the maximum capital expenditures
16 that may be obligated under this certificate. The department
17 shall prescribe, by rules adopted pursuant to section 341, the
18 method to be used to determine capital expenditure maximums,
19 establish procedures to monitor capital expenditures obligated
20 under certificates and establish procedures to review projects
21 for which the capital expenditure maximum is exceeded or expected
22 to be exceeded.

24 3. Periodic review. After the issuance of a certificate of
25 need, the department shall periodically review the progress of
26 the holder of the certificate in meeting the timetable for making
27 the service or equipment available or for completing the project
28 specified in the approved application. A certificate of need
29 expires if the project for which the certificate has been issued
30 is not commenced within 12 months following the issuance of the
31 certificate. The department may grant an extension of a
32 certificate for an additional specified time not to exceed 12
33 months if good cause is shown why the project has not commenced.
34 The department may require evidence of the continuing feasibility
35 and availability of financing for a project as a condition for
36 extending the life of the certificate. In addition if on the
37 basis of its periodic review of progress under the certificate,
38 the department determines that the holder of a certificate is not
39 otherwise meeting the timetable and is not making a good faith
40 effort to meet it, the department may, after a hearing, withdraw
41 the certificate of need. The department shall in accordance with
42 section 341 adopt rules for withdrawal of certificates of need.
43 The applicant shall issue to the department periodic reports as
44 designated in the certificate of need approval notification on
45 the impact of the service on the health status, quality of care
46 and health outcomes of the population served. These reports may
47 not be in less than 12-month intervals following the start of
48 service approved in the certificate of need.

50 **§346. Withholding of license**

2 No new health care facility, as defined in section 328, is
3 eligible to obtain a license under the applicable state law if
4 the facility has not obtained a certificate of need as required
5 by this chapter. The license of any facility does not extend to
6 include and may not otherwise be deemed to allow the delivery of
7 any services, the use of any equipment that has been acquired,
8 the use of any portion of a facility or any other change for
9 which a certificate of need as required by this Act has not been
10 obtained. Any unauthorized delivery of services, use of equipment
11 or a portion of a facility or other change is in violation of the
12 respective chapter under which the facility is licensed.

13 **§347. Withholding of funds**

14
15 No health care facility or other provider may be eligible to
16 apply for or receive any reimbursement, payment or other
17 financial assistance from any state agency or other 3rd-party
18 payor, either directly or indirectly, for any capital expenditure
19 or operating costs attributable to any project for which a
20 certificate of need as required by this Act has not been
21 obtained. For the purposes of this section, the department shall
22 determine the eligibility of a facility to receive reimbursement
23 for all projects subject to the provisions of this Act.

24 **§348. Injunction**

25
26 The Attorney General, upon the request of the department,
27 shall seek to enjoin any project for which a certificate of need
28 as required by this Act has not been obtained and shall take any
29 other action as may be appropriate to enforce this Act.

30 **§349. Penalty**

31
32 Whoever violates any provision of this chapter or any rule,
33 rule or regulation pursuant to this Act is subject to a civil
34 penalty payable to the State of not more than \$5,000 to be
35 recovered in a civil action. The department may hold these funds
36 in a special revenue account that may be used only to support
37 certificate of need reviews, such as for hiring expert analysts
38 on a short-term consulting basis.

39 **§350. Implementation reports**

40
41 The holder of a certificate of need shall make a written
42 report at the end of each 6-month period following its issuance
43 regarding implementation activities, obligations incurred and
44 expenditures made and any other matters as the department may
45 require. A summary report must be made when the service or
46 services for which the certificate of need was issued becomes
47 operational. For a period of one year following the
48 operational. For a period of one year following the
49 operational. For a period of one year following the
50 operational. For a period of one year following the

2 implementation of the service or services for which the
3 certificate of need was granted, the provider shall file, at
4 6-month intervals, reports concerning the costs and utilization.
5 The department, in its rules, shall prescribe the form and
6 contents of the reports. Any holder of a certificate of need that
7 has been issued for the construction or modification of a
8 facility or portion of a facility shall file final plans and
9 specifications for the project with the department within 6
10 months, or any other time that the department may allow,
11 following the issuance of the certificate for review by the
12 department to determine that the plans and specifications are in
13 compliance with the certificate of need and are in compliance
14 with applicable licensure, life safety code and accreditation
15 standards. The department may revoke any certificate of need it
16 has issued when the person to whom it has been issued fails to
17 file reports or plans and specifications required by this section
18 on a timely basis. The department shall review services that
19 fall below the required volume and quality standards of a
20 certificate of need.

21 **Sec. 3. Preview.** The Department of Human Services shall
22 review its rules concerning Certificate of Need Health Care
23 Facility/Agency Space and Needs Guidelines for which the
24 department's Bureau of Medical Services, Division of Licensing
25 and Certification has established service-specific licensure
26 requirements and revise them as necessary to ensure that those
27 guidelines are identical to the licensure requirements.

28 **Sec. 4. Revisor's review; cross-references.** The Revisor of
29 Statutes shall review the Maine Revised Statutes and include in
30 the errors and inconsistencies bill submitted to the Second
31 Regular Session of the 120th Legislature pursuant to Title 1,
32 section 94, any sections necessary to correct and update any
33 cross-references in the statutes to provisions of law repealed in
34 this Act.

35 SUMMARY

36
37
38
39 **40** This bill repeals and replaces the Maine Certificate of Need
41 Act of 1978. This bill requires that health prevention services
42 be part of reviewable projects, clarifies when certificate of
43 need waivers can be granted, clarifies the ability of the
44 Department of Human Services to impose conditions on a
45 certificate of need, changes certain dates, eliminates the
46 Certificate of Need Advisory Committee and authorizes the
47 commissioner to establish a new advisory committee.
48