MAINE STATE LEGISLATURE

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FIRST REGULAR SESSION	
AND TWELFTH LEGISLATURE	
	No. 1264
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ent of Human Services pursuant to J	oint Rule
	the Senate
Najarian of Cumberland and Represen	tative
ATE OF MAINE	
YEAR OF OUR LORD	
the Maine Certificate of Note Inconsistencies Related cutory Provisions and to effective Development of equiring Acquisition of Medical Equipment.	eed
People of the State of Ma	ine as
§303, sub-§§2, 10 and 11, 687, §1, are repealed.	as en-
any business entity or so public or private, prop which is engaged in pro	ubdivi- rietary oviding e, pre-
	In Senate, Appendix of Human Services pursuant to June on Human Resources suggested and JOY J. O'BRIEN, Secretary of Kennebec. Najarian of Cumberland and Represent CATE OF MAINE CYEAR OF OUR LORD UNDRED AND EIGHTY-FIVE The Maine Certificate of Note Inconsistencies Related Sutory Provisions and to effective Development of Equiring Acquisition of Indical Equipment. People of the State of Maine Sand, Sub-§§2, 10 and 11, 687, §1, are repealed. A §303, sub-§§2, 10 and 11, 687, §1, are repealed. A §303, sub-§§11-A, as enaity, §6, is amended to read the care provider. "Home is any business entity or so public or private, proposehabilitative, maintenance is public that ive, maintenance is public that ive, maintenance is publicative, maintenance is pu

- 1 sional nursing and at least one other therapeutic 2 service, such as physical therapy, occupational 3 therapy, speech pathology, home health aides, nurse 4 assistants, medical social work and nutritionist ser-5 vices, either directly or through contractual agree-6 ment, in a client's place of residence. This term 7 does not apply to any sole practitioner providing 8 private duty nursing services or other restorative, 9 rehabilitative, maintenance, preventive or health 10 promotion services in a client's place or of resi-11 dence.
- 12 Sec. 3. 22 MRSA §303, sub-§21, as enacted by PL 13 1977, c. 687, §1, is amended to read:
- 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 Office of Health Planning
 and Development, within the Bureau of Medical
 Services.
- 21 Sec. 4. 22 MRSA §304-A, sub-§2, as enacted by PL 22 1981, c. 705, Pt. V, §16, is repealed.
- 23 Sec. 5. 22 MRSA §304-A, sub-§2-A is enacted to 24 read:
- 25 2-A. Acquisitions of major medical equipment.
 26 The acquisition by any person of major medical equipment that costs \$300,000 or more, as defined in section 303, subsection 12-A.
- There shall be a waiver for the use of major medical equipment on a temporary basis as provided in section 308, subsection 4;
- 32 Sec. 6. 22 MRSA §304-A, sub-§9, ¶B, as amended 33 by PL 1983, c. 579, §8, is further amended to read:

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B. If a person adds a health service not subject to review under subsection 4, paragraph A or C and which was not deemed subject to review under subsection 4, paragraph B at the time it was established and which was not reviewed and approved prior to establishment at the request of the ap-

- plicant, and its actual 3rd fiscal year operating cost, as adjusted by an appropriate inflation deflator promulgated by the department, after consultation with the eemmission, Maine Health Care Finance Commission, exceeds the expenditure minimum for annual operating cost in the 3rd fiscal year of operation following addition of these services.
- 9 Sec. 7. 22 MRSA §304-B, sub-§2, as enacted by PL 10 1981, c. 705, Pt. V, §17, is amended to read:
- 2. <u>Procedures for subsequent review.</u> Any person proposing to undertake any activity requiring subsequent review and approval shall file with the department, within 30 days of the time that person first has actual knowledge of the circumstances requiring subsequent review, a notice setting forth the following information:
- 18 A. The nature of the proposed change;
- B. The rationale for the change including, where appropriate, an explanation of why the change was not set forth in the original application or letter of intent; and
- C. Other pertinent detail subject to the procedures and criteria set forth in section 309.
- 25 The department shall, within 30 days of receipt of the information, advise that person in writing wheth-26 27 er the proposed change is approved. If not approved, 28 the application shall be treated as incomplete 29 reviewed in accordance with the application proce-30 dures in section 306-A, subsection 4. Ιf approved, 31 the department shall amend the certificate of need as 32 appropriate. In either ease, the department shall 33 consult with the Health Systems Agency:
- 34 Sec. 8. 22 MRSA §306-A, as enacted by PL 1981, 35 c. 705, Pt. V, §19, is amended to read:
- 36 §306-A. Application process for a certificate of 37 need

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

- 2. Application filed. Upon a determination by the department, after consultation with the Health Systems Agency, that a certificate of need is required for a proposed expenditure or action, an application for a certificate of need shall be filed with the department if the applicant wishes to proceed with the project. Upon receipt of an application, the department shall immediately transmit a copy of the application to the Health Systems Agency.
- 3. Additional information required. Additional information may be required or requested as follows.
 - A. If, after receipt of an application, the department or the Health Systems Agency determines that additional information is necessary before the application can be considered complete, the department may:
 - (1) Require the applicant to respond to 2 sets of requests for additional information from the department, the Health Systems Agency or both, provided that a 2nd request is directly related to the first information request or to the information provided in response to the first request; and
 - (2) Request, but not require, the applicant to respond to additional sets of requests for information, provided that each request is directly related to the last request or to the information provided in response to the last request.

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

- C. Within 15 business days after the filing of an application or response to any information request, whichever is applicable, with the department, the department shall, after considering the requirements of the Health Systems Agency, notify the applicant in writing that:
 - (1) The application contains all necessary information required and is complete; or
 - (2) Additional information is required by the department or by the Health Systems Agency. If, after receipt of the applicant's response to the 2nd or any subsequent request, the department determines that additional information is required, the notification shall also include a statement of the basis and rationale for that determination.
- 4. Review of incomplete application. Upon receipt of the 3rd or any subsequent notice described in subsection 3, paragraph C, subparagraph 2, the applicant must notify the department in writing that:
 - A. It will provide the additional information requested by the department. Following completion, it shall be entered into the next review cycle; or
 - B. That it is not able to or does not intend to provide the information requested and requests the application be entered into the next appropriate review cycle. In that case, the applicant shall be prohibited from submitting the informa-

tion it had declined to provide into the record after the 25th day of the review cycle and the information shall not be considered in the determination to issue or to deny a certificate of need. If the applicant provides the information requested prior to the 25th day of the review cycle, the application may, at the discretion of the department, be returned to the beginning of the review cycle. Failure to submit additional information requested by the Health Systems Agency or the department may result in an unfavorable recommendation by the Health Systems Agency and may result in subsequent denial of the application by the department, as long as the denial is related to applicable criteria and standards.

- 5. <u>Competitive reviews</u>. In cases of competitive reviews, applicants shall submit additional information requested by the Health Systems Agency or the department within 30 business days or within a longer period of time, provided that the department and all competing applicants agree.
- 6. <u>Automatic withdrawal</u>. Any incomplete application shall be deemed withdrawn if the applicant fails to respond to a request for additional required information within one year of the date such request was forwarded by the department.
- Sec. 9. 22 MRSA §307, sub-§3, as enacted by PL
 1977, c. 687, §1, is amended to read:
 - 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.
- 41 Sec. 10. 22 MRSA §307, sub-§4, as enacted by PL 42 1977, c. 687, §1, is repealed.

Sec. 11. 22 MRSA §307, sub-§5-A, ¶¶B and C, as enacted by PL 1981, c. 705, Pt. V, §27, are amended to read:

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- В. After reviewing each application, the commissioner shall make a decision either to issue a certificate of need or to deny the application for a certificate of need. The decision of the commissioner shall be based on the informational record developed in the course of review as specified in paragraph C. Notice of the decision shall be sent to the applicant, and the committee and the Health Systems Agency. This notice shall incorporate written findings which state the basis of the decision, including the findings required by section 309, subsection 1. If the decision is not consistent with the recommendations of the Health Systems Agency or the Certificate of Need Advisory Committee, the commissioner shall provide a detailed statement of the reasons for the inconsistency.
- C. For purposes of this subsection, "informational record developed in the course of review" includes the following:
 - (1) All applications, filings, correspondence and documentary material submitted by applicants, and interested or affected persons, or the Health Systems Agency prior to the termination of the public comment period under subsection 2-B, paragraph F or, if no hearing is held, prior to the 80th day of a 90-day review cycle and prior to the 140th day of a 150-day review cycle;
 - (2) All documentary material reflecting information generated by the department prior to termination of the public comment period or, if no hearing is held, prior to the 80th day of a 90-day review cycle and prior to the 140th day of a 150-day review cycle;
 - (3) Stenographic or electronic recording of any public hearing or meeting held during the course of review, whether or not transcribed;

1 (4) All material submitted or obtained in 2 accordance with the procedures in subsection 3 2-B, paragraph G;

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- (5) The staff report of the agency, the preliminary staff report of the department and the recommendations of the committee;
- (6) Officially noticed facts; and
- 8 (7) The final staff report of the depart-9 ment.

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

Sec. 12. 22 MRSA §307, sub-§6-A, as enacted by PL 1981, c. 705, Pt. V, §29, is amended to read:

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

- 1 Sec. 13. 22 MRSA §308, sub-§1, as enacted by PL 1977, c. 687, §1, is amended to read:
- 3 Waiver of full review. The department may 4 waive otherwise applicable requirements and establish 5 a simplified review process for projects which do not 6 warrant a full review. Procedures for conducting 7 these reviews shall be established by the department 8 in its rules and regulations. These procedures shall 9 provide for a shortened review by the Health Systems 10 Agency and for a public hearing to be held during the course of a review, if requested by any person di-11 12 rectly affected by the review. In order to waive re-13 quirements for a full review, the department, after 14 consulting with the Health Systems Agency, shall find 15 that the proposed project:

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- 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 expenditures plans required by section 305; and
- C. Is required to meet federal, state or local life safety codes or other applicable requirements.
- 27 Sec. 14. 22 MRSA §308, sub-§2, as repealed and replaced by PL 1979, c. 601, §1, is amended to read:
- 29 2. Waiver of other requirements. In order to expedite the review of an application submitted in response to an emergency situation, the department, after consultation with the Health Systems Agency, may:
- A. Waive the requirement that an applicant shall file a letter of intent with the department no less than 60 30 days prior to the date on which an application is to be filed; and
- 38 B. Limit the period within which the Health Sys-39 tems Agency may comment on the completeness of an

application to less than 10 working days from the date on which it was filed with the department; and

- C. Establish a schedule for the review of an application which commences on a day other than the first day of an established review cycle and requires the Health Systems Agency to submit its recommendations and comments to the department in less than 70 days from the day on which the review period commenced; provided that the Health Systems Agency shall be afforded no less than 2/3 of the time the department has allotted for the completion of its review.
- 14 Sec. 15. 22 MRSA §309, sub-§1, as amended by PL 15 1981, c. 705, Pt. V, §31, is further amended to read:
 - 1. Determinations for issue of certificate. A certificate of need shall be issued whenever the department, after considering the findings and recommendations of the Health Systems Agency, determines:
 - A. That the applicant is fit, willing and able to provide the proposed services at the proper standard of care;
 - B. That economic feasibility of the proposed services is demonstrated in terms of: Effect on the existing and projected operating budget of the applicant; the applicant's ability to establish and operate the facility or services in accordance with licensure regulations promulgated under pertinent state laws; and the projected impact on the facility's costs and rates and the total health care expenditures in the community and the State;
 - C. That there is a public need for the proposed services; and
 - D. That the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State and are in accordance with standards, criteria or plans adopted and approved pursuant to

- 1 the annual implementation plan, the health systems plan and the state health plan developed by 2 3 the Health Systems Agency and the department. 4 Sec. 16. 22 MRSA §309, sub-§2, ¶A, as amended by 5 PL 1981, c. 705, Pt. V, §32, is further amended 6 read: 7 The relationship of the health services being reviewed to the annual implementation plan, the 8 9 health systems plan and the state health plan Sec. 17. 22 MRSA §309, sub-§4, ¶A, as enacted by 10 11 PL 1981, c. 705, Pt. V, §33, is amended to read: Except as provided in paragraph B, the de-12 13 partment shall issue a certificate of need for 14 proposed capital expenditure if: 15 (1)The capital expenditure is required to 16 eliminate or prevent imminent safety hazards, as defined by applicable fire, build-17 ing or life-safety codes and regulations; to 18 19 comply with state licensure standards; or to comply with accreditation or 20 eertificate certification standards which must be met to 21 under the United 22 receive reimbursement States Social Security Act, Title XVIII, or 23 24 payments under a state plan for medical as-25 sistance approved under Title XIX of that 26 Act; and 27 The department has determined that the (2) 28 facility or service for which capital penditure is proposed is needed; the obliga-29 30 tion of the capital expenditure is consist-31 ent with the state health plan; and the cor-32 rective action proposed by the applicant
- 35 Sec. 18. 22 MRSA §314, as amended by PL 1979, c. 36 734, §9, is further amended to read:

ble under the circumstances.

the most cost effective alternative availa-

37 §314. Conflict of interest

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In addition to the limitations of Title 5, section 18, a member or employee of the Department of Human Services or Health Systems Agency Certificate of Need Advisory Committee who has a substantial economic or fiduciary interest which would be affected by a recommendation or decision to issue or deny a certificate of need, or who has a close relative or economic associate whose interest would be so affected shall be ineligible to participate in the review, recommendation or decision making process with respect to any application for which the conflict of interest exists.

- Sec. 19. 22 MRSA §317-A, sub-§3, as enacted by
 PL 1981, c. 705, Pt. V, §38, is amended to read:
- Periodic review. After the issuance of a certificate of need, the department shall periodically review the progress of the holder of the certificate in meeting the timetable for making the service or equipment available or for completing the project specified in the approved application. A certificate of need shall expire if the project for which the certificate has been issued is not commenced within 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 not commenced. The department may require evidence of the continuing feasibility and availability of financing for a project as a condition for extending the life of certificate. In addition if on the basis of its periodic review of progress under the certifithe department determines that the holder of a certificate is not otherwise meeting the timetable and is not making a good faith effort to meet it, the department may, after considering any recommendation made by the Health Systems Agency, and after a hearing, withdraw the certificate of need. The department shall in accordance with section 312 promulgate the necessary procedures for withdrawal of certificates of need.
- 41 Sec. 20. 22 MRSA §319, as enacted by PL 1977, c. 42 687, §1, is amended to read:
- 43 §319. Withholding of funds

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No health care facility or other provider apply for or receive any reimmay be eligible to bursement, payment or other financial assistance from any state agency person, 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 tained. 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 reimbursement for all projects subject to the provisions this Act.

14 Sec. 21. 22 MRSA §322, as enacted by PL 1977, c. 15 687, §1, is amended to read:

§322. Implementation reports

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

- Sec. 22. 22 MRSA §325, as enacted by PL 1981, c.
 705, Pt. V, §41, is repealed.
- 3 Sec. 23. 22 MRSA §382, sub-§2, as enacted by PL 1983, c. 579, §10, is repealed.

5 STATEMENT OF FACT

This bill corrects typographical errors; provides for correct interagency relationships, such as deleting references to the former Health Systems Agency; expands the scope of coverage to include review of the acquisition of all major medical equipment by any person; makes explicit the department's authorization to batch proposals of a similar category; extends to all payors the provision that now requires the State to withhold payments to providers for services implemented that required but did not receive a certificate of need.

Section 1 deletes those definitions which refer only to the Health Systems Agency and its activities. The Health Systems Agency ceased to exist on March 31, 1983.

21 Section 2 corrects a typographical error.

Section 3 removes a reference to a document of the Health Systems Agency, which no longer exists, and corrects the reference to the State Health Planning Agency, which is now known as the Office of Health Planning and Development, an administrative unit of the Bureau of Medical Services, within the department.

Sections 4 and 5 amend the requirement for a certification of need to include all major medical equipment, regardless of its location.

Section 6 replaces a reference to the Health Facilities Cost Review Board, which ceased to exist on June 30, 1983, with the Maine Health Care Finance Commission, the agency that now promulgates this factor.

37 Section 7 removes a reference to the Health Sys-38 tems Agency, which no longer exists. Sections 8 to 11 remove reference to the Health Systems Agency, which no longer exists.

Section 12 makes explicit the department's authority to batch for concurrent review proposals of a similar category. Such an approach is necessary, for example, to provide fair treatment to hospital proposals subject to the annual Certificate of Need Development Account limit set by the Health Care Finance Commission under the Maine Revised Statutes, Title 22, chapter 107, section 396-K.

Sections 13 and 14 remove references to the Health Systems Agency, which no longer exists and section 13 also corrects a typographical error.

Sections 15 and 16 remove references to the Health Systems Agency, which no longer exists and to documents formerly produced by the Health Systems Agency.

Section 17 corrects a typographical error.

Section 18 removes a reference to the Health Systems Agency, which no longer exists, and substitutes the name of the Certificate of Need Advisory Committee which now performs the public hearing responsibilities formerly carried out by the Health Systems Agency. The purpose of the substitution, in this section only, is to clarify that conflict of interest provisions which apply to a specific body within the department which has a key role in the review and recommendation process.

Section 19 removes a reference to the Health Systems Agency, which no longer exists.

Section 20 extends to all payors the ability to withhold payments for services implemented without a required certificate of need.

Section 21 adds a requirement that a provider, once a certificate of need has been implemented, file reports concerning the costs and utilization of the project at 6-month intervals during the first year of operation.

1 2	Section 22 removes a reference to the Health Systems Agency, which no longer exists.
3 4	Section 23 removes a reference to the Bureau of Health Planning and Development.
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