

§335. Approval; record

This section applies to determinations by the commissioner under this chapter. [PL 2001, c. 664, §2 (NEW).]

1. Basis for decision. Based solely on a review of the record maintained under subsection 6, the commissioner shall approve an application for a certificate of need if the commissioner determines that the project:

A. Meets the conditions set forth in subsection 7; [PL 2003, c. 469, Pt. C, §8 (NEW).]

B. [PL 2011, c. 90, Pt. J, §5 (RP).]

C. Ensures high-quality outcomes and does not negatively affect the quality of care delivered by existing service providers; [PL 2003, c. 469, Pt. C, §8 (NEW).]

D. Does not result in inappropriate increases in service utilization, according to the principles of evidence-based medicine adopted by the Maine Quality Forum, as established in Title 24-A, section 6951, when the principles adopted by the Maine Quality Forum are directly applicable to the application; [PL 2023, c. 343, §2 (AMD).]

E. [PL 2013, c. 424, Pt. A, §10 (RP).]

F. In the case of a nursing facility project that proposes to add new nursing facility beds to the inventory of nursing facility beds within the State, is consistent with the nursing facility MaineCare funding pool and other applicable provisions of sections 333-A and 334-A; and [PL 2023, c. 343, §3 (AMD).]

G. In the case of a project requiring a certificate of need pursuant to section 329, subsection 1 or section 329, subsection 4-A, paragraph B, will not cause a reduction in access to, geographic proximity of, timeliness of or quality of any family planning services, as defined in section 1902, subsection 4, or any abortion services, except that the commissioner may approve a project that will cause such a reduction if the commissioner finds:

(1) That the project is economically and financially feasible only if an obstetrical care service is closed or reduced in capacity; and

(2) After considering all reasonable alternatives, that access to other health care services will be substantially reduced if the project is not approved. [PL 2023, c. 343, §4 (NEW).]

[PL 2023, c. 343, §§2-4 (AMD).]

1-A. Competitive review. The commissioner may review applications on a competitive basis if the applications propose the same or similar services.

[PL 2011, c. 648, §6 (AMD).]

2. Communications. Staff of the department with responsibility for the certificate of need program may 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.

[PL 2011, c. 648, §7 (AMD).]

3. Limited communications. All communications regarding any letter of intent or application with the commissioner or 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 an application for certificate of need must be made part of the record described in subsection 5-A. If such communications are not in written form or part of public meetings, these communications must be noted in writing by the commissioner or by department staff and that notation must be made part of the application record.

[PL 2011, c. 648, §8 (AMD).]

4. Decision. The commissioner's decision must be in writing and must contain appropriate references to the record. If the application is denied, the decision must specifically address comments 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.

[PL 2001, c. 664, §2 (NEW).]

5. Record.

[PL 2007, c. 440, §17 (RP).]

5-A. Record. The record created by the department in the course of its review of an application must contain the following:

A. The letter of intent described in section 337, subsection 1, all other materials submitted by the applicant relating to the letter of intent and any written materials relating to the letter of intent; [PL 2007, c. 440, §18 (NEW).]

B. The application and all other materials submitted by the applicant for the purpose of making those documents part of the record; [PL 2007, c. 440, §18 (NEW).]

C. All information generated by or for the department in the course of gathering material to assist the commissioner in determining whether the conditions for granting an application for a certificate of need have or have not been met. This information may include, without limitation, the report of consultants, including reports by panels of experts assembled by the department to advise it on the application, 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; [PL 2007, c. 440, §18 (NEW).]

D. Stenographic or electronic recordings of any public hearing held by the commissioner or the staff of the department at the direction of the commissioner regarding the application; [PL 2007, c. 440, §18 (NEW).]

E. Stenographic or electronic recording of any public informational meeting held by the department pursuant to section 337, subsection 5; [PL 2007, c. 440, §18 (NEW).]

F. Any documents submitted by any person for the purpose of making those documents part of the record regarding any application for a certificate of need or for the purpose of influencing the 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; [PL 2007, c. 440, §18 (NEW).]

G. Preliminary and final analyses of the record prepared by the staff; [PL 2007, c. 440, §18 (NEW).]

H. Except with regard to a project related to nursing facility services, a written assessment by the Director of the Maine Center for Disease Control and Prevention of the impact of the project on the health of persons living in the State, including without limitation an assessment of the impact of the project on access to, geographic proximity of, timeliness of and quality of any family planning services, as defined in section 1902, subsection 4, and any abortion services; and [PL 2023, c. 343, §5 (AMD).]

I. Except with regard to a project related to nursing facility services, or a project that qualifies for a simplified review process under section 336, a written assessment by the Superintendent of Insurance of the impact of the project on the cost of insurance in the region and the State when required by the commissioner. The superintendent may request additional information from the applicant for the purpose of reviewing the application. Any such request must be transmitted

through the department and becomes part of the official record. The applicant shall respond to the request within 30 days. Any such response must be transmitted through the department and becomes part of the official record. The inability of the superintendent to complete the review of the application due to the failure of the applicant to respond timely must be noted in the superintendent's assessment filed with the department and may be cause for the commissioner to deny approval of the project. [PL 2013, c. 424, Pt. B, §9 (AMD).]

[PL 2023, c. 343, §5 (AMD).]

6. Maintenance of the record. The record created pursuant to subsection 5-A first opens on the day the department receives a certificate of need application. From that day, all of the record is a public record. The letter of intent becomes a public record upon the receipt of the letter and is available for review from the date of receipt. Any person may examine all or part of the public record and purchase copies of any or all of that record during the normal business hours of the department.

A. The department shall accept public comments and additional information from the applicant for a period of 30 days after the public informational meeting held under section 337, subsection 5 or the public hearing held under section 339, subsection 2, whichever is later. The record will then close until public notice that the preliminary staff analysis has been made part of the record. [PL 2011, c. 648, §10 (NEW).]

B. A technical assistance meeting with the department must be scheduled at least 10 days before the department publishes the preliminary analysis of a certificate of need application. At the technical assistance meeting the department shall:

- (1) Give applicants an opportunity to hear whether the certificate of need application is likely to be approved or denied;
- (2) Give applicants an opportunity to address issues and concerns expressed by the department regarding compliance with this chapter; and
- (3) Give applicants an opportunity to offer additional information to the department.

Any additional information submitted by the applicant becomes part of the public record. The department shall complete its review after the technical assistance meeting and before the department publishes the preliminary analysis. [PL 2011, c. 648, §10 (NEW).]

C. The department shall give notice that the preliminary analysis is complete and part of the public record by publication in a newspaper of general circulation in Kennebec County, in a newspaper published within the service area of the project and on the department's publicly accessible website. [PL 2011, c. 648, §10 (NEW).]

D. The public and the applicant may submit comments on the preliminary analysis for 15 business days after the notice is published under paragraph C. [PL 2011, c. 648, §10 (NEW).]

E. The department may determine to reopen the record in circumstances that it determines to be appropriate for a limited time to permit submission of additional information, as long as the department gives public notice consistent with the provisions of this subsection. [PL 2011, c. 648, §10 (NEW).]

[PL 2011, c. 648, §10 (RPR).]

7. Expanded review process; approval. Except as provided in section 334-A, subsection 2-B with respect to emergency nursing facility projects, section 336 with respect to the simplified review process and subsection 9 of this section with respect to emergency certificates of need, the commissioner, or the commissioner's designee in the case of a simplified review under section 336 or an emergency review, shall issue a certificate of need if the commissioner or the commissioner's designee determines and makes specific written findings regarding that determination that:

A. The applicant is fit, willing and able to provide the proposed services at the proper standard of care as demonstrated by, among other factors, whether the quality of any health care provided in the past by the applicant or a related party under the applicant's control meets industry standards. If the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the State, the requirements of this paragraph are deemed to have been met if the services previously provided in the State by the applicant are consistent with applicable licensing and certification standards; [PL 2011, c. 648, §11 (AMD).]

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

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

(2) Applicant's ability to establish and operate the project in accordance with existing and reasonably anticipated future changes in federal, state and local licensure and other applicable or potentially applicable rules. If the applicant is a provider of health care services that are substantially similar to those services being reviewed and is licensed in the State, the applicant is deemed to have fulfilled the requirements of this subparagraph if the services provided in the State by the applicant during the most recent 3-year period are of similar size and scope and are consistent with applicable licensing and certification standards; [PL 2011, c. 648, §11 (AMD).]

C. There is a public need for the proposed services as demonstrated by certain factors, including, but not limited to:

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

(2) Whether the project will have a positive impact on the health status indicators of the population to be served;

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

(4) Whether the project will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project; [PL 2003, c. 469, Pt. C, §11 (AMD).]

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

(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;

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

(3) The likelihood that more effective, more accessible or less costly alternative technologies or methods of service delivery may become available; and [PL 2003, c. 469, Pt. C, §11 (AMD).]

E. The project meets the criteria set forth in subsection 1. [PL 2003, c. 469, Pt. C, §12 (NEW).]

In making a determination under this subsection, the commissioner may use data from the Maine Health Data Organization established in chapter 1683 and other information available to the commissioner to the extent such data and information is applicable to the determination being made. The commissioner may give appropriate weight to information that indicates that the proposed health services are

innovations in high-quality health care delivery, that the proposed health services are not reasonably available in the proposed area and that the facility proposing the new health services is designed to provide excellent quality health care.

[PL 2011, c. 648, §11 (AMD).]

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

[PL 2001, c. 664, §2 (NEW).]

9. Emergency certificate of need. Upon the written or oral request of an applicant asserting that an emergency situation exists, 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.

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

A. The necessity for immediate or temporary relief due to a natural disaster, a fire, an unforeseen safety consideration, a major accident, equipment failure, foreclosure, receivership or an action of the department or other circumstances determined appropriate by the department; [PL 2001, c. 664, §2 (NEW).]

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 adopted by the department; and [PL 2001, c. 664, §2 (NEW).]

C. The lack of substantial change in the facility or services that existed before the emergency situation. [PL 2001, c. 664, §2 (NEW).]

[PL 2001, c. 664, §2 (NEW).]

SECTION HISTORY

PL 2001, c. 664, §2 (NEW). PL 2003, c. 469, §§C8-12 (AMD). PL 2003, c. 514, §1 (AMD). PL 2005, c. 369, §§7,8 (AMD). PL 2007, c. 440, §§14-19 (AMD). PL 2009, c. 383, §8 (AMD). PL 2011, c. 90, Pt. J, §§5, 6 (AMD). PL 2011, c. 213, §3 (AMD). PL 2011, c. 424, Pt. B, §15 (AMD). PL 2011, c. 424, Pt. E, §1 (AFF). PL 2011, c. 648, §§6-11 (AMD). PL 2013, c. 424, Pt. A, §10 (AMD). PL 2013, c. 424, Pt. B, §9 (AMD). PL 2023, c. 343, §§2-5 (AMD).

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