

DEPARTMENT OF HEALTH AND HUMAN SERVICES
POLICY, PLANNING AND LEGISLATIVE ADMINISTRATION

CERTIFICATE OF NEED

(By authority conferred on the department of health and human services by sections 2226, 2333, and 22255 of 1978 PA 368, MCL 333.2226, 333.2333, and 333.22255.)

PART 1. GENERAL PROVISIONS

R 325.9101 Definitions; A to D.

Rule 101. As used in these rules:

(a) "Applicant" means the person, as defined in section 1106 of the code, or a governmental entity, as defined in section 1104 of the code, applying for a certificate of need and authorized to conduct business in this state.

(b) "Application" means the department forms, in electronic or in paper format, that are currently in effect at the time the application is submitted, and any information or documentation prespecified in the forms to be provided as attachments or supplements

(c) "Appropriate regional certificate of need review agency" means the regional certificate of need review agency that the department designates under section 22226 of the code that is within the geographical review area where an applicant proposes to locate a project.

(d) "Bureau" means the administrative unit of the department that the director designates as responsible for the certificate of need program.

(e) "Code" means 1978 PA 368, MCL 333.1101 to 333.25211.

(f) "Comparative group" means the applications that have been grouped for the same type of project in the same planning area that are being reviewed comparatively according to these rules.

(g) "Completed application," except as provided in R 325.9229, means the application submitted by the applicant, including any additional information provided by the applicant on or before the date the application is deemed complete under R 325.9201(3).

(h) "Completed project" means a project that the department has determined both of the following:

(i) That all activities and construction necessary to offer the services, beds, facilities, or equipment approved by a certificate of need have been executed in compliance with the terms and conditions of the certificate of need.

(ii) That the project has been implemented as defined in R 325.9103(b).

(i) "Department" means the Michigan department of health and human services.

(j) "Director" means the director of the Michigan department of health and human services.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS; 2016 AACCS.

R 325.9103 Definitions; I, L.

Rule 103. As used in these rules:

(a) "Incur an obligation" means entering into either of the following:

(i) An executed contract or contracts for the construction, acquisition, lease, or financing of all or substantially all, of the project, as determined by the department.

(ii) An executed contract or contracts for the construction, acquisition, lease, or finance of, a phased project. A phased project is a project accomplished in segments over a period of time in compliance with a project timetable acceptable to the department and approved in the certificate of need.

(b) "Implement", except as provided in R 325.9403(5), means 1 of the following:

(i) For a project that involves the performance of the first surgical procedure of either of the following:

(A) Extrarenal organ transplantation (heart, lung, liver, bone marrow).

(B) Open heart surgery.

(ii) For a project that involves any of the following, the performance of the first procedure or the signing of a contract that specifies the installation date of the equipment occurring within 24 months and the first procedure within 30 months of the effective date of the certificate of need:

(A) Urinary extracorporeal shock wave lithotripsy (UESWL).

(B) Megavoltage radiation therapy (MRT).

(C) Positron emission tomography (PET) scanning.

(D) Computed tomography (CT) scanning.

(E) Cardiac catheterization.

(F) Magnetic resonance imaging (MRI).

(G) Air ambulance services.

(iii) For a project that involves beds or surgical services, either of the following:

(A) The signing of a contract for the construction, renovation, purchase or lease of equipment or space to house the beds or operating rooms.

(B) The licensure or certification of the beds or operating rooms for use, whichever occurs first.

(iv) For a project that involves capital expenditures other than projects specified in paragraphs (i) to (iii) of this subdivision when an obligation is incurred or, if the certificate of need expressly defines a series of obligations for discrete components to be incurred over a period of more than 1 year, when each of the designated obligations is incurred.

(v) For a project that involves the acquisition of licensed health facilities, the issuance of a new license by the Michigan department of licensing and regulatory affairs.

(vi) For a project that is not specified in paragraphs (i) to (v) of this subdivision, the occurrence of the implementation event as defined in the applicable certificate of need review standards.

(c) "Letter of intent" means the department form, in electronic or paper format, to determine the reviewability, type of review, and appropriate application forms for a proposed project.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

R 325.9105 Definitions; N to S.

Rule 105. As used in these rules:

(a) "Nonsubstantive review" means review of a project accepted for review under R 325.9205 and R 325.9206.

(b) "Offer" means to perform a procedure or serve a patient, as applicable, as authorized by a certificate of need.

(c) "Qualifying project" means each application in a comparative group which has been reviewed individually and which the department determines to satisfy all the requirements of section 22225 of the code, all other applicable requirements for approval in the code, and all applicable certificate of need review standards.

(d) "Recipient" means a person who validly holds a signed, approved certificate of need under the code and these rules.

(e) "Regional certificate of need review agency" means the agency designated by the department pursuant to section 22226 of the code.

(f) "Single project" means an activity that requires a certificate of need or, in the case of a capital expenditure, an activity or a group of activities involving a distinct physical area or areas of a health facility or involving the same service or similar services.

(g) "Site" means the physical location and address (or legal description of property) of a covered service or beds, unless otherwise defined in the applicable certificate of need review standards.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

R 325.9109 Terms defined in code and certificate of need review standards; establishment of certificate of need review standards.

Rule 109. (1) Terms defined in the code and certificate of need review standards have the same meanings when used in these rules.

(2) All certificate of need review standards used in making determinations on applications under these rules shall be established by law.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

R 325.9121 Computation of time deadline.

Rule 121. Any deadline falling on a nonworking day, will be extended to the next department working day.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

R 325.9123 Designated application dates.

Rule 123. (1) The designated application date is the date that the rules set as the deadline for submitting applications for a certificate of need. An application is considered timely if it is received at the department's Lansing office and date and time stamped as received before 4:00 p.m. on a designated application date. An application received, including

electronic submissions, at the department's Lansing offices after 4:00 p.m. on a designated application date is not considered timely and shall be deemed submitted on the next designated application date.

(2) For an applicant seeking a nonsubstantive review under R 325.9205 and R 325.9206, the designated application date is the department working day that the department received the application.

(3) For an application that is not eligible for nonsubstantive review and not subject to comparative review, the designated application date is the first department working day of each month.

(4) For an application that is subject to comparative review, the designated application dates are February 1, June 1, and October 1 of each year.

(5) An application is not considered submitted to the department until it is submitted to the appropriate regional certificate of need review agency.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

R 325.9125 Extensions.

Rule 125. (1) The department may extend the date to issue a proposed or final decision on an application for not less than 30 days, but not more than 90 days, either under R 325.9229 or upon receipt of a written request from an applicant.

(2) An applicant's written request for an extension shall specify either the date or the number of days being requested for an extension. The department may extend the date to issue a proposed or final decision if in either case, both of the following requirements, as applicable, are met:

(i) The extension will not result in a delay in the start of the review of similar applications filed subsequently as provided by R 325.9207(2)(b).

(ii) All applicants in the comparative group, for applications subject to comparative review request an extension of the same duration.

(3) The department may grant an extension for longer than 90 days if the applicant provides justification that the department considers satisfactory. The department's decision to deny an extension request is not subject to administrative hearing or appeal.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

PART 2. APPLICATIONS; REVIEWS

R 325.9201 Letters of intent; applications; forms; copies; attachments and supplements; content; completeness; additional information; department's authority to consider relevant information not limited; notification of information considered relevant; public availability.

Rule 201. (1) Before applying for a certificate of need for a project, except for projects that are covered by section 22235 of the code, a person shall submit a letter of intent simultaneously to the department and the appropriate regional certificate of need review agency. The letter of intent shall be on a form supplied by the department. Within 15 days

of receipt of a letter of intent, the department shall notify the person proposing the project whether the project requires a certificate of need and, if so, the type of review (nonsubstantive, substantive, potential comparative) and provide the applicant with appropriate forms. The department may decline to process a letter of intent if the same covered service or beds already exists at that site under a different entity that has submitted a letter of intent or application or has previous certificate of need approval before the new letter of intent, or would otherwise result in a conflicting or duplicative CON review. The department shall not review any application it receives before the department finishes processing the letter of intent for that application. A letter of intent expires if an application has not been submitted to the department within 1 year of receipt of the letter of intent by the department. The department shall provide the applicant with a copy of the current work plan of the certificate of need commission indicating the timing by which the certificate of need review standards are being revised or are scheduled to be revised by the commission.

(2) At the time of submission of an application, a person applying for a certificate of need shall simultaneously submit 3 copies of an application, or 3 copies of any supplemental documents for an electronic application, for a single project to the department and, if applicable, 1 additional copy to the appropriate regional certificate of need review agency. The application shall be made on the application forms authorized and provided by the department. The application forms may include requirements for attachments and supplements specified by the department in the forms. An application shall clearly state the persons, buildings and properties to which it applies and clearly define the scope, nature, cost, time limits, and other aspects of the proposal. A letter of intent, application, or an amendment to an approved certificate of need shall be accompanied by the fee, if any, required by law and these rules. A letter of intent or an amendment not accompanied by the required fee if any, will not be processed until the bureau receives the required fee, if any. An application not accompanied by the required fee will not be considered timely and will be deemed submitted on the next designated application date after receipt of the required fee. An application received, including electronic submissions, that does not include statements addressing each of the review criteria listed in section 22225 of the code is not timely and will be deemed submitted on the next designated application date after receipt of the required documents. Statements addressing section 22225 are not required for proposed projects eligible for nonsubstantive reviews under R 325.9205.

(3) The department shall consider only those applications that it deems submitted on or before the designated application date and shall determine if the application is complete. The department may request additional information and provide notification of a determination to the applicant and the appropriate regional certificate of need review agency within 15 days of receipt of the application. The applicant has 15 days from receipt of the department's notice to respond to the request to the department's satisfaction. If the department does not request additional information the department shall consider the application to be complete as submitted by the applicant on the designated application date. If additional information is requested for applications subject to nonsubstantive or substantive review, the department shall consider the application to be complete on the next designated application date with or without the additional information. If additional information is requested for applications subject to comparative review, the department shall consider the application to be complete on the first department working day of the next month, with or without the additional information.

(4) This rule does not limit the department's authority to consider all available information relevant to the department's review of an application.

(5) An applicant may request, and the department may allow, the submission of information after the date the application is deemed complete if the application is not subject to comparative review. When a request under this subrule is made, the department may require that the applicant authorizes an extension to the date a decision must be issued if the department determines that an extension is necessary to perform its review.

(6) The department's review shall be conducted using the completed application and any other information the department considers relevant to the decision and under all applicable provisions in the certificate of need review standards and the code, including information which becomes available or developments which occur after the date an application is deemed complete.

(7) Before issuing a proposed decision, the bureau shall notify an applicant of all information that the department relied upon in conducting the department's review. If the department relies on information other than submitted by the applicant in its application, the bureau or department shall cite in the proposed or final decision letter, as applicable, the information it relied upon. The department shall make this information available to the public upon request.

(8) The department's decision to request additional information is not subject to administrative hearing or appeal.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

R 325.9203 Rescinded.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

R 325.9204 Data and physician commitments.

Rule 204. (1) If a certificate of need review standard requires a data commitment, including Michigan inpatient data base (MIDB) data or cancer registry data, the health facility or freestanding facility committing the data shall be regularly admitting patients and providing services as of the date the director makes the final decision on an application under section 22231 of the code. Further, the department shall not consider any commitment if a health facility or freestanding facility withdrew its commitment before the final decision on an application.

(2) If a certificate of need review standard requires a physician commitment, then all of the following apply, unless otherwise specified in a review standard:

(a) The commitments shall be submitted at the time the application is submitted to the department.

(b) A commitment shall not be withdrawn after the date an application is deemed complete by the department and after a proposed decision to approve an application has been issued by the department.

History: 1996 AACCS; 2014 AACCS.

R 325.9205 Nonsubstantive reviews; eligibility.

Rule 205. (1) A person may submit a letter of intent requesting a nonsubstantive certificate of need review.

(2) The department shall approve the request as appropriate when the department is satisfied that all of the following conditions have been met:

(a) The completed project will not result in any of the following:

(i) An increase in the number of beds licensed to the applicant at the licensed site at which the project is proposed.

(ii) The initiation or expansion of a covered clinical service.

(iii) Beginning operation of a new health facility at a site that is not currently licensed for that type of health facility.

(iv) A capital expenditure in excess of a covered capital expenditure as defined in the code.

(b) The proposed project is not subject to comparative review under the code or the applicable certificate of need review standards.

(3) The department may accept other projects for nonsubstantive review under section 22233 of the code. The department shall maintain a public list of the types of projects eligible for nonsubstantive review under this rule.

History: 1986 AACs; 1996 AACs; 2014 AACs.

R 325.9206 Nonsubstantive review; procedure; time for decision; notice; effect of denial of request for review; department decision to deny review not subject to administrative appeal; review period; submittal of regional certificate of need review agency's recommendations.

Rule 206. (1) The department shall determine whether an application submitted for nonsubstantive review is complete as provided by R 325.9201(3). The department shall notify the applicant of its decision and send a copy of the decision to the appropriate regional certificate of need review agency. The department's decision to deny nonsubstantive review of a project is not subject to administrative hearing or appeal.

(2) If a request for nonsubstantive review is denied, the application is deemed submitted for the purposes of substantive review on the next designated application date after the date of denial and the time frames to determine completeness for substantive review shall be those in R 325.9201(3).

(3) The department shall consider only those applications that are filed on or before the designated application date and will determine whether the application is complete or incomplete. The department shall provide notification of a determination to the applicant and the appropriate regional certificate of need review agency within 15 days of receipt of the application. The applicant has 15 days from receipt of the department's notice to provide additional information or otherwise complete the application. If additional information is not requested by the department, the department will consider the application to be complete as submitted by the applicant on the designated application date. If additional information is requested, the department will consider the application to be complete on the date the department receives the applicant's responses. If the additional information requested is not received within 15 days, the application will be deemed complete.

(4) The period for the review of a nonsubstantive application shall be not more than 45 days from the date the application is deemed complete by the department. The appropriate regional certificate of need review agency shall submit its recommendations with respect to a nonsubstantive application within 30 days of the date the application is accepted for nonsubstantive review by the department so that the recommendations can be included in the department's review process. If new or revised certificate of need review standards applicable to a proposed project become effective before the issuance of a final decision by the director of the department, the review and issuance of proposed and final decisions shall be made according to the provisions of R 325.9229.

(5) The department's review shall be conducted using the completed application and any other information the department considers relevant to the decision and under all applicable provisions in the certificate of need review standards and the code, including information which becomes available or developments which occur after the date an application is deemed complete.

(6) Before issuing a proposed decision, the bureau shall notify an applicant of all information that the department relied upon in conducting the department's review. If the department relies on information, other than submitted by the applicant in its application, the bureau or department shall cite in the proposed or final decision letter, as applicable, the information it relied upon. The department shall make this information available to the public upon request.

History: 1986 AACs; 1996 AACs; 2014 AACs.

R 325.9207 Substantive individual or comparative review; scheduling of reviews; procedures.

Rule 207. (1) Projects subject to comparative review shall be designated under section 22229 of the code or the applicable certificate of need review standards. Proposed projects that are not subject to comparative review and are not eligible for nonsubstantive review will be subject to substantive individual review under this subrule and not subrule (2) of this rule. The bureau will issue a proposed decision on a certificate of need application within 120 days of the date an application is deemed complete under R 325.9201(3). The appropriate regional certificate of need review agency will concurrently review the application and submit its recommendations to the department within 90 days of the date the department determines the application is complete and the review period has commenced. If new or revised certificate of need review standards applicable to a proposed project become effective before the issuance of a final decision by the director of the department, the review and issuance of proposed and final decisions shall be made in accordance with R 325.9229. A review shall commence on the date an application is deemed complete by the department. The department, with the advice of the regional certificate of need review agency will determine if an application filed by each applicant meets all applicable requirements for approval under part 222 of the code.

(2) The following provisions shall apply to projects subject to comparative review under section 22229 of the code:

(a) Within 30 days after the date that all of the applications are deemed complete, the department shall place the timely applications into comparative groups and shall notify the appropriate regional certificate of need review agency and each applicant whether each

comparative group will be subject to comparative review. For comparative reviews, the review period begins on the date in the notice under this subrule. In cases where a final decision on a prior review of similar projects, services or facilities in the same planning area has not yet been issued by the director, the review period begins only after the director issues a final decision on such prior review.

(i) For each comparative group subject to comparative review, the notice shall also include all of the following findings by the department:

(A) The projections of need for the proposed facilities, beds, or services.

(B) That the total proposed facilities beds or services in the comparative group are more than the projections of need.

(C) That the applications, when taken together, are mutually exclusive in that, under existing certificate of need review standards, the approval of 1 or more of the applications will necessarily result in the denial of other applications.

(ii) Applications that are not subject to comparative review shall be reviewed individually in the same manner as a project submitted under subrule (1) of this rule, with the 120-day and concurrent 90-day review periods commencing on the date on which the department determines that the applications are not subject to comparative review. The review period cannot commence when a final decision on a prior review of similar projects, services, or facilities in the same planning area has not been issued by the director. In this case, the review period begins only after the director issues a final decision on such prior review.

(b) If upon review under subdivision (a) of this subrule, the department determines that an application could fall into more than 1 comparative group the department shall notify the applicant. The applicant shall notify the department that the project is amended so that the proposed project involves only services, facilities, equipment, or beds relative to a single comparative group or notify the department that the project in its entirety is withdrawn. If the applicant advises the department that it is amending the application, additional information related to the amendment may be submitted under R 325.9201(3). In the absence of notification by an applicant, the original application is subject to comparative review in the comparative group determined by the department and the portion of the application involving the other comparative group or groups will not be considered by the department in its review of the application. The applicant may submit according to these rules, a separate application for the portion of the application not being considered.

(3) This rule does not limit the department's authority to consider all available information relevant to the department's review of an application.

(4) The department's review shall be conducted using the completed application and any other information the department considers relevant to the decision and under all applicable provisions in the certificate of need review standards and the code, including information which becomes available or developments which occur after the date an application is deemed complete.

(5) Before issuing a proposed decision, the bureau shall notify an applicant of all information that the department relied upon in conducting the department's review. If the department relies on information other than submitted by the applicant in its application, the bureau or department shall cite in the proposed or final decision letter, as applicable, the information it relied upon. The department shall make all other information available to the public upon request.

History: 1986 AACS; 1987 AACS; 1996 AACS; 2014 AACS.

R 325.9208 Comparative reviews; procedures.

Rule 208. (1) For a comparative group, the department, with the advice of the regional certificate of need review agency, shall review the applications within the comparative group pursuant to the following procedure:

(a) A regional certificate of need review agency shall concurrently review the applications and submit its recommendations to the department as soon as practicable, but not later than 90 days after the notification of the start of a comparative review.

(b) The bureau shall concurrently review and issue a single proposed decision regarding the applications in the comparative group subject to comparative review as soon as practicable, but not later than 120 days after notification of the start of a comparative review. If new or revised certificate of need review standards applicable to a proposed project become effective before the director issues a final decision, then R 325.9229 applies to the review and issuance of proposed and final decisions.

(c) The bureau, with the advice of the regional certificate of need review agency, shall determine if the application filed by each applicant meets all applicable requirements for approval under part 222 of the code.

(d) The bureau shall rank all qualifying projects in the comparative group as provided by the applicable certificate of need review standards and shall issue a single proposed decision. The bureau shall approve the highest ranking applications that, in total do not exceed the amount of need as determined by section 22225(1) of the code. If a higher ranking application cannot be approved because its approval would exceed the amount of need, the bureau shall approve the remaining applications in the comparative group from highest to lowest score until the level of need is met. The bureau shall issue a proposed disapproval as part of the single decision for the remaining applications in the comparative group.

(2) This rule and R 325.9207 do not apply to certificates of need applied for and issued under sections 22233 and 22235 of the code.

History: 1986 AACs; 1996 AACs; 2014 AACs.

R 325.9210 Finance Reviews; procedures.

Rule 210. (1) A person applying for a certificate of need for a project shall provide all of the following information as applicable:

(a) Audited financial statements for existing providers including balance sheet, income statement, statement of cash flow, and footnotes to the financial statements.

(b) For new providers, the department may accept evidence of secured capital funding or a letter of interest from a financial institution, if audited financial statements are not available.

(c) Verification for all sources of funds dated within 30 days of submission of the application.

(d) Signed vendor quote dated within 6 months of application submission for applications involving covered clinical equipment.

(e) All applicable proposed lease and purchase agreements.

(f) Designated funds specifying what type of funds are used (for example, cash, bond, etc.).

(g) The book value for the assets of a licensed health facility or covered clinical service verifiable by an unrelated party; as determined by the department.

(2) For construction projects, the applicant will competitively bid capital expenditures among qualified contractors or alternatively, the applicant is proposing an alternative to competitive bidding that will achieve substantially the same results as competitive bidding.

(3) An applicant utilizing future operations (for example, capital/operating lease) as a source of funds shall provide the following, as applicable:

(a) Current bank or financial institution statement or balance and dated within 30 days of submission of the application.

(b) Third party verification of a bank loan, HELP loan, or other equivalent source of funding.

(4) The department's finance review shall be conducted using the completed application and any other information the department considers relevant to the decision and under all applicable provisions in the certificate of need review standards and the code, including information which becomes available or developments which occur after the date an application is deemed complete.

(5) Before issuing a proposed decision, the bureau must notify an applicant of all information that the department relied upon in conducting the department's review. If the department relies on information, other than submitted by the applicant in its application, the bureau or department must cite in the proposed or final decision letter, as applicable, the information it relied upon. The department shall make this information available to the public upon request.

(6) This rule does not limit the department's authority to consider all available financial information relevant to the department's review of an application.

History: 2014 AACs.

R 325.9215 Amendments to applications before proposed decision is issued by the bureau.

Rule 215. (1) An applicant shall not amend an application subject to a comparative review after the designated application date established under R 325.9123, except to the extent that additional information is requested by the department to make the application complete under R 325.9201 or R 325.9229(6) or as provided for in R 325.9207(2)(b). A person desiring to amend an application may do any of the following:

(a) Withdraw the amendment.

(b) Have the project considered under a new application on a subsequent designated application date.

(c) If the application is subject to comparative review, amend the application if all applicants in the comparative group agree to allow an amendment, if the amendment does not increase the scope of the project.

(2) An amendment to an application before a proposed decision is issued by the bureau shall not change the person, the site of a proposed health facility or covered clinical service, or increase the number of beds or covered clinical services proposed in a certificate of need.

(3) A request to amend an application shall be accompanied by the required fee if the amendment request results in higher costs under the fee schedule in section 20161 of the code for the proposed project that would have required a higher application fee when submitted originally. An amendment not accompanied by the required fee will not be processed by the department until the required fee is received.

(4) An application that is not subject to comparative review may be amended by the applicant up to 30 days in advance of the proposed decision date established by these rules. If the department, with the advice of the appropriate regional certificate of need review agency, determines that the proposed amendment substantially changes the original application and that additional review by the department and the regional certificate of need review agency is required to adequately evaluate the proposal according to the code and these rules, the department shall require, as a condition of the amendment, that the applicant agree to extend the date for proposed decision as required to permit the additional review.

(5) The department may consider new or revised information submitted by an applicant for an application that is not being reviewed on a comparative basis, within 30 days of the proposed decision date or at any time after the proposed decision and before a final decision is issued, if an applicant requests an extension to the proposed or final decision date sufficient to allow the department and the appropriate regional certificate review agency, up to 30 days to review the new or revised information. The department may request from an applicant a longer extension, if it is necessary to review new or revised information. The applicant shall also simultaneously submit the new or revised information to the appropriate regional certificate of need review agency. The department shall make the new or revised information available to the public upon request.

(6) If an applicant for a project not originally subject to comparative review proposes to amend the application in such a way as to make it subject to a comparative review, the bureau shall notify the applicant of the need for comparative review. The applicant may then either withdraw the amendment or have the project considered under a new application on a subsequent designated application date.

History: 1986 AACS; 1996 AACS; 2014 AACS; 2016 AACS.

R 325.9227 Emergency review; request; denial.

Rule 227. (1) A request for an emergency certificate of need review under section 22235 of the code may be made electronically or in paper format. The request shall include justification for the project and a statement of the nature and extent of the claimed emergency.

(2) If the department determines that a request filed under subrule (1) of this rule is not covered by section 22235 of the code, it shall inform the applicant, in writing, within 10 working days of receipt of the request, and deny the request for emergency review.

(3) The department's decision to deny emergency review is not subject to administrative hearing or appeal.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9228 Extended care services program (swing bed) review; maximum number of patient days variation.

Rule 228. (1) A request for extended care services program certificate of need review under section 22210 of the code may be made electronically or in paper format. The request shall include justification for the project and demonstration of compliance with the requirements in section 22210 of the code.

(2) Evidence that the hospital has had difficulty in placing patients in skilled nursing home beds during the 12 months immediately preceding the date of application include, but not limited to, evidence that the average occupancy rate for all existing and operating nursing homes within a 20 mile radius of the hospital has been at least 85% for the last 4 quarters based upon the department's staffing/bed utilization ratios report.

(3) The department may grant a 1 year variation from the maximum number of patient days established under section 22210(3)(e) of the code if the applicant demonstrates immediate need for the project by showing that the average occupancy rate for all existing and operating nursing homes within a 100-mile radius of the hospital has been at least 85% for the last 4 quarters based upon the department's Staffing/Bed Utilization Ratios Report.

History: 2014 AACs.

R 325.9229 New or revised certificate of need review standards approved by certificate of need commission.

Rule 229. (1) If new or revised certificate of need review standards become effective between the time an application is filed and when the director issues a final decision on the application, then the bureau shall consider and process the application according to this rule.

(2) If the bureau is reviewing an application, other than on a comparative review basis, and the bureau has not issued a proposed decision before the effective date of the new or revised certificate of need review standards then either of the following apply:

(a) The applicant, within 15 days of the effective date of the new or revised certificate of needed review standards, may request, and the department may grant, an extension, under R 325.9125, of the date by which a proposed decision must be issued by the bureau under these rules and the code. During the extension period, the applicant may submit to the department and the appropriate regional certificate of need review agency, additional information to demonstrate that the application is in compliance with the new or revised certificate of need review standards.

(b) If an applicant requests an extension under this rule the bureau shall issue a proposed decision on the completed application, using the new or revised certificate of need review standards, on or before 45 days for nonsubstantive applications or 120 days for substantive applications, after receipt of the additional information.

(c) If the applicant does not request an extension under this, the bureau shall issue a proposed decision on the completed application reviewed according to the new or revised certificate of need standards and the proposed decision shall be issued according to the date established under R 325.9207.

(3) If the bureau has reviewed an application, other than on a comparative basis, and the bureau has issued a proposed decision, then either of the following applies:

(a) The applicant may request, within 15 days of the effective date of the new or revised certificate of need review standards, and the department may grant a remand of the proposed decision to the bureau. Upon such remand, the date a final decision must be issued by the director of the department is stayed and the applicant may submit, to the department and the appropriate regional certificate of need review agency, additional information to demonstrate that the application complies with the new or revised certificate of need review standards under R 325.9125. Upon remand, the bureau shall issue a proposed decision on the completed application according to the new or revised certificate of need review standards, on or before 45 days for nonsubstantive applications or 120 days for substantive applications, after receipt of the additional information.

(b) If the applicant does not request a remand under this rule, the director of the department shall issue a final decision on the completed application reviewed according to the new or revised certificate of need standards and the final decision shall be issued in accordance with the date established under these rules and the code.

(4) If the bureau has reviewed an application, other than on a comparative basis; the bureau has issued a proposed decision; and the applicant has requested a hearing on a proposed decision under section 22232(1) of the code, then regardless of the stage of the hearing, either of the following apply:

(a) The applicant may request that the matter be remanded to the bureau for further review according to subrule (3) of this rule.

(b) If the applicant does not request a remand under this subrule, the applicant may, within 60 days following the effective date of the new or revised certificate of need review standards augment, for introduction in the hearing its testimony evidence and exhibits in support of its application with regard to the new or revised certificate of need review standards.

(c) If an applicant does not request a remand under this subrule, the department shall submit, to the hearing officer, within 60 days of the effective date of the new or revised certificate of need review standards, or 60 days of the date an applicant has augmented the record, whichever comes later, an analysis of the applicant's compliance with the new or revised certificate of need review standards.

(5) If an application is in a comparative review, regardless whether it is in the process of being reviewed by the bureau or in any stage of a hearing, by the director of the department, any applicant in the comparative group, within 15 days of the effective date of the new or revised certificate of need standards, may request, and the department may grant an extension to review and issue a proposed decision on the comparative group according to the new or revised certificate of need review standards. Upon extension or remand and extension, each applicant in the comparative group may submit, within 60 days following the effective date of the new or revised certificate of need review standards to the department and the appropriate regional certificate of need review agency, additional information to demonstrate that its application complies with the new or revised certificate of need review standards. Upon such an extension or remand and extension, the bureau shall issue a single proposed decision on the completed applications, with the addition of any information submitted under this subrule from the comparative group, according to the new or revised certificate of need review standards on or before 120 days of the last date on which additional information may be submitted under this subrule. If none of the applicants request an extension or a remand and extension, for the review and issuance of

a single decision on the comparative group will be based on each completed application reviewed pursuant to the new or revised certificate of need standards and the decision will be issued in accordance with the date established under these rules and the code.

(6) The bureau shall consider the recommendation of the appropriate regional certificate of need review agency if the recommendation is received more than 30 days before the bureau or department decision dates established under this rule.

History: 1996 AACCS; 2014 AACCS.

PART 3. APPROVAL AND ISSUANCE; DISAPPROVAL

R 325.9301 Bureau and department decision to be written; issuance of 1 decision for all applications in comparative review; conditions and stipulations as integral parts of certificate of need; request for hearing deemed request for hearing on entire decision; issuance of final decision.

Rule 301. (1) The bureau shall issue only 1 proposed decision for all applications, including qualifying and nonqualifying projects, when a comparative group is determined to be subject to comparative review.

(2) The director shall issue only 1 decision for all applications including qualifying and nonqualifying projects, when a comparative group is determined to be subject to comparative review.

(3) A request for hearing filed under section 22231 or 22232 of the code related to any part of a decision, including conditions and stipulations, will be deemed a request for hearing on the entire decision.

(4) The director shall issue a final decision under all applicable requirements and provisions of the code.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

R 325.9303 Effective date of certificate.

Rule 303. Unless otherwise specified in the final decision, a certificate of need is effective on the date director issues the final decision.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

PART 4. TERMS AND CONDITIONS

R 325.9401 Validity of certificate.

Rule 401. (1) A certificate of need is valid only as long as there is compliance with the provisions in the final or amended application, including project timetables except as expressly modified in the certificate of need and its amendments.

(2) As provided by section 20164(2) of the code, the certificate of need is not transferable and shall be valid only for the persons, buildings and properties stated in the certificate. The recipient of a certificate of need shall comply with all of the following provisions:

(a) The certificate of need.

(b) The amendments to the certificate of need.

(c) The application to the extent it has not been modified by the certificate of need and its amendments.

(3) Only the persons authorized by the certificate of need may offer the covered clinical services or beds listed in the certificate of need.

History: 1986 AACCS; 2014 AACCS.

R 325.9403 Term of certificate.

Rule 403. (1) Unless otherwise specified in a certificate of need review standard or final decision, a certificate of need expires 1 year from its effective date, unless the project is implemented as defined in R 325.9103(b).

(2) The bureau, upon written request of the recipient, may extend the implementation period established in subrule (1) of this rule or in a certificate of need review standard by not more than 6 months if the bureau determines all of the following:

(a) The terms of the certificate are not changed.

(b) Substantial progress has been made.

(c) The requirements of R 325.9103(b) will occur within the extended time period.

(3) Any extension granted under subrule (2) of this rule does not change the effective date of the certificate of need.

(4) At any time, the department may request, and the person holding the certificate of need shall immediately provide, any documentation, including project schedules, to determine whether the project is on schedule and within the estimated costs for the project.

(5) For projects subject to the provisions of R 325.9103(b)(i), (ii), or (vi), a certificate of need review standard may establish a term of the certificate other than as established in subrules (1) and (2) of this rule, in which case the certificate of need expires at the end of the time period specified in the standard.

History: 1986 AACCS; 1996 AACCS; 2014 AACCS.

R 325.9413 Amendments to approved certificates of need.

Rule 413. (1) A recipient may request the department to amend an approved certificate of need if the project is not a completed project. After consulting with the appropriate regional certificate of need review agency, the department shall decide whether the amendment requires another review. The department's decision to require another review or deny a request is not subject to the administrative hearing process in the Administrative Procedures Act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

(2) A request to amend a certificate of need shall be accompanied by the required fee if the amendment request results in higher costs under the fee schedule in section 21601 of the code for the proposed project that would have required a higher fee when submitted

originally. An amendment not accompanied by the required fee will not be processed by the department until the required fee is received.

(3) A certificate of need issued after a comparative review shall not be amended to change any of the following:

(a) The scope of the project.

(b) An increase in the cost of the project.

(c) The method of financing the project.

(d) The terms of financing the project, except where a recipient demonstrates to the satisfaction of the department, that an amendment to change the method or terms of financing offers a less costly alternative to the approved method or terms of financing the project.

(4) The department may allow an amendment requesting a change in the site of an approved health facility before completion of the project if both of the following criteria are met:

(a) Sufficient evidence is submitted and deemed reasonable by the bureau detailing an event that could not be reasonably foreseen that prevents the completion of an approved project at the approved site. The event that could not be reasonably foreseen must have occurred after the approval of the project.

(b) The site proposed in the amendment shall meet the exact criteria and scoring, if applicable, as the previously approved site and any new criteria in updated standards.

(5) An amendment for an approved health facility or covered clinical service shall not modify the person, purpose of the property, or the scope of the project. An amendment for an approved health facility or covered clinical service shall not increase the number of beds or clinical services approved in a certificate of need. An amendment cannot change the site of an approved covered clinical service for a nonlicensed facility.

(6) The department may allow an amendment requesting a change in the method and terms of financing, approved capital expenditures, for example, medical equipment, or other costs only in those instances where the recipient is able to demonstrate that the need for amendment arises from circumstances beyond its control or the amendment offers a better alternative as determined by the department with the advice of the appropriate regional certificate of need review agency.

(7) The department may request additional information regarding a proposed amendment under the time periods in R 325.9201(3).

(8) The review period for a request to amend an approved certificate of need shall not be longer than the original review period for the application. When reviewing a proposed amendment to an approved certificate of need, the bureau shall use the standards in effect at the time of the original approval of the certificate of need.

(9) The department may grant an extension to the date a decision will be issued for an amendment upon written request from a recipient. An extension may be granted for not less than 30 days, but not more than 90 days.

(10) Unless waived by the department, amendments to a certificate of need are subject to the same conditions and stipulations imposed on the original certificate and any new conditions and stipulations imposed on the amendment.

History: 1986 AACs; 1996 AACs; 2014 AACs; 2016 AACs.

R 325.9415 Amendment to approved certificates for an increase in project costs.

Rule 415. An amendment to an approved certificate of need for increased project costs will not be required if the total amount of excess does not exceed the sum of 15% of the approved project costs up to \$1,000,000.00 and 10% of the approved project costs in excess of \$1,000,000.00.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9417 Certificate timetables.

Rule 417. (1) An application for a certificate of need shall specify the timetable the applicant will follow in making the health facility, beds, services or equipment available or for beginning and completing construction.

(2) The recipient shall begin construction within 24 months of the effective date of the certificate of need. A recipient may request to extend the time to begin any construction beyond the 24 month period, with an amendment request to the department. The department may approve to extend the period of time to begin construction if the department determines that circumstances justify an extension. Extending the 24-month period does not change the effective date of the certificate of need.

(3) The recipient shall install the medical equipment specified in the certificate of need within 24 months of the effective date of the certificate of need. A recipient may request to extend an installation beyond the 24-month period, with an amendment request to the department. The department may approve to extend the period of time for installation if the department determines that circumstances justify an extension. Extending the 24-month period does not change the effective date of the certificate of need.

(4) For medical equipment, the first procedure must be performed within 6 months of the installation date of the equipment specified in R 325.9103(b)(ii). The department may approve to extend the period of time for the first procedure to be performed if the department determines that circumstances justify an extension. This does not change the effective date of the certificate of need.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9419 Monitoring compliance with approved certificates of need under section 22247 of the code. Rule 419. (1) If the department determines that a recipient has not complied with the terms, conditions, or stipulations of an approved certificate of need, the department shall notify the recipient. The department shall also specify the period of time during which the noncompliance occurred.

(2) In determining the appropriate action to take according to section 22247(2) of the code, the department shall consider the extent and duration of the noncompliance.

(3) The department shall make available, to the public, on request, a list of all certificates of need determined not to be in compliance with the terms, conditions, or stipulations approved in a certificate of need. If required by the department, the recipient shall notify all payers of services provided by the recipient that the approved services are not being provided in compliance with the terms, conditions, or stipulations of an approved certificate of need.

(4) The department decision is final and binding.

History: 1996 AACS; 2014 AACS.

PART 5. ADMINISTRATIVE APPEALS

R 325.9501 Rescinded.

History: 1996 AACS; 2014 AACS.

R 325.9503 Rescinded.

History: 1996 AACS; 2014 AACS.

R 325.9505 Rescinded.

History: 1986 AACS; 2014 AACS.

R 325.9507 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9509 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9511 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9513 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9515 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9517 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9519 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9521 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9523 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9525 Rescinded.

History: 1986 AACS; 1996 AACS; 2014 AACS.

R 325.9551 Hearing request; eligibility; effect.

Rule 551. (1) An applicant that receives either (a) a proposed decision of the bureau which recommends denial of a certificate of need or (b) a notice of reversal by the director, may request a hearing, as authorized by the code. The purpose of the hearing is to allow the applicant the opportunity to demonstrate that the applicant's completed application meets the requirements for approval under part 222 of the code. In a comparative review, approved applicants cannot request a hearing on a proposed decision regarding a different applicant.

History: 2014 AACS.

R 325.9552 Reconsideration.

Rule 552. At any time during the appeals process the department may reconsider the original decision to determine compliance with applicable review standards and code.

History: 2014 AACS.

R 325.9553. Issuance of final decision by the department director.

Rule 553. (1) If an applicant requests a hearing in accordance with Rule 551, after the hearing, and review of the record, the director shall issue a final decision or an order for further proceedings.

- (2) The director shall serve copies of the final decision upon all parties.
- (3) All appeals of applications that are part of a comparative review shall be decided in 1 final decision.
- (4) An applicant may appeal the final decision of the director directly to the circuit court for the county where the applicant has its principal place of business in this state or the circuit court for Ingham county. Judicial review is governed by sections 101 to 103 of 1969 PA 306, MCL 24.301 to 24.306.

History: 2014 AACCS.